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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**  
Washington, D.C. 20549

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**AMENDMENT NO. 2**  
to  
**FORM S-4**

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**REGISTRATION STATEMENT**  
UNDER  
**THE SECURITIES ACT OF 1933**

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**Histogenics Corporation**  
(Exact name of registrant as specified in its charter)

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**Delaware**  
(State or other jurisdiction of  
incorporation or organization)

**3842**  
(Primary Standard Industrial  
Classification Code Number)

**04-3522315**  
(I.R.S. Employer  
Identification Number)

**Histogenics Corporation**  
c/o Gunderson Dettmer Stough Villeneuve Franklin & Hachigian, LLP  
One Marina Park Drive, Suite 900  
Boston, MA 02210  
(781) 312-5013

(Address including zip code, and telephone number, including area code, of registrant's principal executive offices)

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**Adam Gridley**  
President

**Histogenics Corporation**  
c/o Gunderson Dettmer Stough Villeneuve Franklin & Hachigian, LLP  
One Marina Park Drive, Suite 900  
Boston, MA 02210  
(781) 312-5013

(Name, address, including zip code, and telephone number, including area code, of agent for service)

---

*Copies to:*

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Interim Chief Financial Officer  
Histogenics Corporation  
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Approximate date of commencement of proposed sale to the public: As soon as practicable after the effectiveness of this registration statement and the satisfaction or waiver of all other conditions under the Merger Agreement described herein.

If the securities being registered on this Form are being offered in connection with the formation of a holding company and there is compliance with General Instruction G, please check the following box.

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If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
		Emerging growth company	<input checked="" type="checkbox"/>

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 7(a)(2)(B) of the Securities Act.

If applicable, place an X in the box to designate the appropriate rule provision relied upon in conducting this transaction:

Exchange Act Rule 13(e)-4(i) (Cross-Border Issuer Tender Offer)

Exchange Act Rule 14d-1(d) (Cross-Border Third-Party Tender Offer)

### CALCULATION OF REGISTRATION FEE

Title of Each Class of Security Being Registered	Amount to be Registered (1)	Proposed Maximum Offering Price Per Share	Proposed Maximum Aggregate Offering Price (2)	Amount of Registration Fee (3)
Common stock, \$0.01 par value per share	637,797,198	N/A	\$6,392,775	\$774.80

- Relates to common stock, \$0.01 par value per share, of Histogenics Corporation, a Delaware corporation ("Histogenics"), issuable to holders of common stock, \$0.001 par value per share, of Ocugen, Inc., a Delaware corporation ("Ocugen"), in the proposed merger of Restore Merger Sub, Inc., a Delaware corporation and wholly-owned subsidiary of Histogenics, with and into Ocugen (the "merger"). The amount of Histogenics common stock to be registered is based on the estimated number of shares of Histogenics common stock that are expected to be issued pursuant to the merger, after taking into account the expected issuance by Ocugen immediately prior to the merger of 9,148,544 shares of Ocugen common stock (4,574,272 of which will be held in escrow for the benefit of certain accredited investors) pursuant to a securities purchase agreement entered into by and among Ocugen, Histogenics and certain accredited investors dated as of June 13, 2019, as amended (the "Securities Purchase Agreement"), and before taking into account the effect of a reverse stock split of Histogenics common stock, assuming a pre-split exchange ratio of 28.7650 shares of Histogenics common stock for each outstanding share of Ocugen common stock.
- Estimated solely for purposes of calculating the registration fee in accordance with Rule 457(f) of the Securities Act of 1933, as amended, based upon the estimated book value of the Ocugen securities to be exchanged in the merger (which such calculation takes into effect the receipt of gross proceeds of approximately \$25.0 million by Ocugen pursuant to the closing of the transactions contemplated by the Securities Purchase Agreement, which is expected to occur following the date hereof and prior to or concurrently with the consummation of the merger). Ocugen is a private company, and no market exists for its securities.
- This fee has been calculated pursuant to Section 6(b) of the Securities Act of 1933, as amended. \$774.80 of this fee has been previously paid.

**The Registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment that specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933, as amended, or until the registration statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to said Section 8(a), may determine.**

**The information in this proxy statement/prospectus/information statement is not complete and may be changed. Histogenics may not sell its securities pursuant to the proposed transactions until the Registration Statement filed with the Securities and Exchange Commission is effective. This proxy statement/prospectus/information statement is not an offer to sell these securities and is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.**

**PRELIMINARY—SUBJECT TO COMPLETION, DATED AUGUST 2, 2019**

**PROPOSED MERGER  
YOUR VOTE IS VERY IMPORTANT**

To the Stockholders of Histogenics Corporation and Ocugen, Inc.:

Histogenics Corporation (“Histogenics”) and Ocugen, Inc. (“Ocugen”) have entered into an Agreement and Plan of Merger and Reorganization, as amended (the “Merger Agreement”), pursuant to which a wholly-owned subsidiary of Histogenics will merge with and into Ocugen, with Ocugen surviving as a wholly-owned subsidiary of Histogenics (the “merger”). Ocugen and Histogenics believe that the merger will result in a clinical-stage biopharmaceutical company focused on developing innovative therapies to address rare and underserved eye diseases.

At the effective time of the merger (the “Effective Time”), each share of common stock of Ocugen, \$0.001 par value (“Ocugen common stock”), will be converted into the right to receive 28.7650 shares of common stock of Histogenics, \$0.01 par value (“Histogenics common stock”), subject to adjustment for the reverse stock split of Histogenics common stock to be implemented prior to the consummation of the merger as discussed in this proxy statement/prospectus/information statement. Histogenics will assume outstanding and unexercised warrants and options to purchase shares of Ocugen capital stock, and in connection with the merger they will be converted into warrants and options, as applicable, to purchase shares of Histogenics common stock. At the Effective Time, Histogenics’ stockholders will continue to own and hold their existing shares of Histogenics common stock, and all outstanding and unexercised warrants to purchase shares of Histogenics common stock will remain in effect pursuant to their terms. As of immediately prior to the Effective Time, all outstanding and unexercised options to purchase shares of Histogenics common stock will be cancelled and have no further force and effect. In connection with the merger, on June 13, 2019, Ocugen and Histogenics entered into a securities purchase agreement, which was subsequently amended on June 28, 2019 (the “Securities Purchase Agreement”), with certain accredited investors (the “Investors”) pursuant to which, among other things, Ocugen agreed to issue to the Investors shares of Ocugen common stock immediately prior to the merger and Histogenics agreed to issue to the Investors warrants to purchase shares of Histogenics common stock on the fifth trading day following the consummation of the merger (the “Investor Warrants”) in a private placement transaction for an aggregate purchase price of approximately \$25.0 million (subject to setoff for amounts outstanding of approximately \$5.29 million under certain senior secured convertible notes previously issued or to be issued prior to the consummation of the merger to certain of the Investors by Ocugen) (the “Pre-Merger Financing”). Immediately after the merger, after giving effect to the Pre-Merger Financing and based on the exchange ratio of 28.7650, current holders of Ocugen’s capital stock and options and warrants to purchase shares of Ocugen common stock, are expected to own, or hold rights to acquire, in the aggregate approximately 86.24% of the fully-diluted common stock of Histogenics, which for these purposes is defined as the outstanding common stock of Histogenics plus Series A Convertible Preferred Stock and outstanding warrants of Histogenics, excluding the Investor Warrants (the “Fully-Diluted Common Stock of Histogenics”), and Histogenics’ current stockholders and warrant holders are expected to own, or hold rights to acquire, in the aggregate approximately 13.76% of the Fully-Diluted Common Stock of Histogenics.

Shares of Histogenics common stock are currently listed on The Nasdaq Stock Market LLC (“Nasdaq”) under the symbol “HSGX.” Prior to consummation of the merger, Histogenics intends to file an initial listing application with Nasdaq pursuant to Nasdaq’s “reverse merger” rules. After completion of the merger, Histogenics will be renamed Ocugen, Inc. and expects to trade on Nasdaq under the symbol “OCGN.” On August 2, 2019, the last trading day before the date of this proxy statement/prospectus/information statement, the closing sale price of Histogenics common stock on Nasdaq was \$ 1.00 per share.

Histogenics is holding a special meeting of its stockholders (the “Histogenics special meeting”) in order to obtain the stockholder approvals necessary to complete the merger, the Pre-Merger Financing and related matters. At the Histogenics special meeting, which will be held at 9:00 a.m., local time, on September 12, 2019 at the offices of Gunderson Dettmer Stough Villeneuve Franklin & Hachigian, LLP located at One Marina Park Drive, Suite 900, Boston, MA 02210, unless postponed or adjourned to a later date, Histogenics will ask its stockholders to, among other things:

1. approve the Merger Agreement, and the transactions contemplated thereby, including the merger, the issuance of shares of Histogenics common stock to Ocugen’s stockholders pursuant to the terms of the Merger Agreement and the change of control resulting from the merger;

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2. approve an amendment to the sixth amended and restated certificate of incorporation of Histogenics to effect a reverse stock split of Histogenics common stock, within a range, as determined by Histogenics' board of directors, of one new share for every 53 to 67 (or any number in between) shares outstanding;
3. approve an amendment to the sixth amended and restated certificate of incorporation of Histogenics to change the corporate name of Histogenics from "Histogenics Corporation" to "Ocugen, Inc.";
4. approve an amendment to the sixth amended and restated certificate of incorporation of Histogenics to increase the number of authorized shares of Histogenics common stock to a total number of 200,000,000 shares;
5. approve the issuance of: (a) shares of Histogenics common stock upon the exercise of the Investor Warrants to be issued in the Pre-Merger Financing, and (b) additional shares of Histogenics common stock that may be issued following the closing of the Pre-Merger Financing, in each case pursuant to the Securities Purchase Agreement and as required by and in accordance with Nasdaq Listing Rule 5635;
6. consider and vote upon an adjournment of the Histogenics special meeting, if necessary, to solicit additional proxies if there are not sufficient votes in favor of Proposal Nos. 1 or 2; and
7. transact such other business as may properly come before the Histogenics special meeting or any adjournment or postponement thereof.

As described in the accompanying proxy statement/prospectus/information statement, certain of Ocugen's stockholders who in the aggregate own approximately 93% of the outstanding shares of Ocugen common stock (excluding shares of common stock issuable pursuant to the Securities Purchase Agreement), and certain of Histogenics' stockholders who in the aggregate own less than one percent of the outstanding shares of Histogenics common stock, are parties to voting agreements with Histogenics and Ocugen, whereby such stockholders have agreed to vote their shares in favor of the adoption or approval, among other things, of the Merger Agreement and the approval of the transactions contemplated therein, including the merger, the issuance of shares of Histogenics common stock to Ocugen's stockholders and the change of control resulting from the merger, subject to the terms of the voting agreements.

In addition, following the registration statement on Form S-4, of which this proxy statement/prospectus/information statement is a part, being declared effective by the U.S. Securities and Exchange Commission (the "SEC") and pursuant to the conditions of the Merger Agreement and the voting agreements, Ocugen's stockholders who are party to the voting agreements will each execute an action by written consent of Ocugen's stockholders, referred to as the written consent, adopting the Merger Agreement, thereby approving the transactions contemplated therein, including the merger. No meeting of Ocugen's stockholders to adopt the Merger Agreement and approve the merger and related transactions will be held; all of Ocugen's stockholders will have the opportunity to elect to adopt the Merger Agreement, thereby approving the merger and related transactions, by signing and returning to Ocugen a written consent.

After careful consideration, Histogenics' board of directors (the "Histogenics Board") has (i) determined that the merger and all related transactions contemplated by the Merger Agreement are fair to, advisable and in the best interests of Histogenics and its stockholders, (ii) approved and declared advisable the Merger Agreement and the transactions contemplated therein and (iii) determined to recommend, upon the terms and subject to the conditions set forth in the Merger Agreement, that its stockholders vote to approve the Merger Agreement and the transactions contemplated thereby. The Histogenics Board recommends that Histogenics' stockholders vote "FOR" Proposal Nos. 1, 2, 3, 4, 5 and 6.

After careful consideration, Ocugen's board of directors (the "Ocugen Board") has (i) determined that the merger and all related transactions contemplated by the Merger Agreement are fair to, advisable and in the best interests of Ocugen and its stockholders, (ii) approved and declared advisable the Merger Agreement and the transactions contemplated therein and (iii) determined to recommend, upon the terms and subject to the conditions set forth in the Merger Agreement, that its stockholders vote to approve the Merger Agreement and the transactions contemplated thereby. The Ocugen Board recommends that each Ocugen stockholder sign and return the written

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consent, indicating its (i) adoption and approval of the Merger Agreement and the transactions contemplated thereby, (ii) acknowledgement that the approval given is irrevocable and that such stockholder is aware of its rights to demand appraisal for its shares pursuant to Section 262 of the General Corporation Law of the State of Delaware (“DGCL”), and that such stockholder has received and read a copy of Section 262 of the DGCL, and (iii) acknowledgement that by its approval of the merger it is not entitled to appraisal rights with respect to its shares in connection with the merger and thereby waives any rights to receive payment of the fair value of its capital stock under the DGCL (collectively, the “Required Ocugen Stockholder Approval”).

More information about Histogenics, Ocugen and the proposed transaction is contained in this proxy statement/prospectus/information statement. Histogenics and Ocugen urge you to read the accompanying proxy statement/prospectus/information statement carefully and in its entirety. IN PARTICULAR, YOU SHOULD CAREFULLY CONSIDER THE MATTERS DISCUSSED UNDER “[RISK FACTORS](#)” BEGINNING ON PAGE 30.

Histogenics and Ocugen are excited about the opportunities the merger brings to both Histogenics’ and Ocugen’s stockholders, and thank you for your consideration and continued support.

Adam Gridley  
President  
Histogenics Corporation

Shankar Musunuri, Ph.D., MBA  
Chief Executive Officer and Chairman  
Ocugen, Inc.

**Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the adequacy or accuracy of this proxy statement/prospectus/information statement. Any representation to the contrary is a criminal offense.**

The accompanying proxy statement/prospectus/information statement is dated August , 2019, and is first being mailed to Histogenics’ and Ocugen’s stockholders on or about August , 2019.

**Histogenics Corporation**

**c/o Gunderson Dettmer Stough Villeneuve Franklin & Hachigian, LLP  
One Marina Park Drive, Suite 900  
Boston, MA 02210**

**NOTICE OF SPECIAL MEETING OF STOCKHOLDERS  
To Be Held On September 12, 2019**

Dear Stockholder of Histogenics:

On behalf of the board of directors of Histogenics Corporation, a Delaware corporation (“Histogenics”), we are pleased to deliver this proxy statement/prospectus/information statement for the 2019 special meeting of stockholders of Histogenics (the “Histogenics special meeting”) and for the proposed merger between Histogenics and Ocugen, Inc., a Delaware corporation (“Ocugen”), pursuant to which Restore Merger Sub, Inc., a Delaware corporation and wholly-owned subsidiary of Histogenics (“Merger Sub”), will merge with and into Ocugen, with Ocugen surviving as a wholly-owned subsidiary of Histogenics (the “merger”). In connection with the merger, on June 13, 2019, Ocugen and Histogenics entered into a securities purchase agreement, which was subsequently amended on June 28, 2019 (the “Securities Purchase Agreement”), with certain accredited investors (the “Investors”), pursuant to which, among other things, Ocugen agreed to issue to the Investors shares of Ocugen common stock immediately prior to the merger, and Histogenics agreed to issue to the Investors on the fifth trading day following the consummation of the merger warrants to purchase shares of Histogenics common stock (the “Investor Warrants”) in a private placement transaction for an aggregate purchase price of approximately \$25.0 million (subject to setoff for amounts outstanding of approximately \$5.29 million under certain senior secured convertible notes previously issued or to be issued prior to the consummation of the merger to certain of the Investors by Ocugen) (the “Pre-Merger Financing”). The Histogenics special meeting will be held on September 12, 2019, at 9:00 a.m. local time at the offices of Gunderson Dettmer Stough Villeneuve Franklin & Hachigian, LLP located at One Marina Park Drive, Suite 900, Boston, MA 02210 for the following purposes:

1. To consider and vote upon a proposal to approve the Agreement and Plan of Merger and Reorganization, dated as of April 5, 2019, by and among Histogenics, Merger Sub, and Ocugen, a copy of which is attached as *Annex A-1* to this proxy statement/prospectus/information statement, as amended (the “Merger Agreement”), and the transactions contemplated thereby, including the merger, the issuance of shares of Histogenics common stock to Ocugen’s stockholders pursuant to the terms of the Merger Agreement and the change of control resulting from the merger.
2. To approve an amendment to the sixth amended and restated certificate of incorporation of Histogenics to effect a reverse stock split of Histogenics common stock, within a range, as determined by Histogenics’ board of directors, of one new share for every 53 to 67 (or any number in between) shares outstanding, in the form attached as *Annex D* to this proxy statement/prospectus/information statement.
3. To approve an amendment to the sixth amended and restated certificate of incorporation of Histogenics to change the corporate name of Histogenics from “Histogenics Corporation” to “Ocugen, Inc.” in the form attached as *Annex E* to this proxy statement/prospectus/information statement.
4. To approve an amendment to the sixth amended and restated certificate of incorporation of Histogenics to increase the number of authorized shares of Histogenics common stock to a total number of 200,000,000 shares, in the form attached as *Annex F* to this proxy statement/prospectus/information statement.
5. To approve the issuance of: (a) shares of Histogenics common stock upon the exercise of the Investor Warrants to be issued in the Pre-Merger Financing, and (b) additional shares of Histogenics common stock that may be issued following the closing of the Pre-Merger Financing, in each case pursuant to the Securities Purchase Agreement and as required by and in accordance with Nasdaq Listing Rule 5635.
6. To consider and vote upon an adjournment of the Histogenics special meeting, if necessary, to solicit additional proxies if there are not sufficient votes in favor of Proposal Nos. 1 or 2.

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7. To transact such other business as may properly come before the Histogenics special meeting or any adjournment or postponement thereof.

The board of directors of Histogenics (the “Histogenics Board”) has fixed July 15 , 2019, as the record date for the determination of stockholders entitled to notice of, and to vote at, the Histogenics special meeting and any adjournment or postponement thereof. Only holders of record of shares of Histogenics common stock at the close of business on the record date are entitled to notice of, and to vote at, the Histogenics special meeting. At the close of business on the record date, Histogenics had 94,599,601 shares of common stock outstanding and entitled to vote. A complete list of such stockholders entitled to vote at the Histogenics special meeting will be available for examination at the Histogenics offices in Boston, Massachusetts during normal business hours for a period of ten days prior to the Special Meeting.

**Your vote is important. The affirmative vote of the holders of a majority of the shares of Histogenics common stock entitled to vote and present in person or represented by proxy at the Histogenics special meeting is required for approval of Proposal Nos. 1, 5 and 6. The affirmative vote of the holders of a majority of shares of Histogenics common stock having voting power outstanding on the record date for the Histogenics special meeting is required for approval of Proposal Nos. 2, 3 and 4. Each of Proposal Nos. 1 and 2 are conditioned upon each other. Therefore, the merger cannot be consummated without the approval of Proposal Nos. 1 and 2.**

**Proposal Nos. 3, 4 and 5 are conditioned upon the consummation of the merger. If the merger is not completed or the stockholders do not approve Proposal No. 3, Histogenics will not change its name to “Ocugen, Inc.” If the merger is not completed or the stockholders do not approve Proposal No. 4, the increase in the number of authorized shares of Histogenics common stock will not be effected. If the merger is not completed or the stockholders do not approve Proposal No. 5, the Pre-Merger Financing will not be effected except that Histogenics’ stockholders’ approval of the Pre-Merger Financing is a condition to the closing of the Pre-Merger Financing. Proposal Nos. 1 and 2 are not conditioned on Proposal Nos. 3, 4 or 5 being approved.**

**Even if you plan to attend the Histogenics special meeting in person, Histogenics requests that you sign and return the enclosed proxy card to ensure that your shares will be represented at the Histogenics special meeting if you are unable to attend.**

**THE HISTOGENICS BOARD HAS DETERMINED AND BELIEVES THAT EACH OF THE PROPOSALS OUTLINED ABOVE IS ADVISABLE TO, AND IN THE BEST INTERESTS OF, HISTOGENICS AND ITS STOCKHOLDERS AND HAS APPROVED EACH SUCH PROPOSAL. THE HISTOGENICS BOARD RECOMMENDS THAT HISTOGENICS’ STOCKHOLDERS VOTE “FOR” EACH SUCH PROPOSAL.**

By Order of the Histogenics Board of Directors,

Adam Gridley  
*President*  
Boston, Massachusetts  
August , 2019

## REFERENCES TO ADDITIONAL INFORMATION

This proxy statement/prospectus/information statement incorporates important business and financial information about Histogenics that is not included in or delivered with this document. You may obtain this information without charge through the SEC website ([www.sec.gov](http://www.sec.gov)) or upon your written or oral request by contacting Histogenics Corporation, Attention Investor Relations, c/o Gunderson Dettmer Stough Villeneuve Franklin & Hachigian, LLP, One Marina Park Drive, Suite 900, Boston, MA 02210 or by calling (781) 312-5013.

You may also request additional copies from Histogenics' proxy solicitor using the following contact information:

INNISFREE M&A INCORPORATED  
501 Madison Avenue, 20th Floor  
New York, NY 10022  
Stockholders Call Toll-Free: 888-750-5834  
Banks and Brokers Call Collect: 212-750-5833

**To ensure timely delivery of these documents, any request should be made no later than September 5, 2019 to receive them before the special meeting.**

For additional details about where you can find information about Histogenics, please see the section entitled "Where You Can Find More Information" in this proxy statement/prospectus/information statement.



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## QUESTIONS AND ANSWERS ABOUT THE MERGER

Except where specifically noted, the following information and all other information contained in this proxy statement/prospectus/information statement does not give effect to the proposed reverse stock split within a range, as determined by the Histogenics Board, of one new share for every 53 to 67 (or any number in between) shares outstanding, as described in Proposal No. 2 beginning on page 200 in this proxy statement/prospectus/information statement (the “Histogenics Reverse Stock Split”).

The following section provides answers to frequently asked questions about the merger. This section, however, provides only summary information. For a more complete response to these questions and for additional information, please refer to the cross-referenced sections.

**Q: What is the merger?**

**A:** Histogenics, Merger Sub and Ocugen entered into the Agreement and Plan of Merger and Reorganization on April 5, 2019 (the “Original Merger Agreement”). On June 13, 2019, the parties entered into Consent and Amendment No. 1 to Agreement and Plan of Merger and Reorganization, a copy of which is attached as *Annex A-2* (the “Merger Agreement Amendment,” and together with the Original Merger Agreement, the “Merger Agreement”). The Merger Agreement contains the terms and conditions of the proposed merger of Histogenics and Ocugen. Under the Merger Agreement, Merger Sub will merge with and into Ocugen, with Ocugen surviving as a wholly-owned subsidiary of Histogenics. This transaction is referred to as “the merger.”

At the effective time of the merger (the “Effective Time”), each share of Ocugen common stock outstanding immediately prior to the Effective Time (excluding certain shares to be canceled pursuant to the Merger Agreement and shares held by stockholders who have exercised and perfected appraisal rights as more fully described in the section entitled “The Merger—Appraisal Rights” in this proxy statement/prospectus/information statement) will be converted into the right to receive 28.7650 shares of Histogenics common stock, subject to adjustment for the Histogenics Reverse Stock Split (the “exchange ratio”). In connection with the merger, on June 13, 2019, Ocugen and Histogenics entered into a securities purchase agreement, which was subsequently amended on June 28, 2019 (the “Securities Purchase Agreement”), with certain accredited investors (the “Investors”) pursuant to which, among other things, Ocugen agreed to issue to the Investors shares of Ocugen common stock immediately prior to the merger and Histogenics agreed to issue to the Investors warrants to purchase shares of Histogenics common stock on the fifth trading day following the consummation of the merger (the “Investor Warrants”) in a private placement transaction for an aggregate purchase price of approximately \$25.0 million (subject to setoff for amounts outstanding of approximately \$5.29 million under certain senior secured convertible notes previously issued or to be issued prior to the consummation of the merger to certain of the Investors by Ocugen) (the “Pre-Merger Financing”).

As a result of the merger and after giving effect to the Pre-Merger Financing, based on the exchange ratio of 28.7650, current holders of Ocugen’s capital stock and options and warrants to purchase shares of Ocugen common stock, are expected to own, or hold rights to acquire, in the aggregate approximately 86.24% of the fully-diluted common stock of Histogenics, which for these purposes is defined as the outstanding common stock of Histogenics plus Series A Convertible Preferred Stock and outstanding warrants of Histogenics, excluding the Investor Warrants (the “Fully-Diluted Common Stock of Histogenics”), and Histogenics’ current stockholders and warrant holders are expected to own, or hold rights to acquire, in the aggregate approximately 13.76% of the Fully-Diluted Common Stock of Histogenics. Histogenics will assume outstanding and unexercised warrants and options to purchase shares of Ocugen capital stock, and such securities will be converted into warrants and options, as applicable, to purchase shares of Histogenics common stock.

At the Effective Time, Histogenics’ stockholders will continue to own and hold their existing shares of Histogenics common stock and Series A Convertible Preferred Stock, and all outstanding warrants to purchase shares of Histogenics common stock will remain in effect pursuant to their terms. As of immediately prior to the Effective Time, all outstanding and unexercised options to purchase shares of

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Histogenics common stock will be cancelled and have no further force and effect. After the completion of the merger, Histogenics will change its corporate name to “Ocugen, Inc.” as required by the Merger Agreement (the “Histogenics Name Change”).

**Q: What will happen to Histogenics if, for any reason, the merger does not close?**

**A:** If, for any reason, the merger does not close, the Histogenics Board may elect to, among other things, attempt to sell or otherwise dispose of the various assets of Histogenics, dissolve and liquidate its assets or commence bankruptcy proceedings. If Histogenics decides to dissolve and liquidate its assets, Histogenics would be required to pay all of its debts and contractual obligations, and to set aside certain reserves for potential future claims. There can be no assurances as to the amount or timing of available cash left to distribute to stockholders after paying the debts and other obligations of Histogenics and setting aside funds for reserves.

**Q: Why are the two companies proposing to merge?**

**A:** Ocugen and Histogenics believe that the merger will result in a clinical-stage biopharmaceutical company focused on developing innovative therapies to address rare and underserved eye diseases. For a discussion of Histogenics’ and Ocugen’s reasons for the merger, please see the section entitled “The Merger—Histogenics Reasons for the Merger” and “The Merger—Ocugen Reasons for the Merger” in this proxy statement/prospectus/information statement.

**Q: Why am I receiving this proxy statement/prospectus/information statement?**

**A:** You are receiving this proxy statement/prospectus/information statement because you have been identified as a stockholder of Histogenics as of the record date, or a stockholder of Ocugen eligible to execute the Ocugen written consent. If you are a stockholder of Histogenics, you are entitled to vote at the 2019 special meeting of stockholders of Histogenics (the “Histogenics special meeting”), which has been called for the purpose of approving the Merger Agreement and the transactions contemplated thereby, including the merger and the issuance of shares of Histogenics common stock pursuant to the Merger Agreement. If you are a stockholder of Ocugen, you are being requested to sign and return the Ocugen written consent to adopt the Merger Agreement and approve the transactions contemplated thereby, including the merger.

This document serves as:

- a proxy statement of Histogenics used to solicit proxies for the Histogenics special meeting;
- a prospectus of Histogenics used to offer shares of Histogenics common stock in exchange for shares of Ocugen’s capital stock in the merger; and
- an information statement of Ocugen used to solicit the written consent of its stockholders for the adoption of the Merger Agreement and the approval of the merger and related transactions.

**Q: What is required to consummate the merger?**

**A:** To consummate the merger, Histogenics’ stockholders must approve Proposal Nos. 1 and 2.

Proposal No. 1, the approval of the merger and the issuance of Histogenics common stock pursuant to the Merger Agreement by Histogenics’ stockholders and the change of control resulting from the merger, requires the affirmative vote of the holders of a majority of the shares of Histogenics’ outstanding common stock entitled to vote and present in person or represented by proxy at the Histogenics special meeting. Proposal Nos. 2 and 3, the approval of the amendments to the sixth amended and restated certificate of incorporation of Histogenics to effect the Histogenics Reverse Stock Split and the Histogenics Name Change, each requires the affirmative vote of the holders of a majority of the shares of Histogenics common

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stock having voting power outstanding on the record date for the Histogenics special meeting. Each of Proposal Nos. 1 and 2 are conditioned upon each other. Therefore, the merger cannot be consummated without the approval of Proposal Nos. 1 and 2. Proposal Nos. 3, 4 and 5 are conditioned upon the consummation of the merger. If the merger is not completed or the stockholders do not approve Proposal No. 3, Histogenics will not change its name to “Ocugen, Inc.” If the merger is not completed or the stockholders do not approve Proposal No. 4, the increase in the number of authorized shares of Histogenics common stock will not be effected. If the merger is not completed or the stockholders do not approve Proposal No. 5, the Pre-Merger Financing will not be effected. Proposal Nos. 1 and 2 are not conditioned on Proposal Nos. 3, 4 or 5 being approved.

The adoption and approval of the Merger Agreement and the transactions contemplated thereby requires the written consent of the holders of a majority of the shares of Ocugen common stock outstanding as of the record date for the written consent.

Certain of Ocugen’s stockholders who in the aggregate own approximately 93% of the outstanding shares of Ocugen common stock (excluding shares of common stock issuable pursuant to the Securities Purchase Agreement), and certain of Histogenics’ stockholders who in the aggregate own less than one percent of the outstanding shares of Histogenics common stock, are parties to voting agreements with Histogenics and Ocugen, whereby such stockholders have agreed, subject to the terms of the voting agreements, to vote their shares in favor of the adoption or approval, among other things, of the Merger Agreement and the transactions contemplated therein, including the merger and the issuance of Histogenics common stock to Ocugen’s stockholders pursuant to the Merger Agreement. In addition, following the registration statement on Form S-4, of which this proxy statement/prospectus/information statement is a part, being declared effective by the U.S. Securities and Exchange Commission (the “SEC”) and pursuant to the conditions of the Merger Agreement, Ocugen’s stockholders who are party to the voting agreements will each execute written consents approving the merger and related transactions. Stockholders of Ocugen, including those who are parties to voting agreements, are being requested to execute written consents providing such approvals.

In addition to the requirement of obtaining the stockholder approvals described above and appropriate regulatory approvals, each of the other closing conditions set forth in the Merger Agreement must be satisfied or waived. For a more complete description of the closing conditions under the Merger Agreement, we urge you to read the section entitled “The Merger Agreement—Conditions to the Completion of the Merger” in this proxy statement/prospectus/information statement.

**Q: What Proposals are to be voted on at the Histogenics special meeting, other than the merger proposals required in connection with the merger?**

**A:** At the Histogenics special meeting, the holders of Histogenics common stock will also be asked to consider the following proposals, along with any other business that may properly come before the Histogenics special meeting or any adjournment or postponement thereof:

- Proposal No. 3 to approve an amendment to Histogenics’ sixth amended and restated certificate of incorporation to change the corporate name of Histogenics from “Histogenics Corporation” to “Ocugen, Inc.”;
- Proposal No. 4 to approve an amendment to Histogenics’ sixth amended and restated certificate of incorporation to increase the number of authorized shares of Histogenics common stock to a total number of 200,000,000 shares, in the form attached as *Annex F* to this proxy statement/prospectus/information statement;
- Proposal No. 5 to approve the issuance of: (a) shares of Histogenics common stock upon the exercise of the Investor Warrants to be issued in the Pre-Merger Financing, and (b) additional shares of Histogenics common stock that may be issued following the closing of the Pre-Merger Financing, in each case pursuant to the Securities Purchase Agreement and as required by and in accordance with Nasdaq Listing Rule 5635; and

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- Proposal No. 6 to approve an adjournment of the Histogenics special meeting, if necessary, to solicit additional proxies if there are not sufficient votes in favor of Proposal Nos. 1 or 2.

The approval of Proposal Nos. 3, 4, 5 and 6 are not conditions to the merger. Proposal Nos. 3, 4 and 5 are each conditioned upon the consummation of the merger via the approval of Proposal Nos. 1 and 2. If the merger is not completed or the stockholders do not approve Proposal No. 3, the change of Histogenics' name will not become effective. If the merger is not completed or the stockholders do not approve Proposal No. 4, the increase in the number of authorized shares of Histogenics common stock will not be effected. If the merger is not completed or the stockholders do not approve Proposal No. 5, the Pre-Merger Financing will not be effected except that Histogenics' stockholders' approval of the Pre-Merger Financing is a condition to the closing of the Pre-Merger Financing. Proposal Nos. 1 and 2 are not conditioned upon any of Proposal Nos. 3, 4, 5 or 6 being approved. All of such proposals, together with the merger proposals, are referred to collectively in this proxy statement/prospectus/information statement as the proposals.

### **Q: What will Ocugen's stockholders, warrant holders and option holders receive in the merger?**

**A:** As a result of the merger, and after giving effect to the Pre-Merger Financing, based on the exchange ratio of 28.7650, current holders of Ocugen's capital stock and options and warrants to purchase shares of Ocugen common stock will become entitled to receive shares, or rights to acquire shares, of Histogenics common stock equal to, in the aggregate, approximately 86.24% of the Fully-Diluted Common Stock of Histogenics.

Histogenics will assume outstanding and unexercised warrants and options to purchase shares of Ocugen capital stock, and in connection with the merger they will be converted into warrants and options, as applicable, to purchase shares of Histogenics common stock, with the number of Histogenics shares subject to such warrant or option, and the exercise price, being appropriately adjusted to reflect the exchange ratio between Histogenics common stock and Ocugen capital stock determined in accordance with the Merger Agreement.

For a more complete description of what Ocugen's stockholders, warrant holders and option holders will receive in the merger, please see the sections entitled and "The Merger Agreement—Merger Consideration" in this proxy statement/prospectus/information statement.

### **Q: What will Histogenics' stockholders, warrant holders and option holders receive in the merger?**

**A:** At the Effective Time, Histogenics' stockholders will continue to own and hold their existing shares of Histogenics common stock, Series A Convertible Preferred Stock, and all outstanding and unexercised warrants to purchase shares of Histogenics common stock will remain in effect pursuant to their terms. All outstanding and unexercised options to purchase shares of Histogenics common stock will be cancelled for no consideration immediately prior to the Effective Time.

### **Q: Who will be the directors of Histogenics following the merger?**

**A:** In connection with the merger, the Histogenics Board will be expanded to include a total of seven directors. Pursuant to the terms of the Merger Agreement, all of such directors will be designated by Ocugen.

<b>Name</b>	<b>Age</b>	<b>Current Principal Affiliation</b>
Shankar Musunuri, Ph.D., MBA	55	Ocugen Chief Executive Officer, Executive Chairman of the Board, Co-Founder
Uday Kompella, Ph.D.	52	Ocugen Director
Ramesh Kumar, Ph.D.	63	Ocugen Director
Frank Leo	63	Ocugen Director
Manish Potti	33	Ocugen Director
Suha Taspolatoglu, M.D.	57	Ocugen Director
Junge Zhang	52	Ocugen Director

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**Q: Who will be the executive officers of Histogenics immediately following the merger?**

**A:** Immediately following the consummation of the merger, the executive management team of Histogenics is expected to be composed solely of the members of the Ocugen executive management team prior to the merger:

<u>Name</u>	<u>Age</u>	<u>Position</u>
Shankar Musunuri, Ph.D., MBA	55	Chief Executive Officer, Executive Chairman of the Board, Co-Founder
Daniel Jorgensen, M.D., M.P.H., MBA	59	Chief Medical Officer
Rasappa Arumugham, Ph.D.	67	Chief Scientific Officer
Vijay Tammara, Ph.D.	59	Vice President, Regulatory & Quality
Kelly Beck, MBA, SPHR, SHRM-SCP, PMP	42	Vice President, Investor Relations & Administration

**Q: As a stockholder of Histogenics, how does the Histogenics Board recommend that I vote?**

**A:** After careful consideration, the Histogenics Board recommends that Histogenics' stockholders vote:

- "FOR" Proposal No. 1 to approve the Merger Agreement and the transactions contemplated thereby, including the merger, the issuance of shares of Histogenics common stock to Ocugen's stockholders in the merger and the change of control resulting from the merger;
- "FOR" Proposal No. 2 to approve an amendment to the sixth amended and restated certificate of incorporation of Histogenics to effect the Histogenics Reverse Stock Split;
- "FOR" Proposal No. 3 to approve an amendment to the sixth amended and restated certificate of incorporation of Histogenics to effect the Histogenics Name Change;
- "FOR" Proposal No. 4 to approve an amendment to the sixth amended and restated certificate of incorporation of Histogenics to increase the number of authorized shares of Histogenics common stock to a total number of 200,000,000 shares;
- "FOR" Proposal No. 5 to approve the issuance of: (a) shares of Histogenics common stock upon the exercise of the Investor Warrants to be issued in the Pre-Merger Financing, and (b) additional shares of Histogenics common stock that may be issued following the closing of the Pre-Merger Financing, in each case pursuant to the Securities Purchase Agreement and as required by and in accordance with Nasdaq Listing Rule 5635; and
- "FOR" Proposal No. 6 to adjourn the special meeting, if necessary, if a quorum is present, to solicit additional proxies if there are not sufficient votes in favor of Proposal Nos. 1 or 2.

**Q: As a stockholder of Ocugen, how does the Ocugen Board recommend that I vote?**

**A:** After careful consideration, the Ocugen Board recommends that Ocugen's stockholders execute the written consent indicating their vote in favor of the adoption of the Merger Agreement and the approval of the merger and the transactions contemplated by the Merger Agreement.

**Q: What risks should I consider in deciding whether to vote in favor of the merger or to execute and return the written consent, as applicable?**

**A:** You should carefully review the section of this proxy statement/prospectus/information statement entitled "Risk Factors," which sets forth certain risks and uncertainties related to the merger, risks and uncertainties to which the combined company's business will be subject, and risks and uncertainties to which each of Histogenics and Ocugen, as an independent company, is subject.

**Q: When do you expect the merger to be consummated?**

**A:** We anticipate that the merger will occur during the third quarter of 2019, soon after the Histogenics special meeting to be held on September 12, 2019 but we cannot predict the exact timing. For more information, please see the section entitled “The Merger Agreement—Conditions to the Completion of the Merger” in this proxy statement/prospectus/information statement.

**Q: What are the material U.S. federal income tax consequences of the merger to U.S. Holders of Ocugen shares?**

**A:** Ocugen believes that the merger will qualify as a “reorganization” within the meaning of Section 368(a) of the Internal Revenue Code of 1986, as amended (the “Code”). Accordingly, a U.S. Holder (as defined on page 169) of Ocugen common stock should not recognize any gain or loss for U.S. federal income tax purposes on the exchange of shares of Ocugen common stock for shares of Histogenics common stock in the merger, except with respect to cash received by a U.S. Holder of Ocugen common stock in lieu of a fractional share of Histogenics common stock.

Please review the information in the section entitled “The Merger—Material U.S. Federal Income Tax Consequences of the Merger” for a more complete description of the material U.S. federal income tax consequences of the merger to U.S. Holders of Ocugen common stock. The tax consequences to you of the merger will depend on your particular facts and circumstances. Please consult your tax advisors as to the specific tax consequences to you of the merger.

**Q: What are the material U.S. federal income tax consequences of the Histogenics Reverse Stock Split to Histogenics U.S. Holders?**

**A:** A Histogenics U.S. Holder generally should not recognize gain or loss upon the Histogenics Reverse Stock Split, except to the extent a Histogenics U.S. Holder receives cash in lieu of a fractional share of Histogenics common stock. Please review the information in the section entitled “Proposal No. 2: Approval of the Histogenics Reverse Stock Split—Material U.S. Federal Income Tax Consequences of the Histogenics Reverse Stock Split” for a more complete description of the material U.S. federal income tax consequences of the Histogenics Reverse Stock Split to Histogenics U.S. Holders.

The tax consequences to you of Histogenics Reverse Stock Split will depend on your particular facts and circumstances. Please consult your tax advisors as to the specific tax consequences to you.

**Q: What do I need to do now?**

**A:** Histogenics and Ocugen urge you to read this proxy statement/prospectus/information statement carefully, including its annexes and information incorporated herein, and to consider how the merger affects you.

If you are a stockholder of Histogenics, you may provide your proxy instructions in one of four different ways. First, you can mail your signed proxy card in the enclosed return envelope. Second, you may provide your proxy instructions via phone by following the instructions on your proxy card or voting instruction form. Third, you may provide your proxy instructions via the Internet by following the instructions on your proxy card or voting instruction form. Finally, you may vote in person at the Histogenics special meeting, as described below. Please provide your proxy instructions only once, unless you are revoking a previously delivered proxy instruction, and as soon as possible so that your shares can be voted at the Histogenics special meeting.

If you are a stockholder of Ocugen, you may execute and return your written consent to Ocugen in accordance with the instructions provided by Ocugen.

**Q: What happens if I do not return a proxy card or otherwise provide proxy instructions, as applicable?**

**A:** If you are a stockholder of Histogenics, the failure to return your proxy card or otherwise provide proxy instructions (a) will reduce the aggregate number of votes required to approve Proposal Nos. 1, 5 and 6, (b)



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will have the same effect as voting against Proposal Nos. 2, 3 and 4 and (c) your shares will not be counted for purposes of determining whether a quorum is present at the Histogenics special meeting.

**Q: May I vote in person at the special meeting of stockholders of Histogenics?**

**A:** If your shares of Histogenics common stock are registered directly in your name with Histogenics' transfer agent as of the record date, you are considered to be the stockholder of record with respect to those shares, and the proxy materials and proxy card are being sent directly to you by Histogenics. If you are a stockholder of Histogenics of record, you may attend the Histogenics special meeting and vote your shares in person. Even if you plan to attend the Histogenics special meeting in person, Histogenics requests that you sign and return the enclosed proxy to ensure that your shares will be represented at the Histogenics special meeting if you become unable to attend. If your shares of Histogenics common stock are held in a brokerage account or by another nominee, you are considered the beneficial owner of shares held in "street name," and the proxy materials are being forwarded to you by your broker or other nominee together with a voting instruction card. As the beneficial owner, you are also invited to attend the Histogenics special meeting. Because a beneficial owner is not the stockholder of record, you may not vote these shares in person at the Histogenics special meeting unless you obtain a proxy from the broker, trustee or nominee that holds your shares, giving you the right to vote the shares at the Histogenics special meeting.

**Q: When and where is the special meeting of Histogenics' stockholders?**

**A:** The Histogenics special meeting will be held at 9:00 a.m., local time, on September 12, 2019 at the offices of Gunderson Dettmer Stough Villeneuve Franklin & Hachigian, LLP located at One Marina Park Drive, Suite 900, Boston, MA 02210, unless postponed or adjourned to a later date. Subject to space availability, all of Histogenics' stockholders as of the record date, or their duly appointed proxies, may attend the Histogenics special meeting.

**Q: If my Histogenics shares are held in "street name" by my broker, will my broker vote my shares for me?**

**A:** Unless your broker has discretionary authority to vote on certain matters, your broker will not be able to vote your shares of Histogenics common stock without instructions from you. Brokers are not expected to have discretionary authority to vote for any of the Proposals. To make sure that your vote is counted, you should instruct your broker to vote your shares, following the procedures provided by your broker.

**Q: May I change my vote after I have submitted a proxy or provided proxy instructions?**

**A:** Histogenics' stockholders of record, other than those Histogenics' stockholders who are parties to voting agreements, may change their vote at any time before their proxy is voted at the Histogenics special meeting in one of three ways. First, a stockholder of record of Histogenics can send a written notice to the Secretary of Histogenics stating that it would like to revoke its proxy. Second, a stockholder of record of Histogenics can submit new proxy instructions either on a new proxy card or via the Internet. Third, a stockholder of record of Histogenics can attend the Histogenics special meeting and vote in person. Attendance alone will not revoke a proxy. If a stockholder of Histogenics of record or a stockholder who owns Histogenics shares in "street name" has instructed a broker to vote its shares of Histogenics common stock, the stockholder must follow directions received from its broker to change those instructions.

**Q: Who is paying for this proxy solicitation?**

**A:** Histogenics and Ocugen will share equally the cost of printing and filing of this proxy statement/prospectus/information statement and the proxy card. Arrangements will also be made with brokerage firms and other custodians, nominees and fiduciaries who are record holders of Histogenics common stock for the

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forwarding of solicitation materials to the beneficial owners of Histogenics common stock. In addition, Histogenics has engaged Innisfree M&A Incorporated, a proxy solicitation firm, to solicit proxies from Histogenics' stockholders for a fee of \$20,000 plus costs associated with solicitation campaigns. Histogenics will also reimburse Innisfree M&A Incorporated for reasonable out-of-pocket expenses. Histogenics will reimburse these brokers, custodians, nominees and fiduciaries for the reasonable out-of-pocket expenses they incur in connection with the forwarding of solicitation materials.

**Q: Who can help answer my questions?**

**A:** If you are a stockholder of Histogenics and would like additional copies, without charge, of this proxy statement/prospectus/information statement or if you have questions about the merger, including the procedures for voting your shares, you should contact Innisfree M&A Incorporated, Histogenics' proxy solicitor, by telephone at 888-750-5834. Banks and Brokers should contact Innisfree M&A Incorporated by telephone at 212-750-5833.

If you are a stockholder of Ocugen, and would like additional copies, without charge, of this proxy statement/prospectus/information statement or if you have questions about the merger, including the procedures for voting your shares, you should contact:

Ocugen, Inc.  
5 Great Valley Parkway, Suite 160  
Malvern, PA 19355  
(484) 328-4701  
Attn: Kelly Beck

## PROSPECTUS SUMMARY

*This summary highlights selected information from this proxy statement/prospectus/information statement and may not contain all of the information that is important to you. To better understand the merger, the proposals being considered at the Histogenics special meeting and Ocugen's stockholder actions that are the subject of the written consent, you should read this entire proxy statement/prospectus/information statement carefully, including the Original Merger Agreement attached as Annex A-1 and Merger Agreement Amendment attached as Annex A-2 and the other annexes to which you are referred herein. For more information, please see the section entitled "Where You Can Find More Information" in this proxy statement/prospectus/information statement.*

### **The Companies**

#### **Histogenics Corporation**

c/o Gunderson Dettmer Stough Villeneuve Franklin & Hachigian, LLP  
One Marina Park Drive, Suite 900  
Boston, MA 02210  
(781) 312-5013  
Attn: Adam Gridley

Histogenics historically developed restorative cell therapies that may offer rapid-onset pain relief and restored function. Histogenics' technology platform has the potential to be used for a broad range of restorative cell therapy indications.

#### **Ocugen, Inc.**

5 Great Valley Parkway, Suite 160  
Malvern, PA 19355  
(484) 328-4701  
Attn: Shankar Musunuri

Ocugen is clinical-stage biopharmaceutical company focused on discovering, developing and commercializing a pipeline of innovative therapies that address rare and underserved eye diseases. Ocugen's broad pipeline of promising ophthalmology programs in development include:

#### **Modifier Gene Therapy Platform**

Ocugen is developing a modifier gene therapy platform for unmet medical needs in the area of retinal diseases, including inherited retinal diseases ("IRDs"). Ocugen's modifier gene therapy platform is novel in that it targets nuclear hormone receptor ("NHR") genes that have the potential to restore homeostasis to the retina and may target multiple genes that are associated with a range of IRDs. Unlike single-gene replacement therapies, which only target one genetic mutation, Ocugen believes that its gene therapy platform, through its use of NHRs, may impact multiple genes that are associated with a range of genetically diverse diseases. Ocugen's first gene therapy candidate, OCU400, received Orphan Drug Designation ("ODD") from the Food and Drug Administration (the "FDA"), for the treatment of *NR2E3* mutation-associated retinal degenerative disease using an adeno-associated virus vector. Ocugen plans to initiate a Phase 1/2a clinical trial for OCU400 in the next two years.

#### **Ocular Surface Disease Programs**

- Ocugen has a late-stage, Phase 3 program, OCU300, that has also received ODD from the FDA. OCU300 is a small molecule therapeutic currently in Phase 3 clinical development for patients with

ocular graft-versus-host disease (“oGVHD”), and consists of FDA-approved brimonidine tartrate formulated as a topical nanoemulsion based on Ocugen’s OcuNanoE™ technology. Ocugen is the first and only company to receive ODD for the treatment of oGVHD.

- Ocugen has completed a Phase 3 clinical trial for OCU310 (brimonidine 0.2%, OcuNanoE™) for the treatment of dry eye disease (“DED”) that was initiated in September 2018 with the first patient dosed in December 2018. Although the study showed that OCU310 is well-tolerated, as demonstrated by no adverse events regarded as “severe,” it did not meet its co-primary endpoints for symptom and sign. However, a pre-specified exploratory efficacy endpoint of reduction in redness (sign) from the baseline visit, measured by Validated Bulbar Redness score, was significantly better for OCU310 relative to placebo at both Day 14 and Day 28. Post-hoc analysis of the Phase 3 clinical trial is ongoing, subsequent to which a consultation with the FDA will be undertaken. Ocugen is evaluating its options and timing for the continued development of OCU310, including partnering for future clinical trials.

#### **Retinal Disease Programs**

- Ocugen is developing OCU200, a novel fusion protein that is currently in preclinical development for treating wet age-related macular degeneration (“wet AMD”). Ocugen expects to initiate a Phase 1/2 clinical trial for OCU200 within the next two years. In addition, Ocugen plans to expand the therapeutic applications of OCU200 beyond wet AMD.
- Ocugen’s novel biologic, OCU100, for the treatment of retinitis pigmentosa (“RP”) has received ODD in the United States and the European Union.

#### **Restore Merger Sub, Inc.**

Merger Sub is a wholly-owned subsidiary of Histogenics, and was formed solely for the purposes of carrying out the merger.

#### **The Merger (see page 121)**

If the merger is completed, Merger Sub will merge with and into Ocugen, with Ocugen surviving as a wholly-owned subsidiary of Histogenics.

At the Effective Time, each share of Ocugen common stock outstanding immediately prior to the Effective Time (excluding certain shares to be canceled pursuant to the Merger Agreement and shares held by stockholders who have exercised and perfected appraisal rights as more fully described in the section entitled “The Merger—Appraisal Rights” in this proxy statement/prospectus/information statement) will be converted into the right to receive 28.7650 shares of Histogenics common stock, subject to adjustment for the Histogenics Reverse Stock Split (the “exchange ratio”).

Immediately after the merger, after giving effect to the Pre-Merger Financing and based on the exchange ratio of 28.7650, current holders of Ocugen’s capital stock and options and warrant to purchase shares of Ocugen common stock, are expected to own, or hold rights to acquire, in the aggregate approximately 86.24% of the Fully-Diluted Common Stock of Histogenics, and Histogenics’ current stockholders and warrant holders are expected to own, or hold rights to acquire, in the aggregate approximately 13.76% of the Fully-Diluted Common Stock of Histogenics. Histogenics will assume outstanding and unexercised warrants and options to purchase shares of Ocugen capital stock, and such securities will be converted into warrants and options, as applicable, to purchase shares of Histogenics common stock. On May 8, 2019, Histogenics entered into an asset purchase agreement (the “Asset Purchase Agreement”) with Medavate Corp., a Colorado corporation (“Medavate”), pursuant to which Histogenics has agreed to sell substantially all of its assets relating to its NeoCart program,

including, without limitation, intellectual property, business and license agreements and clinical trial data, to Medavate in return for a cash payment of \$6.5 million (the “Asset Consideration”), conditioned upon the consummation of the merger (the “Asset Sale”).

For a more complete description of the exchange ratio, please see the section entitled “The Merger Agreement” in this proxy statement/prospectus/information statement.

The closing of the merger will occur no later than the second business day after the last of the conditions to the merger has been satisfied or waived (other than those conditions that by their nature are to be satisfied at the closing, but subject to the satisfaction or waiver of each such conditions), or at such other time as Histogenics and Ocugen agree. Histogenics and Ocugen anticipate that the consummation of the merger will occur in the third quarter of 2019. However, because the merger is subject to a number of conditions, neither Histogenics nor Ocugen can predict exactly when the closing will occur or if it will occur at all. After completion of the merger, assuming that Histogenics receives the required stockholder approval of Proposal No. 3, Histogenics will be renamed “Ocugen, Inc.”

#### **Reasons for the Merger (see pages 146 and 151)**

The merger will produce a clinical-stage biopharmaceutical company focused on discovering, developing and commercializing a pipeline of innovative therapies that address rare and underserved eye diseases. Histogenics and Ocugen believe that the combined company will have the following characteristics found in successful biotech companies:

- *Broad Product Pipeline.* The combined company will focus on developing innovative therapies to treat rare and underserved eye diseases through a combination of therapeutic approaches that utilize small molecules, biologics, and gene therapies. Ocugen has developed a broad pipeline which includes OCU300, an orphan drug candidate for oGVHD, and OCU310 for DED; and its modifier gene therapy platform and OCU400, a gene augmentation therapy for patients with inherited retinal diseases caused by mutations in the *NR2E3* gene, which recently received ODD from the FDA.
- *Novel Biologic Programs.* The combined company has made pre-clinical progress toward its retinal disease programs which includes novel biologic therapies for wet AMD as well as for RP.
- *Management Team.* The combined company will be led by the experienced senior management from Ocugen.
- *Cash Resources.* The combined company is expected to have approximately \$25 million in cash and cash equivalents at the closing of the merger after giving effect to the Pre-Merger Financing and the Asset Sale, which Ocugen believes is sufficient to enable Ocugen to implement its near-term business plans following the merger.

Each of Histogenics’ and Ocugen’s respective board of directors also considered other reasons for the merger, as described herein. For example, the Histogenics Board considered, among other things:

- the strategic alternatives of Histogenics to the merger, including the discussions that Histogenics’ executive management and the Histogenics Board previously conducted with other potential strategic partners and investors;
- the results of substantial efforts made over a three-month period following Histogenics’ announcement of its disappointing results from its NeoCart Phase 3 clinical trial in September 2018 to solicit strategic alternatives for Histogenics to the merger, including the discussions that Histogenics’ executive management had during this period with other strategic transaction candidates as further discussed in the section titled “The Merger—Background of the Merger”;

- the results of substantial efforts made over a three-month period following Histogenics' announcement of the FDA decision to require another clinical trial of NeoCart in December 2018 to solicit strategic alternatives for Histogenics to the merger, including the discussions that Histogenics' executive management and Canaccord Genuity (as defined below) had on Histogenics' behalf during this period with other strategic transaction candidates (including reverse merger transactions and asset sales) as further discussed in the section titled "The Merger—Background of the Merger";
- the risks associated with, and uncertain value and costs to stockholders of, winding down operations of Histogenics; and
- the risks of continuing to operate Histogenics on a stand-alone basis, including developing its NeoCart program and the need to raise additional funding and expend significant resources to advance this portfolio and to rebuild its infrastructure and management to continue its operations.

In addition, the Ocugen Board approved the merger based on a number of factors, including the:

- potential increased access to sources of capital and a broader range of investors to support the clinical development of its products than it could otherwise obtain if it continued to operate as a privately held company;
- potential to provide its current stockholders with greater liquidity by owning stock in a public company;
- Ocugen Board's belief that no alternatives to the merger were reasonably likely to create greater value for Ocugen's stockholders, or enable accelerated investment in Ocugen's portfolio, after reviewing the various strategic options to enhance stockholder value that were considered by the Ocugen Board;
- cash resources of the combined organization expected to be available at the closing of the merger after giving effect to the Pre-Merger Financing; and
- Ocugen's expectation that the merger will be treated as a reorganization for U.S. federal income tax purposes.

**Opinion of the Histogenics Financial Advisor (see page 152)**

The Histogenics Board engaged Canaccord Genuity LLC ("Canaccord Genuity") to provide financial advisory services and to assist the Histogenics Board in the consideration and evaluation of potential strategic transactions on Histogenics' behalf. At a meeting of the Histogenics Board held on June 13, 2019 to evaluate the merger, Canaccord Genuity delivered to the Histogenics Board an oral opinion, which opinion was confirmed by delivery of a written opinion, dated June 13, 2019, to the effect that, as of that date and based upon and subject to certain assumptions, factors and qualifications set forth in the written opinion, the exchange ratio was fair, from a financial point of view, to Histogenics. Canaccord Genuity did not express any view on, and its opinion did not address, any other term or aspect of any other agreements or arrangements contemplated by the Merger Agreement or entered into in connection with the merger, including, without limitation, the Pre-Merger Financing or the Asset Sale.

The full text of Canaccord Genuity's written opinion is attached to this proxy statement/prospectus/information statement as *Annex B* and is incorporated into this proxy statement/prospectus/information statement by reference. The description of Canaccord Genuity's opinion set forth in this proxy statement/prospectus/information statement is qualified in its entirety by reference to the full text of such opinion. Histogenics stockholders are encouraged to read Canaccord Genuity's opinion carefully and in its entirety for a description of the procedures followed, assumptions made, matters considered and qualifications and limitations on the review undertaken by Canaccord Genuity in connection with its opinion. Canaccord Genuity's opinion was addressed to

the Histogenics Board, was only one of many factors considered by the Histogenics Board in its evaluation of the merger and only addresses the fairness, from a financial point of view and as of the date of the opinion, to Histogenics of the exchange ratio. Canaccord Genuity's opinion does not address the relative merits of the merger as compared to other business strategies or transactions that might be available to Histogenics, nor does it address the underlying business decision of Histogenics to proceed with the merger. Canaccord Genuity's opinion was directed to and for the information of the Histogenics Board only (in its capacity as such) in connection with its evaluation of the merger and does not constitute advice or a recommendation to the Histogenics Board or any other person as to how the Histogenics Board or such person should vote with respect to the merger or otherwise act on any other matter with respect to the merger.

For a more complete description, see the section of this proxy statement/prospectus/information statement captioned "The Merger—Opinion of the Histogenics Financial Advisor."

**Material U.S. Federal Income Tax Consequences of the Merger (see page 167)**

Ocugen believes that the merger will qualify as a "reorganization" within the meaning of Section 368(a) of the Code. Accordingly, a U.S. Holder (as defined on page 169) of Ocugen common stock is not expected to recognize any gain or loss for U.S. federal income tax purposes on the exchange of shares of Ocugen common stock for shares of Histogenics common stock in the merger, except with respect to cash received by a U.S. Holder of Ocugen common stock in lieu of a fractional share of Histogenics common stock.

Please review the information in the section entitled "The Merger—Material U.S. Federal Income Tax Consequences of the Merger" for a more complete description of the material U.S. federal income tax consequences of the merger to U.S. Holders of Ocugen common stock. The tax consequences to you of the merger will depend on your particular facts and circumstances. Please consult your tax advisors as to the specific tax consequences to you of the merger.

**Material U.S. Federal Income Tax Consequences of the Histogenics Reverse Stock Split (see pages 204 and 205)**

A Histogenics U.S. Holder generally should not recognize gain or loss upon the Histogenics Reverse Stock Split, except to the extent a Histogenics U.S. Holder receives cash in lieu of a fractional share of Histogenics common stock. Please review the information in the section entitled "Proposal No. 2: Approval of the Histogenics Reverse Stock Split—Material U.S. Federal Income Tax Consequences of the Histogenics Reverse Stock Split" for a more complete description of the material U.S. federal income tax consequences of the Histogenics Reverse Stock Split to Histogenics U.S. Holders.

The tax consequences to you of the Histogenics Reverse Stock Split will depend on your particular facts and circumstances. Please consult your tax advisors as to the specific tax consequences to you.

**Overview of the Merger Agreement**

**Merger Consideration (see page 175)**

At the Effective Time, each share of Ocugen common stock outstanding immediately prior to the Effective Time (excluding certain shares to be canceled pursuant to the Merger Agreement and shares held by stockholders who have exercised and perfected appraisal rights as more fully described in the section entitled "The Merger—Appraisal Rights" in this proxy statement/prospectus/information statement) will automatically be converted into the right to receive 28.7650 shares of Histogenics common stock, subject to adjustment for the Histogenics Reverse Stock Split (the "exchange ratio").

Immediately after the merger, after giving effect to the Pre-Merger Financing and based on the exchange ratio of 28.7650, current holders of Ocugen's capital stock and options and warrant to purchase shares of Ocugen common stock, are expected to own, or hold rights to acquire, in the aggregate approximately 86.24% of the Fully-Diluted Common Stock of Histogenics, and Histogenics' current stockholders and warrant holders are expected to own, or hold rights to acquire, in the aggregate approximately 13.76% of the Fully-Diluted Common Stock of Histogenics. Histogenics will assume outstanding and unexercised warrants and options to purchase shares of Ocugen capital stock, and such securities will be converted into warrants and options, as applicable, to purchase shares of Histogenics common stock. On May 8, 2019, Histogenics entered into the Asset Purchase Agreement with Medavate, pursuant to which Histogenics will sell substantially all of its assets relating to its NeoCart program, including, without limitation, intellectual property, business and license agreements and clinical trial data, to Medavate in return for the Asset Consideration, conditioned upon the consummation of the merger.

The Merger Agreement does not include a price-based termination right, and there will be no adjustment to the total number of shares of Histogenics common stock that Ocugen's stockholders will be entitled to receive for changes in the market price of Histogenics common stock after the date the Merger Agreement was signed. Accordingly, the market value of the shares of Histogenics common stock issued pursuant to the merger will depend on the market value of the shares of Histogenics common stock at the time the merger closes, and could vary significantly from the market value on the date of this proxy statement/prospectus/information statement.

**Treatment of Histogenics' Series A Convertible Preferred Stock, Stock Options and Warrants (see page 176)**

The number of shares of common stock underlying each outstanding shares of Series A Convertible Preferred Stock will be adjusted to account for the Histogenics Reverse Stock Split. Prior to the closing of the merger, the Histogenics Board will adopt appropriate resolutions and take all other actions necessary and appropriate to provide that each unexpired and unexercised option to purchase Histogenics common stock will be cancelled in full effective as of immediately prior to the Effective Time. The number of shares of common stock underlying each warrant and the exercise price for such warrants will be adjusted to account for the Histogenics Reverse Stock Split. The terms governing the Series A Convertible Preferred Stock and warrants to purchase Histogenics common stock will otherwise remain in full force and effect following the closing of the merger.

**Treatment of Ocugen's Stock Options and Warrants (see page 177)**

Pursuant to the Merger Agreement, at the Effective Time:

- each option to purchase shares of Ocugen common stock that is outstanding and unexercised immediately prior to the Effective Time granted under the Ocugen, Inc. 2014 Stock Option Plan, whether or not vested, will be assumed by Histogenics and will become an option to purchase that number of shares of Histogenics common stock equal to the product obtained by multiplying (i) the number of shares of Ocugen common stock that were subject to such option immediately prior to the Effective Time by (ii) the exchange ratio, rounded down to the nearest whole share. The per share exercise price for shares of Histogenics common stock issuable upon exercise of each Ocugen option assumed by Histogenics shall be determined by dividing (a) the per share exercise price of Ocugen common stock subject to such Ocugen option, as in effect immediately prior to the Effective Time, by (b) the exchange ratio, rounded up to the nearest whole cent. Any restriction on the exercise of any Ocugen option assumed by Histogenics will continue in full force and effect and the term, exercisability, vesting schedule and other provisions of such Ocugen option shall otherwise remain unchanged; and
- each warrant to purchase shares of Ocugen capital stock outstanding and unexercised immediately prior to the Effective Time will be assumed by Histogenics and will become a warrant to purchase that number of shares of Histogenics common stock equal to the product obtained by multiplying (i) the



number of shares of Ocugen common stock that were subject to such warrant immediately prior to the Effective Time by (ii) the exchange ratio, rounded down to the nearest whole share. The per share exercise price for shares of Histogenics common stock issuable upon exercise of each Ocugen warrant assumed by Histogenics shall be determined by dividing (a) the per share exercise price of Ocugen's capital stock subject to such Ocugen warrant, as in effect immediately prior to the Effective Time, by (b) the exchange ratio, rounded up to the nearest whole cent. Any restriction on any Ocugen warrant assumed by Histogenics shall continue in full force and effect and the terms and other provisions of such Ocugen warrant shall otherwise remain unchanged.

**Conditions to the Completion of the Merger (see page 178)**

To consummate the merger, Histogenics' stockholders must approve Proposal Nos. 1 and 2. Additionally, Ocugen's stockholders must (i) adopt and approve the Merger Agreement and the transactions contemplated thereby, (ii) acknowledge that the approval given is irrevocable and that such stockholders are aware of their rights to demand appraisal for their shares pursuant to Section 262 of the General Corporation Law of the State of Delaware ("DGCL"), and that such stockholders have received and read a copy of Section 262 of the DGCL, which is included as *Annex C* in this proxy statement/prospectus/information statement, and (iii) acknowledge that by their approval of the merger the approving stockholders are not entitled to appraisal rights with respect to their shares in connection with the merger and thereby waive any rights to receive payment of the fair value of their capital stock under the DGCL.

In addition to obtaining such stockholder approvals and appropriate regulatory approvals, each of the other closing conditions set forth in the Merger Agreement, as described under the section entitled "The Merger Agreement—Conditions to the Completion of the Merger" in this proxy statement/prospectus/information statement must be satisfied or waived.

**No Solicitation (see page 181)**

Each of Histogenics and Ocugen agreed that, except as described below, from the date of the Merger Agreement until the earlier of the consummation of the merger or the termination of the Merger Agreement in accordance with its terms, Histogenics and Ocugen and any of their respective subsidiaries will not, nor will either party or any of its subsidiaries authorize any of the directors, officers, employees, agents, attorneys, accountants, investment bankers, advisors or representatives retained by it or any of its subsidiaries to, directly or indirectly:

- solicit, initiate or knowingly encourage, induce or facilitate the communication, making, submission or announcement of, any "acquisition proposal" (as defined in the section entitled "The Merger Agreement—No Solicitation" below), or "acquisition inquiry" (as defined in the section entitled "The Merger Agreement—No Solicitation" below);
- furnish any non-public information with respect to it to any person in connection with or in response to an acquisition proposal or acquisition inquiry;
- engage in discussions or negotiations with any person with respect to any acquisition proposal or acquisition inquiry;
- approve, endorse or recommend an acquisition proposal;
- execute or enter into any letter of intent or similar document or any contract contemplating or otherwise relating to an "acquisition transaction" (as defined in the section entitled "The Merger Agreement—No Solicitation" below) (other than a confidentiality agreement as permitted by the Merger Agreement); or
- publicly propose to do any of the above.

**Termination of the Merger Agreement (see page 187)**

Either Histogenics or Ocugen can terminate the Merger Agreement under certain circumstances, which would prevent the merger from being consummated.

**Termination Fee (see page 188)**

If the Merger Agreement is terminated under certain circumstances, Histogenics or Ocugen will be required to pay the other party a termination fee of up to \$0.6 million or \$0.7 million, respectively.

**Securities Purchase Agreement (see page 191)**

On June 13, 2019, Ocugen and Histogenics entered into the Securities Purchase Agreement, which was subsequently amended on June 28, 2019, with the Investors pursuant to which, among other things, (i) Ocugen agreed to sell to the Investors an aggregate of 4,574,272 shares of Ocugen common stock (the “Initial Shares”) and deposit an additional 4,574,272 shares of Ocugen common stock into escrow for the benefit of the Investors if 80% of the volume-weighted average trading price of a share of Histogenics common stock on Nasdaq for the first three trading days immediately following the closing date of the Pre-Merger Financing is lower than the price paid by the Investors for the Initial Shares (the “Additional Shares” and together with the Initial Shares the “Ocugen Financing Shares”), and (ii) Histogenics agreed to issue warrants representing the right to acquire an amount of Histogenics common stock up to the amount issuable in exchange for 200% of the Ocugen Financing Shares upon consummation of the merger, as further described below (the “Series A Warrants”), additional Series B warrants to purchase shares of Histogenics common stock, as further described below (the “Series B Warrants”), and additional Series C warrants to purchase 50 million shares of Histogenics common stock (which number shall not be adjusted as a result of the Histogenics Reverse Stock Split) as further described below (the “Series C Warrants” together with the Series A Warrants and the Series B Warrants, the “Investor Warrants” and, together with the Ocugen Financing Shares, the “Purchased Securities”), and the Investors agreed to purchase the Purchased Securities, for an aggregate purchase price of approximately \$25.0 million (subject to setoff for amounts outstanding of approximately \$5.29 million under certain senior secured convertible notes previously issued or to be issued prior to the consummation of the merger to certain of the Investors by Ocugen) (the “Purchase Price”).

Upon the consummation of the merger, each Initial Share will automatically be converted into the right to receive a number of shares of Histogenics common stock equal to the exchange ratio (the “Converted Initial Shares”). Further, upon consummation of the merger, each Additional Share placed into escrow will automatically be converted into the right to receive a number of shares of Histogenics common stock equal to the exchange ratio (the “Converted Additional Shares”). The number of Converted Additional Shares issuable pursuant to the Securities Purchase Agreement will be determined by subtracting (i) the aggregate number of shares of Histogenics common stock issued in exchange for the Initial Shares (as adjusted for stock splits, stock dividends, recapitalizations, reorganizations, reclassifications, combinations, reverse stock splits and similar events) from (ii) the quotient determined by dividing (a) the aggregate Purchase Price by (b) 80% of the sum of the average of the volume-weighted average price of a share of Histogenics common stock on Nasdaq for the first three trading days immediately following the closing date of the Pre-Merger Financing, divided by three. Any Converted Additional Shares not issuable to the Investors will be returned to Histogenics as treasury shares.

The closing of the Pre-Merger Financing is subject to the satisfaction or waiver of certain conditions.

**Series A Warrants**

The Series A Warrants will have an initial exercise price per share equal to 125% of the aggregate Purchase Price divided by the sum of (i) the number of Converted Initial Shares and (ii) the number of Converted Additional

Shares without giving effect to any limitation on delivery contained in the Securities Purchase Agreement, will be immediately exercisable and will have a term of 60 months from the date of issuance. The Series A Warrants will be exercisable for an amount of Histogenics common stock up to the amount issuable upon consummation of the merger in exchange for 200% of the Ocugen Financing Shares purchased by the holder.

#### **Series B Warrants**

The Series B Warrants will have an exercise price per share of \$0.01, will be immediately exercisable and will expire on the day following the later to occur of (i) the Reservation Date (as defined in the section entitled “Agreements Related to the Merger—Series A Warrants” in this proxy statement/prospectus/information statement), and (ii) the date on which such Series B Warrant has been exercised in full (without giving effect to any limitation on exercise contained therein) and no shares remain issuable thereunder. The Series B Warrants will be initially exercisable for an amount of Histogenics common stock equal to the number (if positive) obtained by subtracting (i) the sum of (a) the number of Converted Initial Shares and (b) the number of Converted Additional Shares delivered or deliverable to the holder pursuant to the Securities Purchase Agreement, from (ii) the quotient determined by dividing (a) the pro rata portion of the Purchase Price paid by such holder by (b) 80% of the sum of the volume-weighted average prices of a share of Histogenics common stock on Nasdaq for the first three trading days immediately following the closing date of the Pre-Merger Financing, divided by three.

Additionally, every ninth trading day up to and including the 45<sup>th</sup> trading day (each, a “Reset Date”) following (i) each date on which a registration statement registering any registrable securities for resale by a holder of Purchased Securities is declared effective and/or is available for use, (ii) if there is no effective registration statement that is available for use registering all of the shares issuable upon exercise of the Series A Warrants and the Series B Warrants, the earlier to occur of (a) the first date on which the holders can sell all the shares issuable upon exercise of the Series A Warrants and the Series B Warrants without restriction or limitation pursuant to Rule 144 under the Securities Act of 1933, as amended (the “Securities Act”), and (b) the six month anniversary of the closing date of the Pre-Merger Financing (such earlier date, the “Six Month Reset Date”) and (iii) in the event of a Public Information Failure (as defined in the section entitled “Agreements Related to the Merger—Securities Purchase Agreement” in this proxy statement/prospectus/information statement) at any time following the Six Month Reset Date, then the earlier to occur of (a) the date the Public Information Failure is cured and no longer prevents the holder from selling all of the shares issuable upon exercise of the Series A Warrants and the Series B Warrants pursuant to Rule 144 without restriction or limitation, (b) the first date on which the holders can sell all the shares issuable upon exercise of the Series A Warrants and the Series B Warrants without restriction or limitation pursuant to Rule 144 under the Securities Act and without the requirement to be in compliance with Rule 144(c)(1), and (c) the one year anniversary of the closing date of the Pre-Merger Financing (such 45 trading day period, the “Reset Period” and each such 45<sup>th</sup> trading day after (i), (ii), or (iii), the “End Reset Date”), the number of shares issuable upon exercise of the Series B Warrants shall be increased to the number (if positive) obtained by subtracting (i) the sum of (a) the number of Converted Initial Shares and (b) the number of Converted Additional Shares delivered or deliverable to the holder pursuant to the Securities Purchase Agreement, from (ii) the quotient determined by dividing (a) the pro rata portion of the Purchase Price paid by such holder, by (b) the greater of (y) 80% of the arithmetic average of the two lowest dollar volume-weighted average prices of a share of Histogenics common stock on Nasdaq during the applicable Reset Period immediately preceding the applicable Reset Date to date and (z) \$1.00 (which amount shall not be adjusted for reverse stock splits or other similar events).

#### **The Series C Warrants**

The Series C Warrants will be exercisable for up to 50 million shares of Histogenics common stock and will have an exercise price equal to 125% of the aggregate Purchase Price divided by the sum of (i) the number of

Converted Initial Shares and (ii) the number of Converted Additional Shares without giving effect to any limitation on delivery contained in the Securities Purchase Agreement, will be immediately exercisable and will expire upon the 45<sup>th</sup> trading day immediately following the earlier to occur of (i) the date the holder can sell all shares issuable upon exercise of the Series C Warrants pursuant to Rule 144 without restriction or limitation and without the requirement to be in compliance with Rule 144(c)(1) and (ii) the date that is 12 months from the date of issuance, provided that if such date falls on a day other than a business day or on which trading does not take place on Nasdaq (a “Holiday”), the next day that is not a Holiday (the “Series C Expiration Date”).

If the volume-weighted average trading price of a share of Histogenics common stock on Nasdaq is less than or equal to \$1.20 per share (as adjusted for stock splits, stock dividends, recapitalizations, reorganizations, reclassifications, combinations, reverse stock splits and similar events) on any five trading days following the date of issuance and prior to the Series C Expiration Date, the holder may, in lieu of making any cash payment in connection with the exercise of the Series C Warrants, elect to receive a number of shares of Histogenics common stock equal to the number of Series C Warrants. The number of shares issuable upon exercise and the exercise price of the Series C Warrants shall not be adjusted by the Histogenics Reverse Stock Split.

#### **Registration Rights Agreement**

In connection with the Pre-Merger Financing, Histogenics entered into the Registration Rights Agreement with the Investors (the “Registration Rights Agreement”). Pursuant to the Registration Rights Agreement, Histogenics is required to file an initial resale registration statement with respect to shares of Histogenics common stock (the “Registrable Securities”) held by or issuable to the Investors, within 10 days of the closing of the Pre-Merger Financing. Additionally, Histogenics is required to file additional resale registration statements with respect to the Registrable Securities within 30 days of each End Reset Date, to the extent that such Registrable Securities are not already registered for resale on a prior registration statement. Histogenics will be required to use its best efforts to maintain the effectiveness of these registration statements until the Registrable Securities covered by these registration statements have been disposed of or are no longer Registrable Securities.

#### **Financing Lock-Up Agreements**

In connection with the Pre-Merger Financing, Histogenics and Ocugen will enter into lock-up agreements with each officer, director or other person that will be subject to Section 16 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), with respect to Histogenics immediately following the consummation of the merger, and each holder of greater than 3% of Ocugen common stock (excluding the shares of Ocugen common stock issuable pursuant to the Securities Purchase Agreement) immediately prior to the consummation of the merger (the “Financing Lock-Up Parties”), pursuant to which each of the Financing Lock-Up Parties will agree that until the date that is 30 calendar days after the Trigger Date (as defined in the section entitled “Agreements Related to the Merger—Securities Purchase Agreement” in this proxy statement/prospectus/information statement), subject to certain customary exceptions, such Financing Lock-Up Party will not and will cause its affiliates not to (i) offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, make any short sale or otherwise transfer or dispose of or lend, directly or indirectly, any shares of Histogenics common stock or any securities convertible into, exercisable or exchangeable for or that represent the right to receive Histogenics common stock, (ii) enter into any swap or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of any of the Financing Lock-Up Party’s shares of Histogenics common stock or such other securities, in cash or otherwise, (iii) make any demand for or exercise any right or cause to be filed a registration statement, including any amendments thereto, with respect to the registration of any shares of Histogenics common stock or such other securities, in cash or otherwise, (iv) grant any proxies or powers of attorney with respect to any shares of Histogenics common stock or such other securities, deposit any shares of Histogenics common stock or such other securities into a voting trust or enter into a voting agreement or similar

arrangement or commitment with respect to any shares of Histogenics common stock or such other securities, or (v) publicly disclose the intention to do any of the foregoing.

**Voting Agreements and Written Consent (see page 190)**

In order to induce Histogenics to enter into the Merger Agreement, certain stockholders of Ocugen are parties to a voting agreement with Ocugen and Histogenics pursuant to which, among other things, each stockholder has agreed, solely in its capacity as a stockholder of Ocugen, to vote all of its shares of Ocugen's capital stock in favor of (i) the adoption and approval of the Merger Agreement and the transactions contemplated thereby, (ii) acknowledgement that the approval given for the Merger Agreement is irrevocable and that the stockholder is aware of its appraisal rights under the DGCL, and (iii) acknowledgement that the stockholder is not entitled to appraisal rights by voting in favor of the transaction and waiving appraisal rights under the DGCL. Additionally, each stockholder has agreed, solely in its capacity as a stockholder of Ocugen, to vote against any competing acquisition proposal and any action, proposal or transaction that would reasonably be expected to result in a material breach of the voting agreement. These stockholders of Ocugen have also granted an irrevocable proxy to Ocugen and its designee to vote their respective Ocugen's capital stock in accordance with the voting agreements. Ocugen's stockholders may vote their shares of Ocugen capital stock on all other matters not referred to in such proxy.

The Ocugen stockholders who are parties to these voting agreements include all directors, executive officers and certain stockholders, which represents approximately 93% of the outstanding shares of Ocugen capital stock on an as converted to common stock basis.

The Ocugen stockholders who are party to a voting agreement held, as of July 12, 2019:

- an aggregate of 12,096,944 shares of Ocugen common stock, representing approximately 93% of all outstanding shares of Ocugen common stock;
- an aggregate of 4,926,193 shares of Ocugen common stock held by Series A Stockholders (as defined in the Amended and Restated Stockholders Agreement, dated as of May 25, 2017, by and among certain stockholders of Ocugen and Ocugen, as amended, the "Ocugen Stockholders Agreement") and Series B Stockholders (as defined in the Ocugen Stockholders Agreement), representing approximately 87% of the outstanding shares held by the Series A Stockholders and Series B Stockholders, considered as a single class; and
- an aggregate of 3,099,209 shares of Ocugen common stock held by Series B Stockholders, representing approximately 94% of the outstanding shares held by the Series B Stockholders as a class.

Following the effectiveness of the registration statement of which this proxy statement/prospectus/information statement is a part and pursuant to the Merger Agreement, these stockholders will execute a written consent providing for such adoption and approval.

Under these voting agreements, subject to certain exceptions, such stockholders have also agreed not to sell or transfer shares of Ocugen's capital stock and securities held by them, or any voting rights with respect thereto, until the earlier of the termination of the Merger Agreement or the completion of the merger. To the extent that any such sale or transfer is permitted pursuant to the exceptions included in the voting agreement, each person to which any shares of Ocugen's capital stock or securities are so sold or transferred must agree in writing to be bound by the terms and provisions of the voting agreement, subject to certain further exceptions.

In addition, in order to induce Ocugen to enter into the Merger Agreement, certain of Histogenics' stockholders have entered into voting agreements with Histogenics and Ocugen pursuant to which, among other things, each such stockholder has agreed, solely in his, her or its capacity as a stockholder of Histogenics, to vote all of his,

her or its shares of Histogenics common stock in favor of Proposal Nos. 1, 2 and 3. Additionally, each such stockholder has agreed, solely in his, her or its capacity as a stockholder of Histogenics, to vote against any competing acquisition proposal and any action, proposal or transaction that would reasonably be expected to result in a material breach of the voting agreement. These stockholders of Histogenics have also granted Histogenics and its designee an irrevocable proxy to vote their respective shares in accordance with the voting agreements. Histogenics' stockholders may vote their shares of Histogenics common stock on all other matters not referred to in such proxy.

The Histogenics stockholders who are parties to these voting agreements are:

- Adam Gridley
- Jonathan Lieber
- David Gill (former director)
- Kevin Rakin (former director)

As of July 12, 2019, the stockholders of Histogenics who are party to a voting agreement (including any affiliated entities) owned an aggregate of 484,964 shares of Histogenics common stock representing less than one percent of the outstanding shares of Histogenics common stock.

Under these voting agreements, subject to certain exceptions, such stockholders also have agreed not to sell or transfer their shares of Histogenics common stock and securities held by them until the earlier of the termination of the Merger Agreement or the completion of the merger. To the extent that any such sale or transfer is permitted pursuant to the exceptions included in the voting agreements, each person to whom any shares of Histogenics common stock or securities are so sold or transferred must agree in writing to be bound by the terms and provisions of the voting agreement, subject to certain further exceptions.

**Lock-up Agreements (see page 191)**

As a condition to the closing of the merger, certain stockholders of each of Histogenics and Ocugen and their affiliates, have entered into lock-up agreements, pursuant to which such parties have agreed not to, except in limited circumstances, offer, pledge, sell, contract to sell, transfer or dispose of, directly or indirectly, engage in swap or similar transactions with respect to, or make any demand for or exercise any right with respect to, any shares of Histogenics common stock or any security convertible into or exercisable or exchangeable for Histogenics common stock, including, as applicable, shares received in the merger and issuable upon exercise of certain warrants and options, during the period commencing at the Effective Time and continuing until the date that is 180 days from the Effective Time.

Each of the stockholders who is party to a Histogenics voting agreement is a party to a lock-up agreement. As of July 12, 2019, Histogenics' stockholders who have executed lock-up agreements owned in the aggregate less than one percent of the outstanding common stock of Histogenics.

As of July 12, 2019, Ocugen's stockholders who have executed lock-up agreements beneficially owned in the aggregate approximately 93% of all outstanding shares of Ocugen common stock.

**Management Following the Merger (see page 322)**

Effective as of the closing of the merger, Histogenics' executive officers are expected to include:

<u>Name</u>	<u>Age</u>	<u>Position</u>
Shankar Musunuri, Ph.D., MBA	55	Chief Executive Officer, Executive Chairman of the Board, Co-Founder

<u>Name</u>	<u>Age</u>	<u>Position</u>
Daniel Jorgensen, M.D., M.P.H., MBA	59	Chief Medical Officer
Rasappa Arumugham, Ph.D.	67	Chief Scientific Officer
Vijay Tammara, Ph.D.	59	Vice President, Regulatory & Quality
Kelly Beck, MBA, SPHR, SHRM-SCP, PMP	42	Vice President, Investor Relations & Administration

**Interests of Certain Directors, Officers and Affiliates of Histogenics and Ocugen (see pages 159 and 161)**

In considering the recommendation of the Histogenics Board with respect to the issuance of common stock of Histogenics pursuant to the Merger Agreement and the other matters to be acted upon by Histogenics' stockholders at the Histogenics special meeting, Histogenics' stockholders should be aware that certain members of the Histogenics Board and executive officers of Histogenics have interests in the merger that may be different from, or in addition to, interests they have as Histogenics' stockholders.

As of July 12, 2019, Histogenics' directors, executive officers (including affiliates) and greater than 5% holders beneficially owned, in the aggregate approximately 5.6% of the outstanding shares of common stock of Histogenics. As of July 12, 2019, Histogenics' directors and officers beneficially owned, in the aggregate, 869,840 options to purchase Histogenics common stock, all of which will be cancelled immediately prior to the closing of the merger.

The compensation arrangements with Histogenics' officers and directors are discussed in greater detail in the section entitled "The Merger—Interests of Histogenics Directors and Executive Officers in the Merger" in this proxy statement/prospectus/information statement.

In addition, Ocugen's directors and executive officers will be entitled to certain indemnification and liability insurance coverage pursuant to the terms of the Merger Agreement. Following completion of the merger, it is expected that the combined organization will provide compensation to non-employee directors. Histogenics' current director compensation program will be suspended at the time of the closing of the merger and the director compensation policies for the combined organization following the merger will be re-evaluated by the compensation committee and board of directors of the combined organization following completion of the merger and may be subject to change. Non-employee directors of the combined organization are, however, expected to receive annual cash retainers and equity compensation, although the amount of such compensation has not yet been determined.

As of July 12, 2019, Ocugen's directors and executive officers beneficially owned: (i) approximately 64% of the outstanding shares of common stock of Ocugen, (ii) approximately 31% of the outstanding shares of common stock of Ocugen held by Series A Stockholders and Series B Stockholders, (iii) approximately 50% of the outstanding shares of common stock of Ocugen held by Series B Stockholders, and (iv) warrants to purchase 575,102 shares of Ocugen common stock, all of which will be converted into warrants to purchase Histogenics common stock in connection with the closing of the merger pursuant to the Merger Agreement, and (iv) options to purchase 421,000 shares of Ocugen common stock, all of which will be converted into options to purchase Histogenics common stock in connection with the closing of the merger pursuant to the Merger Agreement.

The compensation arrangements with Ocugen's officers and directors are discussed in greater detail in the section entitled "The Merger Agreement—Interests of Ocugen Directors and Executive Officers in the Merger" in this proxy statement/prospectus/information statement.

Certain of Ocugen's and Histogenics' executive officers and directors have also entered into voting agreements, pursuant to which certain directors, officers and stockholders of Ocugen and Histogenics, respectively, have agreed, solely in their capacity as stockholders of Ocugen and Histogenics, respectively, to vote all of their shares

of Ocugen capital stock or Histogenics common stock in favor of the adoption or approval, respectively, of the Merger Agreement and the transactions contemplated therein in connection with the merger. The voting agreements are discussed in greater detail in the section entitled “Agreements Related to the Merger—Voting Agreements and Written Consent” in this proxy statement/prospectus/information statement.

**Risk Factors (see page 30)**

Both Histogenics and Ocugen are subject to various risks associated with their businesses and respective assets. In addition, the merger poses a number of risks to each company and its respective stockholders, including the possibility that the merger may not be completed and the following risks:

- the exchange ratio is not adjustable based on the market price of Histogenics common stock, so the merger consideration at the closing may have a greater or lesser value than at the time the Merger Agreement was signed;
- failure to complete the merger may result in either Histogenics or Ocugen paying a termination fee or expenses to the other and could harm the price of Histogenics common stock and the future business and operations of each company;
- the merger is subject to approval by the Histogenics stockholders and Ocugen stockholders;
- the merger may be completed even though material adverse changes may result solely from the announcement of the merger, changes in the operations of Histogenics and Ocugen operate that apply to all companies generally and other causes;
- some of Histogenics’ and Ocugen’s respective officers and directors have interests that are different from or in addition to those considered by other stockholders of Ocugen and Histogenics and which may influence them to support or approve the merger;
- the market price of the combined organization’s common stock may decline as a result of the merger;
- Histogenics’ and Ocugen’s stockholders may not realize a benefit from the merger commensurate with the ownership dilution they will experience in connection with or following the merger;
- the Investor Warrants, if exercised, contain price-based adjustment provisions which, if triggered, may cause substantial additional dilution to the combined organization’s stockholders;
- during the pendency of the merger, Histogenics and Ocugen may not be able to enter into a business combination with another party under certain circumstances because of restrictions in the Merger Agreement, which could adversely affect their respective businesses;
- certain provisions of the Merger Agreement may discourage third parties from submitting alternative takeover proposals, including proposals that may be superior to the arrangements contemplated by the Merger Agreement;
- because the lack of a public market for shares of Ocugen’s capital stock makes it difficult to evaluate the fairness of the merger, Ocugen’s stockholders may receive consideration in the merger that is less than the fair market value of the shares of Ocugen’s capital stock and/or Histogenics may pay more than the fair market value of the shares of Ocugen’s capital stock; and
- if the conditions to the merger are not met, the merger will not occur.

These risks and other risks are discussed in greater detail under the section entitled “Risk Factors” in this proxy statement/prospectus/information statement. Histogenics and Ocugen both encourage you to read and consider all of these risks carefully.



**Regulatory Approvals (see page 167)**

In the United States, Histogenics must comply with applicable federal and state securities laws and the rules and regulations of Nasdaq in connection with the issuance of shares of Histogenics common stock and the filing of this proxy statement/prospectus/information statement with the SEC. As of the date hereof, the registration statement of which this proxy statement/prospectus/information statement is a part has not become effective.

**Nasdaq Stock Market Listing (see page 171)**

Prior to consummation of the merger, Histogenics intends to file an initial listing application with Nasdaq pursuant to Nasdaq “reverse merger” rules. If such application is accepted, Histogenics anticipates that Histogenics common stock will be listed on Nasdaq following the closing of the merger under the trading symbol “OCGN.”

**Anticipated Accounting Treatment (see page 171)**

The merger will be recorded by Histogenics using the equity method of accounting. For accounting purposes, Ocugen is considered to be acquiring Histogenics in the merger.

**Appraisal Rights (see page 171)**

Holders of Histogenics common stock are not entitled to appraisal rights in connection with the merger. Ocugen’s stockholders are entitled to appraisal rights in connection with the merger under Delaware law. For more information about such rights, see the provisions of Section 262 of the DGCL attached hereto as *Annex C*, and the section entitled “The Merger—Appraisal Rights” in this proxy statement/prospectus/information statement.

**Comparison of Stockholder Rights (see page 360)**

Both Histogenics and Ocugen are incorporated under the laws of the State of Delaware and, accordingly, the rights of the stockholders of each are currently, and will continue to be, governed by the DGCL. If the merger is completed, Ocugen’s stockholders will become stockholders of Histogenics, and their rights will be governed by the DGCL, Histogenics’ amended and restated bylaws and, Histogenics’ sixth amended and restated certificate of incorporation, as amended by the amendments set forth in *Annex D*, *Annex E* and *Annex F*, assuming Proposal Nos. 2, 3 and 4 are approved. The rights of Histogenics’ stockholders contained in Histogenics’ sixth amended and restated certificate of incorporation and Histogenics’ amended and restated bylaws differ from the rights of Ocugen’s stockholders under Ocugen’s amended and restated certificate of incorporation and Ocugen’s bylaws, as more fully described under the section entitled “Comparison of Rights of Holders of Histogenics Stock and Ocugen Stock” in this proxy statement/prospectus/information statement.

**SELECTED HISTORICAL AND UNAUDITED PRO FORMA CONDENSED  
COMBINED FINANCIAL DATA**

*The following tables present summary historical financial data for Histogenics and Ocugen, summary unaudited pro forma condensed financial data for Histogenics and Ocugen, and comparative historical and unaudited pro forma per share data for Histogenics and Ocugen.*

**Selected Historical Financial Data of Histogenics**

The selected financial data as of December 31, 2018 and 2017 and for the years ended December 31, 2018 and 2017 are derived from the Histogenics audited financial statements prepared using accounting principles generally accepted in the United States (“U.S. GAAP”), which are included in this proxy statement/prospectus/information statement. The statement of operations data for the three months ended March 31, 2019 and 2018, as well as the balance sheet data as of March 31, 2019, are derived from the Histogenics unaudited condensed financial statements included in this proxy statement/prospectus/information statement. Histogenics’ unaudited condensed consolidated financial statements have been prepared in accordance with U.S. GAAP on the same basis as its audited annual financial statements and, in the opinion of management, reflect all adjustments, consisting only of normal, recurring adjustments, necessary for the fair presentation of those unaudited condensed financial statements. The financial data should be read in conjunction with “Histogenics Management’s Discussion and Analysis of Financial Condition and Results of Operations” and Histogenics’ financial statements and related notes appearing elsewhere in this proxy statement/prospectus/information statement. Histogenics’ historical results are not necessarily indicative of results to be expected in any future period.

	<b>Years Ended December 31,</b>	
	<b>2018</b>	<b>2017</b>
<b>Statements of Operations Data</b>		
<b>(dollars in thousands, except per share data):</b>		
Operating expenses:		
Research and development	\$ 15,634	\$ 15,566
General and administrative	10,204	9,384
Loss due to asset impairment	4,270	—
Total operating expenses	<u>30,108</u>	<u>24,950</u>
Loss from operations	(30,108)	(24,950)
Other income (expense), net	21,465	(1,464)
Net loss	<u>\$ (8,643)</u>	<u>\$ (26,414)</u>
Net loss per share, basic	<u>\$ (0.23)</u>	<u>\$ (0.99)</u>
Net loss per share, diluted	<u>\$ (0.79)</u>	<u>\$ (0.99)</u>
Weighted-average shares of common stock outstanding, basic	<u>36,398,450</u>	<u>22,669,819</u>
Weighted-average shares of common stock outstanding, diluted	<u>37,090,197</u>	<u>22,619,819</u>

	<u>Three Months Ended March 31,</u>	
	<u>2019</u>	<u>2018</u>
	(unaudited)	
<b>Statements of Operations Data (dollars in thousands, except per share data)</b>		
Operating expenses:		
Research and development	1,583	3,286
General and administrative	2,929	2,807
Restructuring	2,789	—
Loss on asset impairment	750	—
Total operating expenses	8,051	6,093
Loss from operations	(8,051)	(6,093)
Other income (expense)	(1,364)	(8,740)
Net loss	\$ (9,415)	\$ (14,833)
Net loss per common share—basic and diluted	\$ (0.12)	\$ (0.52)
Weighted-average shares used to compute net loss per common share—basic and diluted	80,484,113	27,670,118

	<u>December 31,</u>		<u>March 31,</u>
	<u>2018</u>	<u>2017</u>	<u>2019</u>
	(unaudited)		
<b>Balance Sheet Data (in thousands):</b>			
Cash and cash equivalents	\$ 15,542	\$ 7,081	\$ 7,376
Working capital (a)	13,527	4,370	5,823
Total assets	17,428	11,035	14,838
Accumulated deficit	(216,830)	(208,187)	(226,245)
Total stockholders' deficit	(458)	(11,268)	(5,532)

(a) Working capital is defined as current assets less current liabilities.

**Selected Historical Consolidated Financial Data of Ocugen**

The selected consolidated financial data as of December 31, 2018 and 2017 and for the years ended December 31, 2018 and 2017 are derived from Ocugen's audited consolidated financial statements prepared using U.S. GAAP, which are included in this proxy statement/prospectus/information statement. These historical results are not necessarily indicative of results to be expected in any future period. The selected consolidated financial data should be read in conjunction with Ocugen's consolidated financial statements and the related notes to those statements included in this proxy statement/prospectus/information statement and "Ocugen Management's Discussion and Analysis of Financial Condition and Results of Operations."

	Years Ended December 31,	
	2018	2017
<b>Selected Consolidated Statements of Operations Data</b>		
<b>(dollars in thousands, except per share data):</b>		
Operating expenses:		
Research and development	\$ 10,322	\$ 4,927
General and administrative	5,819	2,862
Total operating expenses	16,141	7,789
Loss from operations	(16,141)	(7,789)
Other income (expense):		
Change in fair value of derivative liabilities	1,665	—
Interest income	19	31
Interest expense	(3,751)	(56)
Other expense	(12)	(1)
Total other expense	(2,079)	(26)
Net loss	\$ (18,220)	\$ (7,815)
Net loss per share of common stock, basic and diluted	\$ (1.76)	\$ (0.82)
Basic and diluted weighted average shares outstanding	10,347,418	9,483,504

	<u>Three Months Ended March 31,</u>	
	<u>2019</u>	<u>2018</u>
	(unaudited)	
<b>Selected Consolidated Statements of Operations Data</b>		
<b>(in thousands, except per share data):</b>		
Operating expenses:		
Research and development	\$ 3,793	\$ 3,012
General and administrative	1,048	982
Total operating expenses	<u>4,841</u>	<u>3,994</u>
Loss from operations	(4,841)	(3,994)
Other income (expense):		
Change in fair value of warrant liability	(776)	(245)
Interest income	1	7
Interest expense	(696)	(799)
Other expense	(1)	(8)
Total other income (expense)	<u>(1,472)</u>	<u>(1,045)</u>
Net loss	<u>(6,313)</u>	<u>(5,039)</u>

	<u>December 31,</u>		<u>March 31,</u>
	<u>2018</u>	<u>2017</u>	<u>2019</u>
	(unaudited)		
<b>Selected Consolidated Balance Sheet Data</b>			
<b>(in thousands):</b>			
Cash and cash equivalents	\$ 1,628	\$ 6,202	\$ 309
Working capital (a)	(12,168)	5,082	(18,269)
Total assets	2,454	6,630	1,582
Total liabilities	15,164	2,195	20,189
Additional paid-in capital	18,517	17,442	18,932
Accumulated deficit	(31,237)	(13,018)	(37,550)
Total stockholders' (deficit) equity	(12,710)	4,435	(18,607)

(a) Working capital is defined as current assets less current liabilities.

**Selected Unaudited Pro Forma Condensed Combined Financial Data of Histogenics and Ocugen**

*The following information does not give effect to the Histogenics Reverse Stock Split described in Proposal No. 2 discussed in this proxy statement/prospectus/information statement.*

The following selected unaudited pro forma condensed combined financial data was prepared using the equity method of accounting under U.S. GAAP. For accounting purposes, Ocugen is considered to be acquiring Histogenics and the merger is expected to be accounted for as an equity transaction as the fair value of the acquired preclinical assets is deemed to be substantially concentrated in a group of similar assets that do not meet the definition of a business. The Histogenics and Ocugen unaudited pro forma combined balance sheet data assume that the merger took place on March 31, 2019, and combines the Histogenics and Ocugen historical balance sheets at March 31, 2019. The Histogenics and Ocugen unaudited pro forma condensed combined statements of operations data assume that the merger took place as of January 1, 2018, and combines the historical results of Histogenics and Ocugen for the three months ended March 31, 2019 and the year ended December 31, 2018.

The selected unaudited pro forma condensed combined financial data are presented for illustrative purposes only and are not necessarily indicative of the combined financial position or results of operations of future periods or

the results that actually would have been realized had the entities been a single entity during these periods. The selected unaudited pro forma condensed combined financial data as of and for the three months ended March 31, 2019 and the year ended December 31, 2018 are derived from the unaudited pro forma condensed combined financial information and should be read in conjunction with that information. For more information, please see “Unaudited Pro Forma Condensed Combined Financial Information” elsewhere in this proxy statement/prospectus/information statement.

The unaudited pro forma condensed combined financial information assumes that, at the Effective Time, each share of Ocugen common stock will be converted into the right to receive shares of Histogenics common stock such that, immediately following the Effective Time, and after giving effect to the Pre-Merger Financing, Histogenics’ stockholders and warrant holders as of immediately prior to the Effective Time are expected to own, or hold rights to acquire, in the aggregate approximately 13.76% of the Fully-Diluted Common Stock of Histogenics, and current holders of Ocugen’s capital stock and options and warrant to purchase shares of Ocugen common stock, are expected to own, or hold rights to acquire, in the aggregate approximately 86.24% of the Fully-Diluted Common Stock of Histogenics. Histogenics will assume outstanding and unexercised warrants and options to purchase shares of Ocugen capital stock, and such securities will be converted into warrants and options, as applicable, to purchase shares of Histogenics common stock. On May 8, 2019, Histogenics entered into the Asset Purchase Agreement with Medavate, pursuant to which Histogenics will sell substantially all of its assets relating to its NeoCart program, including, without limitation, intellectual property, business and license agreements and clinical trial data, to Medavate in return for the Asset Consideration, conditioned upon the consummation of the merger.

	Year Ended December 31, 2018	Three Months Ended March 31, 2019
<b>Selected Unaudited Pro Forma Condensed Combined Statement of Operations (in thousands, except per share data)</b>		
Revenue	\$ —	\$ —
Total operating expenses	29,420	11,029
Net loss	(7,141)	(13,330)
Net loss per share, basic and diluted	(0.01)	(0.02)

	As of March 31, 2019
<b>Selected Unaudited Pro Forma Condensed Combined Balance Sheet Data (in thousands)</b>	
Cash and cash equivalents	\$ 37,895
Total assets	39,440
Total liabilities	19,678
Stockholders’ equity	19,762

**Comparative Historical and Unaudited Pro Forma Per Share Data**

The information below reflects the historical net loss and book value per share of Histogenics common stock and the historical net loss and book value per share of Ocugen common stock in comparison with the unaudited pro forma net loss and book value per share after giving effect to the proposed merger of Histogenics with Ocugen on a pro forma basis. The unaudited pro forma net loss and book value per share does not give effect to the Histogenics Reverse Stock Split.

You should read the tables below in conjunction with the audited financial statements of Histogenics included in this proxy statement/prospectus/information statement and the audited financial statements of Ocugen included in this proxy statement/prospectus/information statement and the related notes and the unaudited pro forma condensed combined financial information and notes related to such financial statements included elsewhere in this proxy statement/prospectus/information statement.

	<u>Year Ended</u> <u>December 31, 2018</u>	<u>Three</u> <u>Months Ended</u> <u>March 31, 2019</u>
<b>Histogenics Historical Per Share Data</b>		
Net loss per share, basic and diluted	\$(0.23) and (0.79)	\$ (0.12)
Book value per share	\$ (0.01)	\$ (0.06)
<b>Ocugen Historical Per Share Data</b>		
Net loss per share, basic and diluted	\$ (1.76)	\$ (0.61)
Book value per share	\$ (1.23)	\$ (1.80)
<b>Combined Organization Per Share Data</b>		
Net loss per share, basic and diluted	\$ (0.57)	\$ (0.17)
Book value per share	\$ (0.28)	\$ (0.27)

## RISK FACTORS

*The combined organization will be faced with a market environment that cannot be predicted and that involves significant risks, many of which will be beyond its control. In addition to the other information contained in this proxy statement/prospectus/information statement, you should carefully consider the material risks described below before deciding how to vote your shares of stock. In addition, you should read and consider the risks associated with Histogenics' business because these risks may also affect the combined organization—these risks can be found under the heading “Risk Factors—Risks Related to Histogenics” in this proxy statement/prospectus/information statement and in Histogenics' Annual Report on Form 10-K, as updated by subsequent Quarterly Reports on Form 10-Q, and other documents Histogenics has filed with the SEC and incorporated by reference into this proxy statement/prospectus/information statement. You should also read and consider the other information in this proxy statement/prospectus/information statement and the other documents incorporated by reference into this proxy statement/prospectus/information statement. Please see the section entitled “Where You Can Find More Information” in this proxy statement/prospectus/information statement.*

### **Risks Related to the Proposed Merger**

***The exchange ratio set forth in the Merger Agreement is not adjustable based on the market price of Histogenics common stock, so the merger consideration at the closing of the merger may have a greater or lesser value than at the time the Merger Agreement was signed.***

The Merger Agreement has set the exchange ratio for the Ocugen capital stock at 28.7650, subject to adjustment for the reverse stock split of Histogenics common stock to be implemented prior to the consummation of the merger. Applying the exchange ratio of 28.7650, current holders of Ocugen's capital stock and options and warrant to purchase shares of Ocugen common stock, are expected to own, or hold rights to acquire, in the aggregate approximately 86.24% of the Fully-Diluted Common Stock of Histogenics, and Histogenics' current stockholders and warrant holders are expected to own, or hold rights to acquire, in the aggregate approximately 13.76% of the Fully-Diluted Common Stock of Histogenics.

Any changes in the market price of Histogenics common stock before the completion of the merger will not affect the number of shares of Histogenics common stock issuable to Ocugen's stockholders pursuant to the Merger Agreement. Therefore, if before the completion of the merger the market price of Histogenics common stock increases from the market price of Histogenics common stock on the date of the Merger Agreement, then Ocugen's stockholders could receive merger consideration with substantially greater value than the value of such merger consideration on the date of the Merger Agreement. Similarly, if before the completion of the merger the market price of Histogenics common stock declines from the market price on the date of the Merger Agreement, then Ocugen's stockholders could receive merger consideration with substantially lower value than the value of such merger consideration on the date of the Merger Agreement. The Merger Agreement does not include a price-based termination right. Because the exchange ratio does not adjust as a result of changes in the market price of Histogenics common stock, for each one percentage point change in the market price of Histogenics common stock, there is a corresponding one percentage point rise or decline, respectively, in the value of the total merger consideration payable to Ocugen's stockholders pursuant to the Merger Agreement.

***Failure to complete the proposed merger may result in Histogenics and Ocugen paying a termination fee to the other party and could significantly harm the market price of Histogenics common stock and negatively affect the future business and operations of each company.***

If the proposed merger is not completed and the Merger Agreement is terminated under certain circumstances, Histogenics or Ocugen may be required to pay the other party a termination fee of up to \$600,000 or \$700,000, respectively. Even if a termination fee is not payable in connection with a termination of the Merger Agreement, each of Histogenics and Ocugen will have incurred significant fees and expenses, which must be paid whether or not the merger is completed. Further, if the proposed merger is not completed, it could significantly harm the market price of Histogenics common stock.



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In addition, if the Merger Agreement is terminated and the board of directors of Histogenics or Ocugen determines to seek another business combination, there can be no assurance that either Histogenics or Ocugen will be able to find a partner and close an alternative transaction on terms that are as favorable or more favorable than the terms set forth in the Merger Agreement.

***The proposed merger is subject to approval of the Merger Agreement by Histogenics' stockholders and the Ocugen stockholders. Failure to obtain these approvals would prevent the closing of the merger.***

Before the proposed merger can be completed, the stockholders of each of Histogenics and Ocugen must approve the Merger Agreement. Failure to obtain the required stockholder approvals may result in a material delay in, or the abandonment of, the merger. Any delay in completing the proposed merger may materially adversely affect the timing and benefits that are expected to be achieved from the proposed merger.

***The Merger may be completed even though certain events occur prior to the closing that materially and adversely affect Histogenics or Ocugen.***

The Merger Agreement provides that either Histogenics or Ocugen can refuse to complete the proposed merger if there is a material adverse change affecting the other party between April 5, 2019, the date of the Merger Agreement, and the closing of the merger. However, certain types of changes do not permit either party to refuse to complete the proposed merger, even if such change could be said to have a material adverse effect on Histogenics or Ocugen, including:

- general business, economic or political conditions or conditions generally affecting the industries in which Ocugen or Histogenics, as applicable, operates;
- any natural disaster or any acts of war, armed hostilities or terrorism;
- any changes in financial, banking or securities markets;
- with respect to Histogenics, any change in the stock price or trading volume of Histogenics excluding any underlying effect that may have caused such change;
- with respect to Histogenics, failure to meet internal or analysts' expectations or projects or the results of operations;
- any clinical trial programs or studies, including any adverse data, event or outcome arising out of or related to any such programs or studies;
- any change in accounting requirements or principles or any change in applicable laws, rules, or regulations or the interpretation thereof;
- any effect resulting from the announcement or pendency of the proposed merger or any related transactions; and
- the taking of any action, or the failure to take any action, by either Histogenics or Ocugen required to comply with the terms of the Merger Agreement.

If adverse changes occur and Histogenics and Ocugen still complete the merger, the market price of the combined organization's common stock may suffer. This in turn may reduce the value of the merger to the stockholders of Histogenics, Ocugen individually or on a combined basis.

***Some Histogenics and Ocugen officers and directors have interests in the proposed merger that are different from the respective stockholders of Histogenics and Ocugen and that may influence them to support or approve the merger without regard to the interests of the respective stockholders of Histogenics and Ocugen.***

Certain officers and directors of Histogenics and Ocugen participate in arrangements that provide them with interests in the proposed merger that are different from the interests of the respective stockholders of Histogenics

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and Ocugen, including, among others, the continued service as an officer or director of the combined organization, severance benefits, the acceleration of stock option vesting, continued indemnification and the potential ability to sell an increased number of shares of common stock of the combined organization in accordance with Rule 144 under the Securities Act.

For example, Ocugen has entered into certain employment and severance benefits agreements with certain of its executive officers that may result in the receipt by such executive officers of cash severance payments and other benefits in the event of a covered termination of employment of each executive officer's employment. In addition, and for example, certain of Ocugen's directors and executive officers have options, subject to vesting, to purchase shares of Ocugen common stock which, at the closing of the merger, shall be converted into and become options to purchase shares of Histogenics common stock, certain of Ocugen's directors and executive officers are expected to become directors and executive officers of Histogenics upon the closing of the merger, and all of Histogenics' and Ocugen's directors and executive officers are entitled to certain indemnification and liability insurance coverage pursuant to the terms of the Merger Agreement. These interests, among others, may influence the officers and directors of Histogenics and Ocugen to support or approve the proposed merger.

### ***The market price of Histogenics common stock following the merger may decline as a result of the merger.***

The market price of Histogenics common stock may decline as a result of the merger for a number of reasons including if:

- investors react negatively to the prospects of the combined organization's product candidates, business and financial condition following the merger;
- the effect of the merger on the combined organization's business and prospects is not consistent with the expectations of financial or industry analysts; or
- the combined organization does not achieve the perceived benefits of the merger as rapidly or to the extent anticipated by financial or industry analysts.

### ***Histogenics and Ocugen securityholders will have a reduced ownership and voting interest in, and will exercise less influence over the management of, the combined organization following the closing of the merger as compared to their current ownership and voting interest in the respective companies.***

After the completion of the merger, the current securityholders of Histogenics and Ocugen will own a smaller percentage of the combined organization than their ownership in their respective companies prior to the merger. Immediately after the merger, it is currently estimated that Ocugen securityholders will own, or hold rights to acquire, approximately 86.24% of the Fully-Diluted Common Stock of Histogenics, and Histogenics securityholders, whose shares of Histogenics common stock will remain outstanding after the merger, will own, or hold rights to acquire, approximately 13.76% of the Fully-Diluted Common Stock of Histogenics. These estimates are based on the anticipated exchange ratio and are subject to adjustment as provided in the Merger Agreement. See also the risk factor above titled, "*The exchange ratio is not adjustable based on the market price of Histogenics common stock, so the merger consideration at the closing may have a greater or lesser value than at the time the Merger Agreement was signed.*"

### ***Histogenics and Ocugen stockholders may not realize a benefit from the merger commensurate with the ownership dilution they will experience in connection with or following the merger.***

If the combined organization is unable to realize the strategic and financial benefits currently anticipated from the proposed merger, Histogenics' and Ocugen's stockholders will have experienced substantial dilution of their ownership interests in their respective companies without receiving the expected commensurate benefit, or only receiving part of the commensurate benefit to the extent the combined organization is able to realize only part of the expected strategic and financial benefits currently anticipated from the proposed merger.

***The combined company will need to raise additional capital by issuing securities or debt or through licensing or other strategic arrangements, which may cause dilution to the combined company's stockholders or restrict the combined company's operations or impact its proprietary rights.***

The combined company may be required to raise additional funds sooner than currently planned. Although the Merger Agreement does not condition the completion of the merger upon either company holding a minimum amount of cash at the effective time of the merger, if either or both of Histogenics or Ocugen hold less cash at the time of the closing of the merger than the parties currently expect, the combined company will need to raise additional capital sooner than expected. Additional financing may not be available to the combined company when it needs it or may not be available on favorable terms. To the extent that the combined company raises additional capital by issuing equity securities, such an issuance may cause significant dilution to the combined company's stockholders' ownership and the terms of any new equity securities may have preferences over the combined company's common stock. Any debt financing the combined company enters into may involve covenants that restrict its operations. These restrictive covenants may include limitations on additional borrowing and specific restrictions on the use of the combined company's assets, as well as prohibitions on its ability to create liens, pay dividends, redeem its stock or make investments. In addition, if the combined company raises additional funds through licensing, partnering or other strategic arrangements, it may be necessary to relinquish rights to some of the combined company's technologies or product candidates and proprietary rights, or grant licenses on terms that are not favorable to the combined company.

***During the pendency of the proposed merger, Histogenics and Ocugen may not be able to enter into a business combination with another party at a favorable price because of restrictions in the Merger Agreement, which could adversely affect their respective businesses.***

Covenants in the Merger Agreement impede the ability of Histogenics and Ocugen to make acquisitions, subject to certain exceptions relating to fiduciary duties, as set forth below, or to complete other transactions that are not in the ordinary course of business pending completion of the proposed merger. As a result, if the merger is not completed, the parties may be at a disadvantage to their competitors during such period. In addition, while the Merger Agreement is in effect, each party is generally prohibited from soliciting, initiating, encouraging or entering into certain extraordinary transactions, such as a merger, sale of assets, or other business combination outside the ordinary course of business with any third party, subject to certain exceptions relating to fiduciary duties. Any such transactions could be favorable to such party's stockholders.

***Certain provisions of the Merger Agreement may discourage third parties from submitting alternative takeover proposals, including proposals that may be superior to the arrangements contemplated by the Merger Agreement.***

The terms of the Merger Agreement prohibit each of Histogenics and Ocugen from soliciting alternative takeover proposals or cooperating with persons making unsolicited takeover proposals, except in limited circumstances when such party's board of directors determines in good faith that an unsolicited alternative takeover proposal is or is reasonably likely to lead to a superior takeover proposal and that failure to cooperate with the proponent of the proposal would be reasonably likely to be inconsistent with the applicable board's fiduciary duties.

***Because the lack of a public market for Ocugen's capital stock makes it difficult to evaluate the value of Ocugen's capital stock, the stockholders of Ocugen may receive shares of Histogenics common stock in the merger that have a value that is less than, or greater than, the fair market value of Ocugen's capital stock.***

The outstanding capital stock of Ocugen is privately held and is not traded in any public market. The lack of a public market makes it extremely difficult to determine the fair market value of Ocugen. Because the percentage of Histogenics common stock to be issued to Ocugen's stockholders was determined based on negotiations between the parties, it is possible that the value of Histogenics common stock to be received by Ocugen's stockholders will be less than the fair market value of Ocugen, or Histogenics may pay more than the aggregate fair market value for Ocugen.

***If the conditions to the merger are not met, the merger will not occur.***

Even if the merger is approved by the stockholders of Histogenics and Ocugen, specified conditions must be satisfied or waived to complete the merger. Histogenics and Ocugen cannot assure you that all of the conditions will be satisfied or waived. If the conditions are not satisfied or waived, the merger will not occur or will be delayed, and Histogenics and Ocugen each may lose some or all of the intended benefits of the proposed merger. Additionally, if the merger does not occur, Histogenics may not have sufficient cash to conduct an orderly wind-down and dissolution of Histogenics. Histogenics would not be able to raise additional capital through the sale of its NeoCart program prior to approval from its stockholders as such assets constitute substantially all of Histogenics' assets. Histogenics may seek an immediate dissolution, subject to a vote of its stockholders, in the event the merger is not completed.

***Litigation relating to the proposed merger could require Histogenics or Ocugen to incur significant costs and suffer management distraction, and could delay or enjoin the proposed merger.***

Histogenics and Ocugen could be subject to demands or litigation related to the proposed merger, whether or not the merger is consummated. Such actions may create uncertainty relating to the merger, or delay or enjoin the merger, and responding to such demands. In addition, such demands or litigation could lead to a dissolution or bankruptcy if the costs associated with such demands or litigation are significant enough.

**Risks Related to Histogenics**

**Risks Related to Histogenics' Financial Condition and Histogenics' Need for Additional Financing, and Additional Risks Related to the Merger**

***There is no assurance that the merger will be completed in a timely manner or at all. If the merger is not consummated, Histogenics' business could suffer materially and Histogenics' stock price could decline.***

The closing of the merger is subject to the satisfaction or waiver of a number of closing conditions, as described above, including the required approvals by Histogenics and Ocugen stockholders and other customary closing conditions. See the risk factors above titled, "*The proposed merger is subject to approval of the Merger Agreement by Histogenics' stockholders and the Ocugen stockholders. Failure to obtain these approvals would prevent the closing of the merger*" and "*If the conditions to the merger are not met, the merger will not occur.*" If the conditions are not satisfied or waived, the merger may be materially delayed or abandoned. If the merger is not consummated, Histogenics' ongoing business may be adversely affected and, without realizing any of the benefits of having consummated the merger, Histogenics will be subject to a number of risks, including the following:

- Histogenics has incurred and expects to continue to incur significant expenses related to the merger even if the merger is not consummated;
- Histogenics could be obligated to pay Ocugen a termination fee of up to \$600,000 under certain circumstances set forth in the Merger Agreement;
- the market price of Histogenics common stock may decline to the extent that the current market price reflects a market assumption that the merger will be completed; and
- matters relating to the merger have required and will continue to require substantial commitments of time and resources by Histogenics' remaining employees and consultants, which could otherwise have been devoted to other opportunities that may have been beneficial to Histogenics.

Histogenics also could be subject to litigation related to any failure to consummate the merger or to perform its obligations under the Merger Agreement. If the merger is not consummated, these risks may materialize and may adversely affect its business, financial condition and the market price of Histogenics common stock.

***If the merger is not completed, Histogenics may be unsuccessful in completing an alternative transaction on terms that are as favorable as the terms of the merger with Ocugen, or at all, and Histogenics may otherwise be unable to continue to operate its business. The Histogenics Board may decide to pursue a dissolution and liquidation of Histogenics. In such an event, the amount of cash available for distribution to its stockholders will depend heavily on the timing of such liquidation as well as the amount of cash that will need to be reserved for commitments and contingent liabilities.***

Histogenics' assets currently consist primarily of cash, cash equivalents and short-term investments, Histogenics' NeoCart assets, the remaining value, if any, of Histogenics' deferred tax assets, Histogenics' listing on the Nasdaq Capital Market and the Merger Agreement with Ocugen. While Histogenics has entered into the Merger Agreement with Ocugen, the closing of the merger may be delayed or may not occur at all and there can be no assurance that the merger will deliver the anticipated benefits Histogenics expects or enhance stockholder value. If Histogenics is unable to consummate the merger, the Histogenics Board may elect to pursue an alternative strategy, one of which may be a strategic transaction similar to the merger. Attempting to complete an alternative transaction like the merger will be costly and time consuming, and Histogenics can make no assurances that such an alternative transaction would occur at all. Alternatively, the Histogenics Board may elect to continue its operations to advance NeoCart into a further Phase 3 clinical trial, which would require that Histogenics obtain additional funding, which it does not currently believe could be completed, and to resume its efforts to seek potential collaborative, partnering or other strategic arrangements for Histogenics' NeoCart assets, including a sale or other divestiture of its NeoCart assets, or the Histogenics Board could instead decide to pursue a dissolution and liquidation of Histogenics' company. In such an event, the amount of cash available for distribution to Histogenics' stockholders will depend heavily on the timing of such decision, as with the passage of time the amount of cash available for distribution will be reduced as Histogenics continues to fund Histogenics' operations. In addition, if the Histogenics Board were to approve and recommend, and Histogenics' stockholders were to approve, a dissolution and liquidation of Histogenics' company, Histogenics would be required under Delaware corporate law to pay Histogenics' outstanding obligations, as well as to make reasonable provision for contingent and unknown obligations, prior to making any distributions in liquidation to Histogenics' stockholders. Histogenics' commitments and contingent liabilities may include severance obligations, regulatory, clinical and preclinical obligations, and fees and expenses related to the merger. As a result of this requirement, a portion of Histogenics' assets would need to be reserved pending the resolution of such obligations. In addition, Histogenics may be subject to litigation or other claims related to a dissolution and liquidation. If a dissolution and liquidation were pursued, the Histogenics Board, in consultation with its advisors, would need to evaluate these matters and make a determination about a reasonable amount to reserve. Accordingly, holders of Histogenics common stock could lose all or a significant portion of their investment in the event of a liquidation, dissolution or winding up of the company.

***The issuance of shares of Histogenics common stock to Ocugen stockholders in the merger will substantially dilute the voting power of Histogenics' current stockholders.***

If the merger is completed, each outstanding share of Ocugen common stock will be converted into the right to receive a number of shares of Histogenics common stock equal to the exchange ratio. Immediately following the merger, after giving effect to the Pre-merger Financing, the former Ocugen securityholders immediately before the merger are expected to own, or hold rights to acquire, approximately 86.24% of the Fully-Diluted Common Stock of Histogenics, and Histogenics' securityholders immediately before the merger are expected to own, or hold rights to acquire, approximately 13.76% of the Fully-Diluted Common Stock of Histogenics. The issuance of shares of Histogenics common stock to Ocugen stockholders in the merger will reduce significantly the relative voting power of each share of Histogenics common stock held by Histogenics' current stockholders. Consequently, Histogenics' stockholders as a group will have significantly less influence over the management and policies of the combined company after the merger than prior to the merger. See also the risk factor above titled, "*The exchange ratio set forth in the Merger Agreement is not adjustable based on the market price of Histogenics common stock, so the merger consideration at the closing of the merger may have a greater or lesser value than at the time the Merger Agreement was signed.*"

***Histogenics has incurred losses since inception, and Histogenics anticipates that it will incur continued losses for the foreseeable future.***

Histogenics has incurred net losses in each year since its inception, including net losses of \$8.6 million in 2018 and \$26.4 million in 2017. As of March 31, 2019, Histogenics had an accumulated deficit of \$226.2 million. Histogenics anticipates that its existing cash, cash equivalents and marketable securities will be sufficient to fund its operations into the middle of 2019. Accordingly, these factors, among others, raise substantial doubt about Histogenics' ability to continue as a going concern. The amount of its future net losses will depend, in part, on the amount and timing of its expenses. These net losses have had, and will continue to have, an adverse effect on its stockholders' equity and working capital.

As a result of Histogenics' decision to discontinue its NeoCart development efforts, Histogenics' activities are focused solely on completing the merger. Accordingly, if, for any reason, the merger is not consummated, Histogenics will resume its efforts to seek additional funds through potential collaborative, partnering or other strategic arrangements to provide it with the necessary resources to complete another alternative strategic transaction or wind-down and dissolve. However, Histogenics does not have sufficient capital resources and Histogenics will require significant additional financial resources in order to initiate and complete a further Phase 3 clinical trial for NeoCart. Based on its recent strategic process, Histogenics does not believe that it would be able to consummate a financing on reasonable terms sufficient to obtain such additional financial resources.

If the merger is not completed and Histogenics is unable to raise sufficient additional funds for the development of its NeoCart program, whether through potential collaborative, partnering or other strategic arrangements or otherwise, which it does not believe it would be able to do on reasonable terms, Histogenics will likely determine to cease operations, wind-down and dissolve (whether in or out of a bankruptcy or court proceeding to do so).

***If Histogenics does not successfully complete the merger, it will need to raise substantial additional capital and will likely be unable to raise the capital necessary to permit the continued development of its NeoCart program, which would likely cause it to cease operations.***

At March 31, 2019, Histogenics had cash, cash equivalents and short-term investments of \$7.4 million. If the merger is not completed, based on Histogenics' current business plan and spending assumptions as a standalone company, Histogenics estimates that its current cash, cash equivalents and short-term investments, together with interest thereon, will be sufficient to meet its projected operating requirements through the expected closing of the merger in the third quarter of 2019. Histogenics has based its cash sufficiency estimates on its current business plan and its assumptions that may prove to be wrong. Histogenics could utilize its available capital resources sooner than it currently expects, and it could need additional funding sooner than currently anticipated.

Histogenics' future funding requirements will depend on many factors, including:

- its ability to successfully complete the merger;
- the scope, rate of progress and cost of its NeoCart program;
- the terms and timing of any potential collaborative, partnering and other strategic arrangements that Histogenics may establish;
- the amount and timing of any licensing fees, milestone payments and royalty payments from potential collaborators, if any;
- potential future clinical trial results;
- the cost and timing of regulatory filings and/or approvals to commercialize any potential future product candidates and any related restrictions, limitations, and/or warnings in the label of an approved product candidate;
- the effect of competing technological and market developments; and

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- the cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights, and the cost of defending any other litigation claims.

While Histogenics has been able to fund its operations to date, Histogenics has no source of revenue, nor does it expect to generate product revenue for the foreseeable future. Histogenics does not have any commitments for future external funding.

Until Histogenics can generate a sufficient amount of product revenue, which it may never do, it will need to finance future cash needs through potential collaborative, partnering or other strategic arrangements, as well as through public or private equity offerings or debt financings or a combination of the foregoing. If Histogenics is unable to raise additional funds, it will need to continue to reduce its expenditures in order to preserve its cash. Further cost-cutting measures that Histogenics may take may not be sufficient to enable it to meet its cash requirements, and they may negatively affect Histogenics' business and its ability to derive any value from its NeoCart program. In any event, in order to further the development of its NeoCart program, Histogenics will need to raise substantial additional capital, which it does not currently believe it will be able to do on reasonable terms, if at all. Histogenics' failure to do so would likely result in it determining to cease operations.

To the extent that Histogenics raises additional funds through potential collaborations, partnering or other strategic arrangements, it may be necessary to relinquish rights to some of its technologies or product candidates and intellectual property rights thereof, or grant licenses on terms that are not favorable to it, any of which could result in Histogenics' stockholders having little or no continuing interest in its NeoCart assets as stockholders or otherwise. To the extent Histogenics raises additional funds by issuing equity securities, Histogenics' stockholders would experience significant dilution, particularly given its currently-depressed stock price, and debt financing, if available, may involve restrictive covenants. Histogenics' stockholders will experience additional, perhaps substantial, dilution should Histogenics again raise additional funds by issuing equity securities. Any additional debt or equity financing that Histogenics raises may contain terms that are not favorable to it or its stockholders. Histogenics' ability to raise additional funds and the terms upon which it is able to raise such funds have been severely harmed by the failure of the NeoCart Phase 3 clinical trial to meet its primary endpoint and the resulting significant uncertainty regarding Histogenics' prospects to continue as a going concern. If Histogenics is unable to complete the merger, its ability to raise additional funds and the terms upon which it is able to raise such funds may also be adversely affected by the uncertainties regarding its financial condition, uncertainties with respect to the prospects for its NeoCart program, the sufficiency of its capital resources, potential future management turnover, and volatility and instability in the global financial markets. As a result of these and other factors, there is no guarantee that sufficient additional funding will be available to Histogenics on acceptable terms, or at all.

***If the sale of Histogenics' assets relating to its NeoCart program, including patents, other intellectual property, licenses and clinical trial data is not completed, Histogenics will have less cash than currently anticipated.***

On May 8, 2019, Histogenics entered into the Asset Purchase Agreement with Medavate pursuant to which Medavate will acquire all of the assets relating to the NeoCart program, including patents, other intellectual property, licenses and clinical trial data, in consideration for the payment of the Asset Consideration, conditioned upon the consummation of the merger. Completion of the Asset Sale is subject to and expected to take place immediately following the closing of the merger. It is possible, however, that factors outside of Histogenics' control could require the parties to complete the Asset Sale at a later time, or not to complete the Asset Sale at all.

***Histogenics is substantially dependent on its remaining employee and key consultants to facilitate the consummation of the merger.***

In January and March 2019, the Histogenics Board implemented restructuring plans involving reductions in headcount to reduce operating costs and conserve cash, along with other cash conservation measures relating to

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its facilities. The positions eliminated as part of the restructuring plans together represented all but one member of its workforce, including its Chief Executive Officer, Chief Operating Officer, Chief Medical Officer and Chief Business Officer. Histogenics has engaged Mr. Adam Gridley, its former Chief Executive Officer, Mr. Stephen Kennedy, its former Chief Operating Officer, and certain former key employees as consultants to assist with its ongoing operation and in order to consummate the merger. Despite Histogenics' efforts to retain these persons, one or more may terminate their services with Histogenics on short notice. The loss of the services of any of these persons could potentially harm Histogenics' ability to consummate the merger, to run its day-to-day business operations, as well as to fulfill its reporting obligations as a public company.

***The pendency of the merger could have an adverse effect on the trading price of Histogenics common stock and its business, financial condition and prospects.***

While there have been no significant adverse effects to date, the pendency of the merger could disrupt Histogenics' business in many ways, including:

- the attention of its remaining consultants and employees may be directed toward the completion of the merger and related matters and may be diverted from Histogenics' day-to-day business operations; and
- third parties may seek to terminate or renegotiate their relationships with Histogenics as a result of the merger, whether pursuant to the terms of their existing agreements with Histogenics or otherwise.

Should they occur, any of these matters could adversely affect the trading price of Histogenics common stock or harm its business, financial condition and prospects.

### **Risks Related to Histogenics' Historical Business**

***The FDA has indicated an additional Phase 3 clinical trial for NeoCart would be required before the FDA would consider accepting a BLA submission for NeoCart.***

On December 20, 2018, Histogenics had a telephonic meeting with senior members of the FDA. Based on the feedback received from the FDA, while the NeoCart Phase 3 clinical trial resulted in certain compelling data, the FDA indicated that an additional Phase 3 clinical trial would need to be completed before it would accept a submission of a Biologics License Application ("BLA") for NeoCart. The FDA indicated receptivity to novel clinical trial methodologies and regenerative medicine advanced therapy designations in order to support additional data for a future potential submission. However, considering the time and funding required to conduct such a trial, Histogenics discontinued the development of NeoCart and does not plan to submit a BLA.

***Histogenics has historically been a clinical-stage cell therapy company with a limited operating history of developing late-stage product candidates. There is a limited amount of information about Histogenics upon which to evaluate its product candidates and business prospects, making an investment in its common stock unsuitable for many investors.***

Histogenics has historically been a clinical-stage company focused on the development of restorative cell therapies ("RCTs"), a class of products that are designed to offer patients rapid-onset pain relief and restored function through the repair of damaged or worn tissue. Histogenics was formed in 2000 and has a limited operating history. Since inception Histogenics has devoted substantially all of its resources to the development of its therapy technology platform, the clinical and preclinical advancement of its product candidates, the creation, licensing and protection of related intellectual property rights and the provision of general and administrative support for these operations. Histogenics has not yet obtained regulatory approval for any product candidates in any jurisdiction or generated any significant revenues from product sales. Histogenics has discontinued its development of NeoCart and it is currently in the process of completing the merger, as described elsewhere in these Risk Factors.



***Histogenics' inability to utilize its net operating loss carryforwards before they expire may adversely affect its results of operations and financial condition.***

As of December 31, 2018, Histogenics had federal and state net operating loss carryforwards of approximately \$67 million and \$67 million, respectively, which may be utilized against future federal and state income taxes. In general, a corporation that undergoes an "ownership change" is subject to limitations on its ability to utilize its pre-change net operating loss carryforwards ("NOLs") to offset future taxable income. In general, an ownership change occurs if the aggregate stock ownership of certain stockholders, generally stockholders beneficially owning five percent or more of its common stock, applying certain look-through and aggregation rules, increases by more than 50% over such stockholders' lowest percentage ownership during the testing period, generally three years. Purchases of Histogenics common stock in amounts greater than specified levels, which will be beyond its control, could create a limitation on its ability to utilize its NOLs for tax purposes in the future. In addition, the closing of a strategic transaction may result in the limitation of Histogenics' NOLs, which may affect the value it receives in such a strategic transaction. Limitations imposed on its ability to utilize NOLs could cause it to pay U.S. federal and state income taxes earlier than it would otherwise be required if such limitations were not in effect and could cause such NOLs to expire unused. Furthermore, Histogenics may not be able to generate sufficient taxable income to utilize its NOLs before they expire beginning in 2037. In addition, at the state level there may be periods during which the use of NOLs is suspended or otherwise limited, which would accelerate or may permanently increase state taxes owed. If any of these events occur, Histogenics may not derive some or all of the expected benefits from its NOLs, and its results of operations and financial condition may be adversely affected as a result.

***Histogenics may fail to comply with any of its obligations under existing agreements pursuant to which it licenses rights or technology, which could result in the loss of rights or technology that are material to its business and as a result possibly material to a potential strategic partner.***

Histogenics is a party to several technology licenses that are important to its business including material licenses from Purpose Co., Ltd., Angiotech Pharmaceuticals (US), Inc. and Angiodevice International GmbH. The rights licensed under these agreements, including rights relating to its tissue processor and bioadhesives are material to its cell therapy technology platform and the continued development of NeoCart and any future product candidates a strategic partner may choose to develop. These licenses impose various commercial, contingent payment, royalty, insurance, indemnification and other obligations on Histogenics. If Histogenics fails to comply with these obligations, the licensor may have the right to terminate the license, in which event Histogenics would lose valuable rights under its license agreements and the ability to develop or commercialize product candidates. Any termination or reversion of its rights under the foregoing agreements may have a material adverse effect on its business, prospects and results of operations and could significantly impair its ability to successfully complete the merger or any potential strategic transaction on terms that are favorable to its stockholders, or at all.

***Histogenics may face product liability claims and, if successful claims are brought against it, Histogenics may incur substantial liability and costs. If the use of its product candidates harms patients, or is perceived to harm patients even when such harm is unrelated to its product candidates, Histogenics' regulatory approvals could be revoked or otherwise negatively impacted and it could be subject to costly and damaging product liability claims.***

The use of NeoCart in clinical trials exposes it to the risk of product liability claims. Product liability claims might be brought against Histogenics by participants in clinical trials, consumers, healthcare providers, pharmaceutical companies or others selling or otherwise coming into contact with its product candidates and any products for which Histogenics obtains marketing approval. There is a risk that NeoCart could result in future adverse events in patients who were previously treated, and that such adverse events may not be detected for a long period of time. Such events could subject Histogenics to costly litigation, and if it cannot successfully defend against product liability claims require it to pay substantial amounts of money to injured patients. In addition, regardless of merit or eventual outcome, product liability claims may result in:

- increased costs due to related litigation;

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- distraction of management’s attention from its primary business;
- substantial monetary awards to patients or other claimants; and
- potential impairment of its ability to successfully complete a potential strategic transaction.

Histogenics carries product liability insurance that it believes is sufficient in light of its historical clinical programs; however, it may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect it against losses due to liability. On occasion, large judgments have been awarded in class action lawsuits based on cell or tissue therapies or medical treatments that had unanticipated adverse effects. In addition, under some of Histogenics’ agreements with clinical trial sites, it was required to indemnify the sites and their personnel against product liability and other claims. A successful product liability claim or series of claims brought against Histogenics or any third parties whom it is required to indemnify could cause its stock price to decline further and, if judgments exceed its insurance coverage, could adversely affect its results of operations and business.

Histogenics does not carry insurance for all categories of risk that its business may encounter and it may not be able to receive or maintain insurance with adequate levels of coverage. Any significant uninsured liability may require it to pay substantial amounts, which would adversely affect its financial position and results of operations and could significantly impair its ability to successfully complete the merger or any potential strategic transaction on terms that are favorable to its stockholders, or at all.

***Changes in government funding for the FDA and other government agencies could hinder their ability to hire and retain key leadership and other personnel, properly administer drug innovation, or prevent new products and services from being developed or commercialized by Histogenics’ life science tenants, which could negatively impact its business.***

The ability of the FDA to review and approve new products can be affected by a variety of factors, including budget and funding levels, government closures or shutdowns, the ability to hire and retain key personnel, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Budgetary pressures and or the closure of the federal government may result in a reduced ability by the FDA to perform its role. Specifically, over the last several years, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical employees. If a prolonged government shutdown occurs, it could delay the ability of a prospective strategic partner to discuss any potential regulatory path forward for NeoCart and as a result delay the merger or any potential strategic transaction.

***Legislative or regulatory healthcare reforms in the United States and abroad may make it more difficult and costly for a future partner to obtain regulatory approval of NeoCart and to produce, market and distribute NeoCart if an approval is obtained.***

From time to time, legislation is drafted and introduced in Congress that could significantly change the statutory provisions governing the regulatory approval, manufacture and marketing of regulated products or the reimbursement thereof. In addition, FDA regulations and guidance are often revised or reinterpreted by the FDA in ways that may significantly affect NeoCart or any other products that a strategic partner may choose to develop. Any new regulations or revisions or reinterpretations of existing regulations may impose additional costs or lengthen review times of NeoCart or any future product candidates. Recent presidential and congressional elections in the U.S. could result in significant changes in, and uncertainty with respect to, legislation, regulation and government policy that could significantly impact Histogenics’ business and the health care industry. Histogenics cannot determine what effect changes in regulations, statutes, legal interpretation or policies, when and if promulgated, enacted or adopted may have on its business in the future. Such changes could, among other things, require:

- changes to manufacturing methods;

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- additional studies, including clinical studies;
- recall, replacement, or discontinuance of NeoCart;
- the payment of additional taxes; or
- additional record keeping.

Each of these requirements would likely entail substantial time and cost and could adversely harm the future prospects for its business and its financial results which could impair its ability to successfully complete the merger or any potential strategic transaction on terms that are favorable to its stockholders, or at all.

***Histogenics has identified material weaknesses in its internal controls over financial reporting and may identify additional material weaknesses in the future that may cause it to fail to meet its reporting obligations or result in material misstatements of its financial statements.***

Histogenics' management team is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with U.S. generally accepted accounting principles. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of annual or interim financial statements will not be prevented or detected on a timely basis.

Histogenics has identified a material weakness in its internal controls relating to the accounting for transactions that are either highly complex and/or unusual in nature. In such instances, Histogenics seeks to augment its internal accounting capabilities by obtaining assistance from third-parties who have greater expertise in such areas. Examples of situations such as these include (but are not limited to) the determination of the initial and periodic fair value of warrants that are liability classified and the accounting treatment for the termination of Histogenics' collaboration agreement with Intrexon Corporation ("Intrexon"). For example, during the third quarter of 2018, Histogenics identified a material weakness in its internal controls relating to the valuation of the warrant liability. Because the valuation of the warrants is exceedingly complex and requires highly specialized skills to perform and review, Histogenics uses the assistance of a third-party service provider to perform such valuation. In the third quarter of 2018, the third-party service provider made an error in the valuation that was not detected by management in its review process but was identified by Histogenics' independent registered public accounting firm. In the fourth quarter of 2018, Histogenics identified a material weakness in its internal controls related to the accounting treatment for the contingent liability associated with the termination agreement entered into with Intrexon which terminated Histogenics' collaboration agreement with Intrexon. In this instance, Histogenics concluded after numerous discussions with its independent registered public accounting firm that it had incorrectly accounted for the contingent liability. In both cases these items were discovered prior to the issuance of the financial statements. The identified material weakness did not result in a misstatement to its consolidated financial statements or disclosures; however, it could result in misstatements of certain account balances (such as warrant liability, change in fair value of warrant liability and accrued expenses due to Intrexon) or disclosures that would result in a material misstatement to the annual or interim consolidated financial statements that would not be prevented or detected. Histogenics has implemented additional review procedures, including engaging a second third-party service provider to assist in its review of the work of the third-party service provider preparing the warrant valuation analysis and will seek to implement a similar procedure for other unusual or complex transactions going forward.

Histogenics cannot assure you that it will not have additional material weaknesses or significant deficiencies in its internal control over financial reporting. If Histogenics identifies any other material weaknesses or significant deficiencies that may exist, the accuracy and timing of its financial reporting may be adversely affected, it may be unable to maintain compliance with securities law requirements regarding timely filing of periodic reports in addition to applicable stock exchange listing requirements. These could result in a material decline in its stock price and could significantly impair its ability to successfully complete the merger or any potential strategic transaction on terms that are favorable to its stockholders, or at all.

***Histogenics' internal computer systems, or those of its development partners, third-party clinical research organizations or other contractors or consultants, may fail or suffer security breaches, which could result in a material disruption of its product development programs.***

Despite the implementation of security measures, Histogenics' internal computer systems and those of its development partners, third-party clinical research organizations, data management organizations and other contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. While Histogenics has not experienced any such system failure, accident or security breach to date, if such an event were to occur and cause interruptions in its operations, it could result in a material disruption of its programs. For example, the loss of any NeoCart clinical trial data could result in delays in Histogenics regulatory approval efforts and significantly increase its costs to recover or reproduce the data. To the extent that any disruption or security breach results in a loss of or damage to Histogenics' data or applications or other data or applications relating to its technology or product candidates, or inappropriate disclosure of confidential or proprietary information, Histogenics could incur liabilities and the further development NeoCart or any future product candidates could be delayed.

Histogenics relies on email and other messaging services in connection with its operations. Histogenics may be targeted by parties using fraudulent spoofing and phishing emails to misappropriate passwords, payment information or other personal information or to introduce viruses through Trojan horse programs or otherwise through its networks, computers, smartphones, tablets or other devices. Despite its efforts to mitigate the effectiveness of such malicious email campaigns through a variety of control and non-electronic checks, spoofing and phishing may damage Histogenics' business and increase its costs. Histogenics does not currently maintain a cyber insurance policy. Any of these events or circumstances could materially adversely affect Histogenics' business, financial condition and operating results and could significantly impair its ability to successfully complete the merger or any potential strategic transaction on terms that are favorable to its stockholders, or at all.

***Histogenics uses hazardous chemicals and biological materials in its business. Any claims relating to improper handling, storage or disposal of these materials could be time consuming and costly. Histogenics may incur significant costs complying with environmental laws and regulations.***

Histogenics' research and development and manufacturing processes involve the controlled use of hazardous materials, including chemicals and biological materials. Histogenics' operations produce hazardous waste products. Histogenics cannot eliminate the risk of accidental contamination or discharge and any resultant injury from these materials. Histogenics may be sued for any injury or contamination that results from its use or the use by third parties of these materials, and its liability may exceed its insurance coverage and its total assets. Federal, state and local laws and regulations govern the use, manufacture, storage, handling and disposal of these hazardous materials and specified waste products, as well as the discharge of pollutants into the environment and human health and safety matters.

Compliance with environmental laws and regulations may be expensive and may impair Histogenics' research, development and production efforts. If Histogenics fails to comply with these requirements, it could incur substantial costs, including civil or criminal fines and penalties, clean-up costs or capital expenditures for control equipment or operational changes necessary to achieve and maintain compliance. In addition, Histogenics cannot predict the impact on its business of new or amended environmental laws or regulations or any changes in the way existing and future laws and regulations are interpreted and enforced.

***Histogenics' employees or consultants may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements and insider trading.***

Histogenics is exposed to the risk of employee and consultant fraud or other misconduct. Misconduct by employees or consultants could include intentional failures to comply with the regulations of the FDA or foreign regulators, failure to provide accurate information to regulatory authorities, failure to comply with manufacturing

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standards Histogenics has established, failure to comply with federal and state health care fraud and abuse laws and regulations in the United States and abroad, failure to report financial information or data accurately, and failure to comply with its own internal company policies. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Employee or consultant misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and cause harm to Histogenics' reputation. Histogenics has adopted a code of business conduct and ethics, but it is not always possible to identify and deter employee misconduct, and the precautions Histogenics takes to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting Histogenics from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against Histogenics, and it is not successful in defending itself or asserting its rights, those actions could have a significant impact on its business, including the imposition of significant fines or other sanctions.

In addition, during the course of Histogenics' operations its directors, executives, employees and consultants may have access to material, nonpublic information regarding its business, its results of operations or potential transactions it is considering. Histogenics may not be able to prevent a director, executive, employee or consultant from trading in its common stock on the basis of, or while having access to, material, nonpublic information. If a director, executive, employee or consultant was to be investigated or an action was to be brought against a director, executive, employee or consultant for insider trading, it could have a negative impact on Histogenics' reputation and its stock price. Such a claim, with or without merit, could also result in substantial expenditures of time and money and divert attention of Histogenics' management team from other tasks important to the success of its business.

***Costs associated with being a public reporting company are significant, and public reporting requirements divert significant company resources and management attention.***

Histogenics is subject to the reporting requirements of the Exchange Act and the other rules and regulations of the SEC. Compliance with the various reporting and other requirements applicable to public reporting companies requires considerable time, attention of management and financial resources and Histogenics will need to maintain such compliance in order to complete the merger.

Further, the listing requirements of Nasdaq require that Histogenics satisfy certain corporate governance requirements relating to director independence, distributing annual and interim reports, stockholder meetings, approvals and voting, soliciting proxies, conflicts of interest and a code of conduct. Histogenics management and other personnel will need to devote a substantial amount of time to ensure that it complies with all of these requirements. Moreover, the reporting requirements, rules and regulations will increase Histogenics' legal and financial compliance costs and will make some activities more time-consuming and costly. These reporting requirements, rules and regulations, coupled with the increase in potential litigation exposure associated with being a public company, could also make it more difficult for Histogenics to obtain certain types of insurance, including directors' and officers' insurance, on acceptable terms.

***Histogenics' business is subject to the risks of earthquakes, fire, power outages, floods and other catastrophic events, and to interruption by manmade problems such as terrorism. If any of Histogenics' manufacturing, processing or storage facilities are damaged or destroyed, its business and prospects would be adversely affected.***

A significant natural disaster, such as an earthquake, fire or flood, or a significant power outage, could have a material adverse impact on Histogenics' business, operating results and financial condition. If any of Histogenics' manufacturing, processing or storage facilities, or any of the equipment in such facilities were to be

damaged or destroyed, it may result a lack of any definitive offer to consummate a strategic transaction, or, if Histogenics receives such a definitive offer, the terms may not be as favorable as anticipated or may not result in the consummation of a transaction.

Histogenics has historically produced materials for its clinical trials at its manufacturing facilities located in Waltham, Massachusetts, and produced its critical raw materials for use in NeoCart production in its facilities located in Lexington, Massachusetts. If these facilities or the equipment in them are significantly damaged or destroyed, a strategic partner may not be able to quickly or inexpensively replace such manufacturing capacity. In addition, natural disasters could affect Histogenics' third-party service providers' and manufacturers ability to perform services and provide materials for it or a strategic partner on a timely basis. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, Histogenics' efforts to complete a strategic transaction may be impeded. For example, acts of terrorism could cause disruptions in Histogenics' business or the business of its third-party service providers, partners, customers or the economy as a whole which could significantly impair its ability to successfully complete the merger or any potential strategic transaction on terms that are favorable to its stockholders, or at all.

***Histogenics is increasingly dependent on information technology systems, infrastructure and data.***

Histogenics is increasingly dependent upon information technology systems, infrastructure and data. Its computer systems may be vulnerable to service interruption or destruction, malicious intrusion and random attack. Security breaches pose a risk that sensitive data, including intellectual property, clinical data, trade secrets or personal information may be exposed to unauthorized persons or to the public. Cyber-attacks are increasing in their frequency, sophistication and intensity, and have become increasingly difficult to detect. Cyber-attacks could include the deployment of harmful malware, denial-of service, social engineering and other means to affect service reliability and threaten data confidentiality, integrity and availability. Histogenics' key business partners face similar risks, and a security breach of their systems could adversely affect Histogenics' security posture. While Histogenics continues to invest in data protection and information technology, there can be no assurance that its efforts will prevent service interruptions, or identify breaches in its systems, that could adversely affect its business and operations and/or result in the loss of critical or sensitive information or the illegal transfer of funds to unknown persons, which could result in financial, legal, business or reputational harm. Any of these issues could significantly impair Histogenics' ability to successfully complete the merger or any potential strategic transaction on terms that are favorable to its stockholders, or at all.

**Risks Related to Regulatory Matters**

***Histogenics is subject to numerous U.S. federal and state laws pertaining to health care fraud and abuse, including anti-kickback, self-referral, false claims and fraud laws, and any violation by Histogenics of such laws could result in fines or other penalties.***

The Foreign Corrupt Practices Act and similar worldwide anti-bribery laws generally prohibit companies and their intermediaries from making improper payments to non-U.S. officials for the purpose of obtaining or retaining business. Histogenics cannot assure you that its internal control policies and procedures will protect it from reckless or negligent acts committed by its employees, future distributors, partners, collaborators or agents. Violations of these laws, or allegations of such violations, could result in fines, penalties or prosecution and have a negative impact on Histogenics' business, results of operations and reputation.

**Risks Related to Histogenics' Intellectual Property**

***Histogenics' ability to execute a strategic transaction may depend on its ability to protect its intellectual property and its proprietary technologies.***

Histogenics' ability to execute a strategic transaction may depend in part on its ability to maintain patent protection and trade secret protection for its product candidates, proprietary technologies and their uses as well as

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Histogenics' ability to operate without infringing upon the proprietary rights of others. There can be no assurance that Histogenics' patent applications or those of its licensors will result in additional patents being issued or that issued patents will afford sufficient protection against competitors with similar technology, nor can there be any assurance that the patents issued will not be infringed, designed around, or invalidated by third parties. Even issued patents may later be found unenforceable or may be modified or revoked in proceedings instituted by third parties before various patent offices or in courts. The degree of future protection for Histogenics' proprietary rights is uncertain. Only limited protection may be available and may not adequately protect Histogenics' rights or permit it to gain or keep any competitive advantage. This failure to properly protect the intellectual property rights relating to these product candidates could have a material adverse effect on Histogenics financial condition and results of operations and ability to complete the merger.

Composition-of-matter patents are generally considered to be the strongest form of intellectual property protection as such patents provide protection without regard to any method of use. Histogenics cannot be certain that the claims in its patent applications covering composition-of-matter of its product candidates will be considered patentable by the U.S. Patent and Trademark Office and courts in the United States or by the patent offices and courts in foreign countries, nor can Histogenics be certain that the claims in its issued composition-of-matter patents will not be found invalid or unenforceable if challenged. Method-of-use patents protect the use of a product for the specified method. This type of patent does not prevent a competitor from making and marketing a product that is identical to Histogenics' product for a use that is outside the scope of the patented method. Moreover, even if competitors do not actively promote their product for Histogenics' targeted indications, physicians may prescribe these products "off-label." Although off-label prescriptions may infringe or contribute to the infringement of method-of-use patents, the practice is common and such infringement is difficult to prevent or prosecute.

The patent application process is subject to numerous risks and uncertainties, and there can be no assurance that Histogenics or any of its future development partners will be successful in protecting its product candidates by obtaining and defending patents. These risks and uncertainties include the following:

- The U.S. Patent and Trademark Office and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent process. There are situations in which noncompliance can result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, competitors might be able to enter the market earlier than would otherwise have been the case.
- Patent applications may not result in any patents being issued.
- Patents that may be issued or in-licensed may be challenged, invalidated, modified, revoked, circumvented, found to be unenforceable, or otherwise may not provide any competitive advantage.
- Histogenics' competitors, many of whom have substantially greater resources than Histogenics does and many of whom have made significant investments in competing technologies, may seek or may have already obtained patents that will limit, interfere with, or eliminate its ability to make, use and sell Histogenics' potential product candidates.
- There may be significant pressure on the U.S. government and international governmental bodies to limit the scope of patent protection both inside and outside the United States for treatments that prove successful, as a matter of public policy regarding worldwide health concerns.
- Countries other than the United States may have patent laws less favorable to patentees than those upheld by U.S. courts, allowing foreign competitors a better opportunity to create, develop, and market competing product candidates.

In addition, Histogenics relies on the protection of its trade secrets and proprietary know-how. Although Histogenics has taken steps to protect its trade secrets and unpatented know-how, including entering into

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confidentiality agreements with third parties, and confidential information and inventions agreements with employees, consultants and advisors, third parties may still obtain this information or may come upon this or similar information independently. If any of these events occurs or if Histogenics otherwise loses protection for its trade secrets or proprietary know-how, the value of this information may be greatly reduced.

***If Histogenics or any of its future development or collaborative partners are sued for infringing intellectual property rights of third parties, it will be costly and time consuming, and an unfavorable outcome in that litigation could have a material adverse effect on Histogenics' business.***

Histogenics' success also depends on its ability and the ability of its current or future development or collaborative partners to develop, manufacture, market and sell its product candidates without infringing upon the proprietary rights of third parties. Numerous U.S. and foreign-issued patents and pending patent applications owned by third parties exist in the fields in which Histogenics is developing product candidates, some of which may contain claims that overlap with the subject matter of its intellectual property or are directed at its product candidates, technologies or methods of manufacture. When Histogenics becomes aware of patents held by third parties that may implicate the manufacture, development or commercialization of its product candidates, Histogenics evaluates its need to license rights to such patents. If Histogenics needs to license rights from third parties to manufacture, develop or commercialize its product candidates, there can be no assurance that it will be able to obtain a license on commercially reasonable terms or at all. Failure to obtain a license on commercially reasonable terms or at all could impair Histogenics' ability to successfully complete the merger or any potential strategic transaction on terms that are favorable to its stockholders, or at all.

Because patent applications can take many years to issue there may be currently pending applications, unknown to Histogenics, that may later result in issued patents upon which Histogenics' product candidates or proprietary technologies may infringe. Similarly, there may be issued patents relevant to its product candidates of which Histogenics is not aware.

There is a substantial amount of litigation involving patent and other intellectual property rights in the biologics industry generally. If a third-party claims that Histogenics or any of its licensors, suppliers or development partners infringe upon a third-party's intellectual property rights, Histogenics may have to:

- seek to obtain licenses that may not be available on commercially reasonable terms, if at all;
- abandon an infringing product candidate or redesign its products or processes to avoid infringement;
- pay substantial damages including, in an exceptional case, treble damages and attorneys' fees, which Histogenics may have to pay if a court decides that the product candidate or proprietary technology at issue infringes upon or violates the third-party's rights;
- pay substantial royalties or fees or grant cross-licenses to its technology; or
- defend litigation or administrative proceedings that may be costly whether Histogenics wins or loses, and which could result in a substantial diversion of its financial and management resources.

***Histogenics may be involved in lawsuits to protect or enforce its patents or the patents of its licensors, which could be expensive, time consuming and unsuccessful.***

Third parties may infringe upon Histogenics' patents or the patents of its licensors. To counter infringement or unauthorized use, Histogenics may be required to file infringement claims, which can be expensive and time consuming. An adverse result in any litigation or defense proceedings could put one or more of its patents at risk of being invalidated, found to be unenforceable or interpreted narrowly and could put Histogenics' patent applications at risk of not issuing. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of Histogenics' confidential information could be compromised by disclosure during this type of litigation.

Most of Histogenics' competitors are larger than it is and have substantially greater resources. They are, therefore, likely to be able to sustain the costs of complex patent litigation longer than Histogenics could. In



addition, the uncertainties associated with litigation could have a material adverse effect on Histogenics ability to raise the funds necessary to continue its clinical trials, continue its internal research programs, in-license needed technology, or enter into development partnerships that would help Histogenics bring its product candidates to market.

In addition, any future patent litigation, interference or other administrative proceedings will result in additional expense and distraction of Histogenics' personnel. An adverse outcome in such litigation or proceedings may expose Histogenics, or any of its future development partners to loss of its proprietary position, expose it to significant liabilities or require it to seek licenses that may not be available on commercially acceptable terms, if at all. Failure to obtain a license on commercially reasonable terms or at all could impair Histogenics' ability to successfully complete the merger or any potential strategic transaction on terms that are favorable to its stockholders, or at all.

***Histogenics issued patents could be found invalid or unenforceable if challenged in court which could have a material adverse effect on Histogenics' business could impair its ability to successfully complete a potential strategic transaction.***

If Histogenics or any of its future development partners were to initiate legal proceedings against a third party to enforce a patent covering one of Histogenics' product candidates or one of its future product candidates, technologies or methods of manufacture, the defendant could counterclaim that Histogenics' patent is invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the U.S. Patent and Trademark Office, or made a misleading statement, during prosecution. Third parties may also raise similar claims before the U.S. Patent and Trademark Office even outside the context of litigation. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, Histogenics cannot be certain that there is no invalidating prior art, of which Histogenics and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, Histogenics would lose at least part, and perhaps all, of the patent protection on such product candidate. Such a loss of patent protection would have a material adverse impact on Histogenics' business and could impair its ability to successfully complete the merger or any potential strategic transaction on terms that are favorable to its stockholders, or at all.

***Histogenics may be subject to claims that its consultants or independent contractors have wrongfully used or disclosed alleged trade secrets of their other clients or former employers to it, which could subject Histogenics to costly litigation.***

As is common in the biotechnology industry, Histogenics engages the services of consultants to assist it in the development of its product candidates. Many of these consultants were previously employed at, or may have previously or may be currently providing consulting services to, other biotechnology or pharmaceutical companies, including its competitors or potential competitors. Histogenics may become subject to claims that its company or a consultant inadvertently or otherwise used or disclosed trade secrets or other information proprietary to their former employers or their former or current clients. Litigation may be necessary to defend against these claims. Even if Histogenics is successful in defending against these claims, litigation could result in substantial costs and be a distraction to its management team and could impair its ability to successfully complete the merger or any potential strategic transaction on terms that are favorable to its stockholders, or at all.

***Changes in U.S. patent law could diminish the value of patents in general, which could materially impair Histogenics' ability to protect its product candidates.***

As is the case with other biotechnology companies, Histogenics' success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biotechnology industry involve

technological and legal complexity. Therefore, obtaining and enforcing biotechnology patents is costly, time consuming and inherently uncertain. In addition, Congress recently passed patent reform legislation. The Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to Histogenics' ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the U.S. Congress, the federal courts and the U.S. Patent and Trademark Office, the laws and regulations governing patents could change in unpredictable ways that would weaken Histogenics' ability to obtain new patents or to enforce its existing patents and patents it might obtain in the future.

***Histogenics may not be able to protect its intellectual property rights throughout the world which could materially, negatively affect its business.***

Filing, prosecuting and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and Histogenics' intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, Histogenics may not be able to prevent third parties from practicing its inventions in all countries outside the United States, or from selling or importing products made using its inventions in and into the United States or other jurisdictions. Competitors may use Histogenics' technologies in jurisdictions where it has not obtained patent protection to develop their own products and further, may export otherwise infringing products to territories where Histogenics has patent protection, but enforcement is not as strong as that in the United States. These products may compete with Histogenics' product candidates and its patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to biotechnology, which could make it difficult for Histogenics to stop the infringement of its patents or marketing of competing products in violation of its proprietary rights generally. Proceedings to enforce Histogenics' patent rights in foreign jurisdictions could result in substantial costs and divert its efforts and attention from other aspects of its business, could put its patents at risk of being invalidated or interpreted narrowly and its patent applications at risk of not issuing and could provoke third parties to assert claims against it. Histogenics may not prevail in any lawsuits that it initiates and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, Histogenics' efforts to enforce its intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that it develops or license and may adversely affect its business and could significantly impair its ability to successfully complete a potential strategic transaction on terms that are favorable to its stockholders, or at all.

***If Histogenics' trademarks and trade names are not adequately protected, then it may not be able to build name recognition in its markets of interest and its business may be adversely affected.***

Histogenics' registered or unregistered trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. Histogenics may not be able to protect its rights to these trademarks and trade names, which it needs to build name recognition by potential partners or customers in its markets of interest. Over the long term, if Histogenics is unable to establish name recognition based on its trademarks and trade names, then it may not be able to compete effectively and its business may be adversely affected.

## Risks Related to Histogenics Common Stock

*Histogenics received deficiency letters in October 2018 and December 2018 from the Nasdaq Listing Qualifications Department (the “Staff”) of Nasdaq notifying Histogenics that it was not in compliance with Nasdaq Listing Rule 5550(a)(2) and Nasdaq Listing Rule 5550(b)(2). If Histogenics were to fail to regain compliance, its shares could be delisted from the Nasdaq Capital Market, which could materially reduce the liquidity of its common stock and have an adverse effect on its market price. A delisting could limit Histogenics’ strategic alternatives and ability to consummate a potential transaction.*

On October 17, 2018, Histogenics received a deficiency letter from the Staff notifying it that, for the 30 consecutive business days prior to October 17, 2018, the closing bid price for Histogenics common stock had closed below a minimum \$1.00 per share required for continued listing on The Nasdaq Capital Market pursuant to Nasdaq Listing Rule 5550(a)(2) (“Rule 5550(a)(2)”). The Nasdaq deficiency letter has no immediate effect on the listing of its common stock, and its common stock will continue to trade on The Nasdaq Capital Market under the symbol “HSGX” at this time. In accordance with Nasdaq Listing Rule 5810(c)(3)(A), Histogenics was given 180 calendar days, or until April 15, 2019 to regain compliance with Rule 5550(a)(2).

On April 16, 2019, Histogenics received a letter (the “Letter”) from the Staff notifying Histogenics that, based upon Histogenics’ continuing non-compliance with Rule 5550(a)(2), the Staff had determined that Histogenics common stock would be delisted from Nasdaq unless Histogenics timely requested a hearing before a Nasdaq Hearings Panel (the “Panel”). The Letter also noted that Histogenics was not eligible for a second 180 day grace period as it does not comply with the stockholders’ equity initial listing requirement for The Nasdaq Capital Market.

Accordingly, Histogenics timely requested a hearing before the Panel, which took place in May 2019. On May 31, 2019, Histogenics received a decision letter from the Panel (the “Decision”), indicating that the Panel had granted Histogenics’ request to continue its listing on The Nasdaq Capital Market in order to complete the proposed merger with Ocugen. The Decision specifies that Histogenics shall complete the merger no later than September 30, 2019, and demonstrate to the satisfaction of the Staff and the Panel that the combined entity meets all of the applicable requirements for initial listing on The Nasdaq Capital Market. The Panel reserved the right to reconsider the terms of the extension based on any event, condition or circumstance that exists or develops that would, in the opinion of the Panel, make continued listing of Histogenics’ common stock on The Nasdaq Capital Market inadvisable or unwarranted. Histogenics’ common stock will continue to trade on The Nasdaq Capital Market under the symbol “HSGX” through the earlier of the expiration of the extension period granted by the Panel or the closing of the proposed merger.

Further, on December 19, 2018, Histogenics received a deficiency letter from the Staff notifying it that for the last 30 consecutive business days prior to December 18, 2018, the market value of its listed securities were less than \$35 million, which does not meet the requirement for continued listing on The Nasdaq Capital Market under Nasdaq Listing Rule 5550(b)(2) (“Rule 5550(b)(2)”). In accordance with Nasdaq Listing Rule 5810(c)(3)(C), Nasdaq provided Histogenics until June 17, 2019 to regain compliance with Rule 5550(b)(2).

On June 19, 2019, Histogenics received a letter (the “June Letter”) from the Staff notifying Histogenics that it had failed to regain compliance with the Rule 5550(b)(2) and that such compliance failure serves as an additional basis for delisting Histogenics’ common stock from The Nasdaq Capital Market. The June Letter also noted that such letter served as formal notification that the Panel will consider the failure to regain compliance with the Rule 5550(b)(2) in its decision regarding Histogenics’ continued listing on The Nasdaq Capital Market, and that Histogenics should present its views with respect to this additional compliance deficiency to the Panel in writing no later than June 26, 2019. Histogenics timely presented its views to the Panel on June 26, 2019.

A delisting would also likely make it more difficult for Histogenics to obtain financing through the sale of its equity. Any such sale of equity would likely be more dilutive to its current stockholders than would be the case if Histogenics’ shares were listed.

***Histogenics may not satisfy The Nasdaq Capital Market's other requirements for continued listing. If Histogenics cannot satisfy these requirements, Nasdaq could delist its common stock and could impact its ability to consummate the merger.***

Histogenics common stock is listed on The Nasdaq Capital Market under the symbol "HSGX." To continue to be listed on Nasdaq, Histogenics' is required to satisfy a number of conditions. Other than the deficiency letters discussed in the immediately prior risk factor, Histogenics previously received two letters from Nasdaq, with the first letter in November 2016 notifying it of its failure to maintain a minimum market value of listed securities of \$50,000,000 for the 30 consecutive business days. Histogenics subsequently regained compliance with this listing standard in March 2017. The second letter in May 2017 notified Histogenics of its failure to maintain a minimum of \$10,000,000 in stockholders' equity as required for companies trading on The Nasdaq Global Market. In response to the second letter, Histogenics transferred its securities to The Nasdaq Capital Market in June 2017 to regain compliance with the minimum stockholders' equity requirement.

Histogenics cannot assure you that it will be able to satisfy the Nasdaq listing requirements in the future. If Histogenics is delisted from Nasdaq, trading in its shares of common stock may be conducted, if available, on the "OTC Bulletin Board Service" or, if available, via another market. In the event of such delisting, an investor would likely find it significantly more difficult to dispose of, or to obtain accurate quotations as to the value of the shares of Histogenics common stock, and its ability to raise future capital through the sale of the shares of its common stock or other securities convertible into or exercisable for its common stock could be severely limited. A determination could also then be made that Histogenics common stock is a "penny stock" which would require brokers trading in its common stock to adhere to more stringent rules and possibly result in a reduced level of trading. This could have a long-term impact on Histogenics' ability to raise future capital through the sale of its common stock.

***The trading price of Histogenics common stock has been, and is likely to continue to be, volatile, and you might not be able to sell your shares at or above the price you paid.***

Histogenics' stock price has been and will likely continue to be volatile for the foreseeable future. The realization of any of the risks described in these risk factors or other unforeseen risks could have a dramatic and adverse effect on the market price of its common stock. The trading price of its common stock is likely to continue to be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond Histogenics' control. These factors include those discussed elsewhere in this "Risk Factors" section and others such as:

- its ability to consummate a strategic transaction, the value of such transaction including whether it is deemed to enhance stockholder value or deliver expected benefits;
- announcements about Histogenics or about its competitors including clinical trial results, regulatory approvals, or new product candidate introductions and the revenue and growth potential of such new products;
- developments concerning its current or future development partners, licensors or product candidate manufacturers;
- litigation and other developments relating to its patents or other proprietary rights or those of its competitors;
- conditions in the pharmaceutical or biotechnology industries, regulations or concerns related to cell and gene therapies, and the economy as a whole;
- governmental regulation and legislation;
- the recruitment or departure of members of its Board, management team or other key personnel;
- changes in its operating results;

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- any changes in the financial projections it may provide to the public, its failure to meet these projections, or changes in recommendations by any securities analysts that elect to follow its common stock;
- any change in securities analysts' estimates of its performance, or its failure to meet analysts' expectations;
- the expiration of market standoff or contractual lock-up agreements;
- sales or potential sales of substantial amounts of its common stock; and
- price and volume fluctuations in the overall stock market or resulting from inconsistent trading volume levels of its shares.

In recent months and years, the stock market in general, and the market for pharmaceutical and biotechnological companies in particular, has experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to changes in the operating performance of the companies whose stock is experiencing those price and volume fluctuations. In addition, Brexit or actions taken by the current presidential administration and Congress could adversely affect United States, European or worldwide economic or market conditions and could contribute to instability and volatility in global financial markets. Broad market and industry factors may seriously affect the market price of Histogenics common stock, regardless of its actual operating performance.

***Histogenics' quarterly operating results may fluctuate substantially, which may cause the price of its common stock to fluctuate substantially.***

Histogenics expects its quarterly operating results to be subject to fluctuations. Histogenics' net income or loss and other operating results may be affected by numerous factors, including:

- its ability to complete the merger or any strategic transaction;
- derivative instruments recorded at fair value, including but not limited to the change in fair value of warrants issued in connection with a private placement completed in 2016;
- asset impairments, severance costs, lease termination costs, transaction and other costs triggered by a wind down of its operations; and
- any lawsuits in which it may become involved.

If Histogenics' quarterly operating results fall below the expectations of investors or securities analysts, the price of its common stock could decline substantially. Furthermore, any quarterly fluctuations in its operating results may, in turn, cause the price of its stock to fluctuate substantially.

***Histogenics expects its stock price to continue to be volatile, and securities class action litigation has often been instituted against companies following periods of volatility of their stock price or after the announcement of a change in control transaction. Any such litigation, if instituted against Histogenics, could result in substantial costs and a diversion of its management's attention and resources.***

In the past, following periods of volatility in the overall market and the market price of a particular company's securities, securities class action litigation has often been instituted against these companies. This litigation, if instituted against Histogenics, could result in substantial costs and a diversion of its management's attention and resources. This litigation, if instituted against it could also impair its ability to successfully complete a potential strategic transaction on terms that are favorable to its stockholders, or at all.

***If securities analysts do not publish research, publish unfavorable research about Histogenics' business (or the combined company's business) or cease coverage of the company, its stock price and trading volume could decline.***

The trading market for Histogenics common stock will depend in part on the research and reports that securities and industry analysts publish about it or its business (including the business of the combined company following consummation of the merger). In the event one or more of the analysts who covers Histogenics downgrades its stock or publishes unfavorable research about its business, or if its clinical trials or operating results fail to meet the analysts' expectations, its stock price would likely decline. Recently, several securities analysts ceased coverage of Histogenics, and if one or more of the remaining analysts ceases coverage of Histogenics or fails to publish reports on it regularly, demand for Histogenics' stock could decrease, which could cause its stock price and trading volume to decline.

***Raising additional funds by issuing securities or through licensing or lending arrangements may cause dilution to Histogenics' existing stockholders, restrict its operations or require it to relinquish proprietary rights.***

To the extent that Histogenics raises additional capital by issuing equity securities, the share ownership of existing stockholders will be diluted. Any future debt financing may involve covenants that restrict Histogenics' operations, including limitations on its ability to incur liens or additional debt, pay dividends, redeem its stock, make certain investments, and engage in certain merger, consolidation, or asset sale transactions. In addition, if Histogenics seeks funds through arrangements with collaborative partners, these arrangements may require it to relinquish rights to some of its technologies or product candidates or otherwise agree to terms unfavorable to it.

***Histogenics has never paid and does not intend to pay cash dividends and, consequently, your ability to achieve a return on your investment will depend on appreciation in the price of Histogenics common stock.***

Histogenics has never paid cash dividends on any of its capital stock, and it currently intends to retain future earnings, if any, to fund the development and growth of its business. Therefore, you are not likely to receive any dividends on Histogenics common stock for the foreseeable future or at all. Since Histogenics does not intend to pay dividends, your ability to receive a return on your investment will depend on any future appreciation in the market value of Histogenics common stock. There is no guarantee that Histogenics common stock will appreciate or even maintain the price at which you have purchased it.

***Provisions in Histogenics' sixth amended and restated certificate of incorporation and amended and restated bylaws and Delaware law might discourage, delay or prevent a change in control of Histogenics or changes in its management and, therefore, depress the market price of its common stock.***

Histogenics' sixth amended and restated certificate of incorporation and amended and restated bylaws contain provisions that could depress the market price of its common stock by acting to discourage, delay or prevent a change in control of Histogenics or changes in its management that the stockholders of Histogenics may deem advantageous. These provisions among other things:

- establish a classified board of directors so that not all members of the board are elected at one time;
- permit the board of directors to establish the number of directors;
- provide that directors may only be removed "for cause";
- require super-majority voting to amend some provisions in Histogenics' certificate of incorporation and bylaws;
- authorize the issuance of "blank check" preferred stock that the Histogenics Board could use to implement a stockholder rights plan;
- eliminate the ability of Histogenics' stockholders to call special meetings of stockholders;

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- prohibit stockholder action by written consent, which requires all stockholder actions to be taken at a meeting of Histogenics' stockholders;
- provide that the board of directors is expressly authorized to make, alter or repeal Histogenics' bylaws; and
- establish advance notice requirements for nominations for election to the Histogenics Board or for proposing matters that can be acted upon by stockholders at annual stockholder meetings.

In addition, Section 203 of the DGCL may discourage, delay or prevent a change in control of Histogenics. Section 203 imposes certain restrictions on merger, business combinations and other transactions between Histogenics and holders of 15% or more of its common stock.

***Histogenics is an emerging growth company and the extended transition period for complying with new or revised financial accounting standards and reduced disclosure and governance requirements applicable to emerging growth companies could make Histogenics common stock less attractive to investors.***

Histogenics is an emerging growth company. Under the Jumpstart Our Business Startups Act (the "Jobs Act"), emerging growth companies can delay adopting new or revised accounting standards until such time as those standards apply to private companies. Histogenics plans to avail itself of this exemption from new or revised accounting standards and, therefore, it may not be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

For as long as Histogenics continues to be an emerging growth company, it also intends to take advantage of certain other exemptions from various reporting requirements that are applicable to other public companies, including reduced disclosure obligations regarding executive compensation in its periodic reports and proxy statements, exemptions from the requirements of holding a nonbinding advisory stockholder vote on executive compensation and any golden parachute payments not previously approved, exemption from the requirement of auditor attestation on its internal control over financial reporting and exemption from any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements (auditor discussion and analysis). If Histogenics does, the information that it provides stockholders may be different than what is available with respect to other public companies.

Investors could find Histogenics common stock less attractive because it will rely on these exemptions, which may make it more difficult for investors to compare its business with other companies in its industry. If some investors find Histogenics common stock less attractive as a result, there may be a less active trading market for its common stock and its stock price may be more volatile. In addition, it may be difficult for Histogenics to raise additional capital as and when needed. If Histogenics is unable to do so, its financial condition and results of operations could be materially and adversely affected.

Histogenics will remain an emerging growth company until the earliest of: (1) the end of the fiscal year in which the market value of its common stock that is held by non-affiliates exceeds \$700.0 million as of the end of the second fiscal quarter; (2) the end of the fiscal year in which it has total annual gross revenue of \$1.07 billion or more during such fiscal year; (3) the date on which it issues more than \$1.0 billion in non-convertible debt in a three-year period or (4) December 31, 2019, the end of the fiscal year following the fifth anniversary of the completion of its initial public offering.

## Risks Related to Ocugen

### Risks Related to Ocugen's Financial Position and Capital Requirements

*Ocugen has incurred significant losses from operations and negative cash flows from operations since its inception. Ocugen expects to incur losses over the next several years and may never achieve or maintain profitability.*

Since inception, Ocugen has incurred significant net losses and expects to continue to incur net losses for the foreseeable future. Ocugen has not generated any revenue to date and has funded its operations to date through the sale of common stock, warrants to purchase common stock, the issuance of convertible notes, and borrowings under credit facilities. Ocugen incurred net losses of approximately \$6.3 million for the three months ended March 31, 2019, \$18.2 million for the year ended December 31, 2018, and \$7.8 million for the year ended December 31, 2017. As of March 31, 2019, Ocugen had an accumulated deficit of \$37.5 million and a cash and cash equivalents balance of \$0.3 million.

Ocugen has devoted substantially all of its financial resources and efforts to research and development, including preclinical studies and clinical trials. Ocugen expects that over the next several years it will continue to incur losses from operations as it increases its expenditures in research and development in connection with clinical trials and other development activities. Ocugen's net losses may fluctuate significantly from quarter to quarter and year to year.

Ocugen anticipates that its expenses will increase substantially as compared to prior periods as it completes its Phase 3 trial with respect to OCU300, prepares to commence Phase 1 trials with respect to OCU400 and OCU200, and otherwise develops and prepares for commercialization of its product candidates, as a result of increased headcount, including management personnel to support its clinical, manufacturing and commercialization activities, expanded infrastructure, increased legal, compliance, accounting and investor and public relations expenses associated with being a public company, and increased insurance premiums, among other factors. Ocugen may seek to obtain additional financing in the future through the issuance of common stock, through other equity or debt financings or through collaborations or partnerships with other companies. Ocugen may not be able to raise additional capital on terms acceptable to it, or at all, and any failure to raise capital as and when needed could compromise its ability to execute on its business plan and cause it to delay or curtail operations until such funding is received.

In addition, Ocugen's license agreements with the University of Colorado, the University of Illinois at Chicago and The Schepens Eye Research Institute impose, among other obligations, royalty, milestone payment, and other financial obligations on it, and Ocugen may enter into additional licensing and funding arrangements with third parties that may impose additional royalty, milestone payment, insurance and other obligations on it.

Due to the inherently unpredictable nature of preclinical and clinical development, Ocugen is unable to estimate with any certainty the costs it will incur and the timelines it will require in its continued development efforts. Additionally, its expenses will also increase if, and, as it:

- pursues the clinical development of OCU300 and OCU310, through Phase 3 clinical development and otherwise pursues the preclinical and clinical development of its product candidates;
- initiates preclinical studies and clinical trials for any additional product candidates that it may pursue in the future;
- seeks marketing approvals for product candidates that successfully complete clinical development;
- establishes sales, marketing and distribution capabilities for its product candidates for which it obtains marketing approval;
- scales up its manufacturing processes and capabilities to support its clinical trials of its product candidates and commercialization of any of its product candidates for which it obtains marketing approval;



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- expands its operational, financial and management systems and increases personnel, including personnel to support its clinical development, manufacturing and commercialization efforts and its operations as a public company;
- hires additional clinical, quality control, scientific and management personnel;
- leverages its proprietary OcuNanoE™ technology to advance high-value therapeutics into preclinical and clinical development;
- in-licenses or acquires the rights to other products, product candidates or technologies;
- develops, maintains, expands and protects its intellectual property portfolio; and
- increases its product liability insurance coverage as it expands its commercialization efforts.

Because of the numerous risks and uncertainties associated with pharmaceutical product development, Ocugen is unable to predict the timing or amount of increased expenses or when, or if, it will be able to achieve profitability. Ocugen's expenses will increase if:

- it is required by the FDA, European Medicines Agency ("EMA") or other foreign regulatory agencies to perform trials or studies in addition to those currently expected;
- there are any delays in enrollment of patients in or completing its clinical trials or the development of its product candidates; or
- there are any third-party challenges to Ocugen's intellectual property portfolio, or the need arises to defend against intellectual property-related claims.

Ocugen's ability to become and remain profitable depends on its ability to generate revenue. Ocugen does not expect to generate revenue that is sufficient to achieve profitability unless and until it obtains marketing approval for and commercializes one of its product candidates. Ocugen does not expect to commercialize any of its product candidates before 2021, if ever. This will require it to be successful in a range of challenging activities, including:

- completing and obtaining favorable results from its ongoing Phase 3 clinical trial of OCU300 for the treatment of ocular redness and discomfort in patients with oGVHD;
- completing and obtaining favorable results from Phase 3 clinical trials of OCU310 for relief from the signs and symptoms of DED;
- obtaining marketing approval for OCU300, OCU310, or any other product candidates;
- discovering additional product candidates;
- manufacturing at commercial scale, marketing, selling and distributing those products for which it obtains marketing approval;
- achieving an adequate level of market acceptance of and obtaining and maintaining coverage and adequate reimbursement from third-party payors for its products; and
- obtaining, maintaining and protecting its intellectual property rights.

Ocugen is only in the preliminary stages of many of these activities, and it may never succeed in these activities or generate revenue that is sufficient to achieve profitability. Even if Ocugen does achieve profitability, it may not be able to sustain or increase profitability on a quarterly or annual basis. If it fails to become profitable or is unable to sustain profitability on a continuing basis, then it may be unable to continue its operations at planned levels and be forced to reduce or terminate its operations. Ocugen's failure to become profitable or inability to remain profitable would decrease the value of the company and could impair its ability to raise capital, expand its business, maintain its research and development efforts, continue or undertake commercialization efforts, diversify its product offerings or even continue its operations. A decline in the value of the company could also cause you to lose all or part of your investment.

***Ocugen's recurring operating losses have raised substantial doubt regarding its ability to continue as a going concern.***

Ocugen's recurring operating losses raise substantial doubt about its ability to continue as a going concern. For the year ended December 31, 2018, Ocugen had a net loss of \$18.2 million, working capital of \$(12.2) million and net cash used in operating activities of \$11.6 million. Ocugen has no current source of revenue to sustain its present activities, and it does not expect to generate revenue until and unless it receives regulatory approval of and successfully commercialize its product candidates. As a result, Ocugen concluded that there is substantial doubt about its ability to continue as a going concern, and its independent registered public accounting firm included an explanatory paragraph with regard to its ability to continue as a going concern in its report on Ocugen's financial statements as of and for the year ended December 31, 2018 included elsewhere in this proxy statement/prospectus/information statement. The perception of Ocugen's ability to continue as a going concern may make it more difficult for it to obtain financing for the continuation of its operations and could result in the loss of confidence by investors, suppliers and employees.

***Ocugen's limited operating history may make it difficult for you to evaluate the success of its business to date and to assess its future viability.***

Ocugen has a limited operating history, and its operations to date have been limited to organizing and staffing the company, acquiring rights to intellectual property, business planning, raising capital and developing OCU300, OCU310 and other product candidates. Consequently, any predictions you make about Ocugen's future success or viability may not be as accurate as they could be if it had a longer operating history.

In addition, as a new business, Ocugen may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors. Ocugen will need to transition from a company with a research and development focus to a company capable of supporting commercial activities. It may not be successful in such a transition.

Ocugen expects its financial condition and operating results to fluctuate significantly from quarter-to-quarter and year-to-year due to a variety of factors, many of which are beyond its control. Accordingly, you should not rely upon the results of any quarterly or annual periods as indications of future operating performance.

***Ocugen will need substantial additional funding. If Ocugen is unable to raise capital when needed, it could be forced to delay, reduce or eliminate its product development programs or commercialization efforts.***

Ocugen expects to devote substantial financial resources to its ongoing and planned activities, particularly as it conducts multiple clinical trials and, assuming positive results from these trials, seeks marketing approval for OCU300 and continues the development of and potentially seeks marketing approval for other clinical and preclinical product candidates, including OCU310, OCU400, OCU200 and OCU100. Ocugen expects its expenses to increase substantially in connection with its ongoing activities, particularly as it advances its preclinical activities and clinical trials. In addition, its expenses will further increase if it suffers any delay in its ongoing Phase 3 clinical program for OCU300, or commencement of its Phase 1/2 clinical programs for OCU400 and OCU200, including delays in enrollment of patients. Ocugen also expects to devote additional financial resources to conducting research and development, initiating clinical trials of, and potentially seeking regulatory approval for, other potential product candidates, including product candidates that it may develop from its OcuNanoE™ program.

If Ocugen obtains marketing approval for OCU300, or any other product candidate that it develops, it expects to incur significant commercialization expenses related to product sales, marketing, distribution and manufacturing. Furthermore, upon the closing of this offering, Ocugen expects to incur additional costs associated with operating as a public company, hiring additional personnel and expanding its facilities. Accordingly, Ocugen may need to obtain substantial additional funding in connection with its continuing operations. If it is unable to raise capital when needed or on attractive terms, it could be forced to delay, reduce or eliminate its research and development programs or any future commercialization efforts.

Ocugen's future capital requirements will depend on many factors, including:

- the progress, costs and results of its Phase 3 clinical trials for OCU300 and OCU310, any clinical trials for its preclinical product candidates, and any clinical activities for regulatory review of OCU300, OCU310, or its other product candidates outside of the United States;
- the costs and timing of process development and manufacturing scale-up activities associated with OCU300, OCU310, and its preclinical product candidates;
- the costs, timing and outcome of regulatory review of OCU300, OCU310 and its preclinical product candidates;
- the costs of commercialization activities for OCU300, OCU310, or its preclinical product candidates if it receives, or expects to receive, marketing approval, including the costs and timing of establishing product sales, marketing, distribution and outsourced manufacturing capabilities;
- subject to receipt of marketing approval, revenue received from commercial sales of OCU300, OCU310, or its preclinical product candidates;
- its ability to establish and maintain strategic collaborations, licensing or other agreements and the financial terms of such agreements;
- the scope, progress, results and costs of any product candidates that it may derive from its OcuNanoE™ program or any other product candidates that it may develop;
- the extent to which it in-licenses or acquires rights to other products, product candidates or technologies; and
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and protecting its intellectual property rights and defending against any intellectual property-related claims.

As of March 31, 2019, Ocugen had cash and cash equivalents of approximately \$0.3 million. Ocugen believes that the net proceeds from the Pre-Merger Financing and the Asset Sale, together with the existing cash and cash equivalents of the combined company, will enable it to fund its operating expenses and capital expenditure requirements through mid-2020. However, Ocugen has based this estimate on assumptions that may prove to be wrong, and its operating plan may change as a result of many factors currently unknown to it. As a result, it could deplete its capital resources sooner than it currently expects and may need additional funding sooner than it estimates.

Conducting preclinical testing and clinical trials is a time-consuming, expensive and uncertain process that takes years to complete. Ocugen may never generate the necessary data or results required to obtain regulatory approval of products with the market potential sufficient to enable it to achieve profitability. Ocugen does not expect to generate revenue from sales of any product candidates until at least 2021, if at all. Accordingly, it will need to obtain substantial additional financing to achieve its business objectives. In addition, it may seek additional capital due to favorable market conditions or strategic considerations, even if it believes it has sufficient funds for its current or future operating plans. Adequate additional financing may not be available to it on acceptable terms, or at all. If adequate funds are not available to it on a timely basis, it may be required to delay, limit, reduce or terminate preclinical studies, clinical trials or other development activities for one or more of its product candidates or delay, limit, reduce or terminate its establishment of sales and marketing capabilities or other activities that may be necessary to commercialize its product candidates.

***Raising additional capital may cause dilution to stockholders, including Histogenics stockholders after the merger, restrict Ocugen's operations or require it to relinquish rights to its technologies or product candidates.***

Until such time, if ever, as Ocugen can generate substantial product revenues, it expects to finance its cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances, licensing

arrangements and marketing and distribution arrangements. To the extent that Ocugen raises additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting its ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

If Ocugen raises additional funds through collaborations, strategic alliances, licensing arrangements or marketing and distribution arrangements, it may have to relinquish valuable rights to its technologies, future revenue streams, research programs or product candidates, or grant licenses on terms that may not be favorable to it. If Ocugen is unable to raise additional funds through equity or debt financings when needed, it may be required to delay, limit, reduce or terminate its product development or future commercialization efforts or grant rights to develop and market products or product candidates that it would otherwise prefer to develop and market on its own.

***If Ocugen is unable to use carryforward tax losses or benefit from favorable tax legislation to reduce its taxes, its business, results of operations and financial condition may be adversely affected.***

Ocugen has incurred significant net operating losses since its inception. As of December 31, 2018, Ocugen had federal net operating loss carryforwards of approximately \$23.7 million. State net operating losses are not materially different from federal net operating losses. If it is unable to use carryforward tax losses to reduce its future taxable income and liabilities in its business, results of operations and financial condition may be adversely affected.

Under Section 382 of the Internal Revenue Code of 1986, as amended, if a corporation undergoes an “ownership change,” which will occur if there is a cumulative change in ownership by “5-percent shareholders” that exceeds 50 percentage points over a rolling three-year period, the corporation’s ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes to offset its post-change income may be limited. A corporation that experiences an ownership change will generally be subject to an annual limitation on the use of its pre-ownership change net operating losses equal to the value of the corporation immediately before the ownership change, multiplied by the long-term tax-exempt rate (subject to certain adjustments). The annual limitation for a taxable year generally is increased by the amount of any “recognized built-in gains” for such year and the amount of any unused annual limitation in a prior year. This could limit the amount of tax attributes that can be utilized annually to offset future taxable income or tax liabilities.

***Recent U.S. tax legislation may materially adversely affect Ocugen’s financial condition, results of operations and cash flows.***

Recently-enacted U.S. tax legislation has significantly changed the U.S. federal income taxation of U.S. corporations, including by reducing the U.S. corporate income tax rate, limiting interest deductions, modifying or repealing many business deductions and credits (including reducing the business tax credit for certain clinical testing expenses incurred in the testing of certain drugs for rare diseases or conditions generally referred to as “orphan drugs”), adopting elements of a territorial tax system, imposing a one-time transition tax, or repatriation tax, on all undistributed earnings and profits of certain U.S.-owned foreign corporations, revising the rules governing net operating losses and the rules governing foreign tax credits, and introducing new anti-base erosion provisions. Many of these changes are effective immediately, without any transition periods or grandfathering for existing transactions. The legislation is unclear in many respects and could be subject to potential amendments and technical corrections, as well as interpretations and implementing regulations by the Treasury and Internal Revenue Service (the “IRS”), any of which could lessen or increase certain adverse impacts of the legislation. In addition, it is unclear how these U.S. federal income tax changes will affect state and local taxation, which often uses federal taxable income as a starting point for computing state and local tax liabilities.

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While some of the changes made by the tax legislation may adversely affect Ocugen in one or more reporting periods and prospectively, other changes may be beneficial on a going forward basis. Ocugen continues to work with its tax advisors and auditors to determine the full impact that the recent tax legislation as a whole will have on it. Ocugen urges its investors to consult with their legal and tax advisors with respect to such legislation.

### ***Ocugen's existing and future indebtedness may limit cash flow available to invest in the ongoing needs of its business.***

As of March 31, 2019, Ocugen had \$1.0 million of outstanding principal borrowings under the EB-5 Loan Agreement, which it is required to repay on the seventh anniversary of the date of the last disbursement under the EB-5 Loan Agreement (unless terminated earlier pursuant to the terms of the EB-5 Loan Agreement). Ocugen is also eligible to borrow an additional \$9.0 million under the EB-5 Loan Agreement, limited by the amount of funds raised by the Lender and subject to availability under the program and certain job creation requirements by it. Ocugen's obligations under this agreement are secured by substantially all of its assets other than its intellectual property. Ocugen could in the future incur additional indebtedness beyond its borrowings under the EB-5 Loan Agreement.

Ocugen's debt combined with its other financial obligations and contractual commitments could have significant adverse consequences, including:

- requiring it to dedicate a substantial portion of cash flow from operations or cash on hand to the payment of interest on, and principal of, its debt, which will reduce the amounts available to fund working capital, capital expenditures, product development efforts and other general corporate purposes;
- increasing its vulnerability to adverse changes in general economic, industry and market conditions;
- subjecting it to restrictive covenants that may reduce its ability to take certain corporate actions or obtain further debt or equity financing;
- limiting its flexibility in planning for, or reacting to, changes in its business and its industry; and
- placing it at a competitive disadvantage compared to its competitors that have less debt or better debt servicing options.

Ocugen intends to satisfy its current and future debt service obligations with its existing cash and funds from external sources. Nonetheless, it may not have sufficient funds or may be unable to arrange for additional financing to pay the amounts due under its existing debt. Funds from external sources may not be available on acceptable terms, if at all. In addition, a failure to comply with the covenants under the EB-5 Loan Agreement could result in an event of default and acceleration of amounts due. If an event of default occurs and the Lender accelerates the amounts due under the EB-5 Loan Agreement, Ocugen may not be able to make accelerated payments, and the Lender could seek to enforce security interests in the collateral securing such indebtedness.

### **Risks Related to Ocugen's Business and the Development of its Product Candidates**

***Ocugen is substantially dependent on the success of its product candidates and cannot guarantee that these product candidates will successfully complete development, receive regulatory approval, or be successfully commercialized.***

Ocugen currently has no products approved for commercial distribution. Ocugen has invested a significant portion of its efforts and financial resources in the development of its product candidates. Ocugen's business depends entirely on the successful development and commercialization of its product candidates, which may never occur. Ocugen's ability to generate revenues in the near term is substantially dependent on its ability to develop, obtain regulatory approval for, and then successfully commercialize its product candidates. Ocugen currently generates no revenues from sales of any products, and it may never be able to develop or commercialize a marketable product.

Ocugen currently has limited experience with its product candidates. For OCU300, it has not conducted any clinical studies specifically with its nanoemulsion in patients with oGVHD. The formulation used in previous clinical studies conducted in patients with oGVHD is different from Ocugen's proposed OCU300 nanoemulsion. The different formulation may impact the final Phase 3 clinical study results for OCU300. As further described in this prospectus, Ocugen has evaluated results from an investigator-led retrospective analyses of the use of brimonidine tartrate 0.15% eye drops in patients with oGVHD and an investigator-led prospective Phase 1/2 clinical trial assessing the use of 0.15% and 0.075% brimonidine tartrate eye drops in patients with oGVHD. The formulations used in these studies are different than its proposed OCU300 formulation. These studies and results are not sufficient to establish the safety and efficacy of OCU300 and the results from these studies should be viewed with caution. The results from these studies may not be predictive of adequate and well-controlled prospective studies. Additionally, these clinical studies were not powered for statistical significance due to their small sample size and the Phase 1/2 clinical study was discontinued early due to slow enrollment. These studies may not be predictive of the results of later studies conducted with the OCU300 formulation for which Ocugen intends to seek marketing approval. Moreover, although a dose ranging study was recommended but not required by FDA, Ocugen does not intend to conduct such a study and has proceeded directly into Phase 3 clinical trials. Ocugen's Phase 3 clinical program for OCU300 consists of two clinical trials evaluating OCU300, the first of which is expected to include approximately 60 patients with oGVHD. Ocugen initiated the first Phase 3 trial of OCU300 in June 2018 and the first patient was dosed in December 2018. The timing of the completion of the Phase 3 clinical trials for OCU300 is dependent, in part, on its ability to locate and enroll a sufficient number of eligible patients on a timely basis, as well as a sample size re-estimation based on data from the first 50% of enrolled patients. Ocugen may need to conduct additional studies before it can submit a marketing application for approval of OCU300.

Ocugen has completed a Phase 3 clinical trial for OCU310 that was initiated in September 2018 with the first patient dosed in December 2018. Although the study showed that OCU310 is well-tolerated, as demonstrated by no adverse events regarded as "severe," it did not meet its co-primary endpoints for symptom and sign. However, a pre-specified exploratory efficacy endpoint of reduction in redness (sign) from the baseline visit, measured by Validated Bulbar Redness score, was significantly better for OCU310 relative to placebo at both Day 14 and Day 28. Post-hoc analysis of the Phase 3 clinical trial is ongoing, subsequent to which a consultation with the FDA will be undertaken. Ocugen is evaluating its options and timing for the continued development of OCU310, including partnering for future clinical trials. Ocugen will need to conduct additional studies before it can submit a marketing application for approval of OCU310.

Ocugen's product candidates will require additional clinical and non-clinical development, regulatory approval, commercial manufacturing arrangements, establishment of a commercial organization, significant marketing efforts, and further investment before it generates any revenues from product sales. Ocugen cannot assure you that it will meet its timelines for its clinical trials, which may be delayed or not completed for a number of reasons.

Ocugen is not permitted to market or promote any of its product candidates before it receives regulatory approval from the FDA or comparable foreign regulatory authorities, and it may never receive such regulatory approval for any of its product candidates. Even if its product candidates are approved, they may be subject to limitations on the indicated uses and populations for which they may be marketed. They may also be subject to other conditions of approval, may contain significant safety warnings, including boxed warnings, contraindications, and precautions, may not be approved with label statements necessary or desirable for successful commercialization, or may contain requirements for costly post-market testing and surveillance, or other requirements, including the submission of a risk evaluation and mitigation strategy ("REMS") to monitor the safety or efficacy of the products. If Ocugen does not receive FDA approval for, and successfully commercialize its product candidates, it will not be able to generate revenue from these product candidates in the United States in the foreseeable future, or at all. Any significant delays in obtaining approval for and commercializing its product candidates will have a material adverse impact on its business and financial condition.

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Ocugen has not previously submitted a marketing application to the FDA, or similar marketing application to comparable foreign authorities, for any product candidate, and it cannot be certain that its product candidates will be successful in clinical trials or receive regulatory approval.

Its product candidates are susceptible to the risks of failure inherent at any stage of product development, including the appearance of unexpected or unacceptable adverse events or failure to demonstrate efficacy in clinical trials. Further, its product candidates may not receive regulatory approval even if they are successful in clinical trials.

The success of Ocugen's product candidates and its ability to generate revenues from its product candidates will depend on many factors including its ability to:

- complete and obtain favorable results from its clinical and preclinical trials with respect to its product candidates;
- apply for and receive marketing approval from the applicable regulatory authorities;
- receive approval for its manufacturing processes and third-party manufacturing facilities from the applicable regulatory authorities;
- recruit and enroll qualified patients for clinical trials with respect to its product candidates in a timely manner;
- expand and maintain a workforce of experienced scientists and others with experience in the relevant technology to continue to develop its product candidates;
- launch and create market demand for its product candidates through marketing and sales activities, and any other arrangements to promote these product candidates that it may otherwise establish;
- receive regulatory approval for claims that are necessary or desirable for successful marketing;
- hire, train, and deploy marketing and sales representatives or contract with a third-party for marketing and sales representatives to commercialize product candidates in the United States;
- manufacture product candidates in sufficient quantities and at acceptable quality and manufacturing cost to meet commercial demand at launch and thereafter;
- establish and maintain agreements with wholesalers, distributors, and group purchasing organizations on commercially reasonable terms;
- pursue partnerships with, or offer licenses to, qualified third-parties to promote and sell product candidates in domestic and key foreign markets where it receives marketing approval;
- maintain patent and trade secret protection and regulatory exclusivity for its product candidates;
- qualify for, identify, register, maintain, enforce and defend intellectual property rights and claims covering its products and intellectual property portfolio;
- not infringe on others' intellectual property rights;
- launch commercial sales of its product candidates, whether alone or in collaboration with others;
- achieve market acceptance of its product candidates by patients, the medical community, and third-party payors;
- achieve appropriate reimbursement, pricing, and payment coverage for its product candidates;
- effectively compete with other therapies and establish a market share; and
- maintain a continued acceptable safety and efficacy profile of its product candidates following launch.

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To the extent Ocugen is not able to do any of the foregoing, its business may be materially harmed. Moreover, successful development of its product candidates for additional indications, if any, or for use in broader patient populations and its ability to broaden the label for any approved product candidates will depend on similar factors.

If it is required to conduct additional clinical trials or other testing of its product candidates that it develops beyond those that it currently expects, if it is unable to successfully complete clinical trials of its product candidates or other testing, if the results of these trials or tests are not positive or are only modestly positive or if there are safety concerns, Ocugen may:

- be delayed in obtaining marketing approval for its product candidates;
- not obtain marketing approval at all;
- obtain approval for indications or patient populations that are not as broad as intended or desired;
- obtain approval without labeled claims necessary for Ocugen to successfully market its products;
- obtain approval with labeling that includes significant use or distribution restrictions or safety warnings, including boxed warnings, and contraindications;
- be subject to additional post-marketing testing requirements, surveillance requirements, or REMS; or
- have the product removed from the market after obtaining marketing approval.

To the extent any of the foregoing should occur, its business may be materially harmed.

***The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time consuming and inherently unpredictable. If Ocugen is not able to obtain, or if there are delays in obtaining, required regulatory approvals, it will not be able to commercialize its product candidates as expected, and its ability to generate revenue will be materially impaired.***

The time required to obtain approval by the FDA and comparable foreign authorities is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. These may require Ocugen to amend its clinical trial protocols, conduct additional studies that require regulatory or Institutional Review Board ("IRB") approval, or otherwise cause delays in the approval or rejection of an application. Ocugen has not obtained regulatory approval for any product candidate and it is possible that none of its existing product candidates or any product candidates it may seek to develop in the future, will ever obtain regulatory approval. Moreover, its product candidates will require additional studies, as well as additional manufacturing development before it will be able to submit marketing applications to the applicable regulatory authorities. Any delay in obtaining or failure to obtain required approvals could materially adversely affect its ability to generate revenue from the particular product candidate, which likely would result in significant harm to its financial position and adversely impact its stock price.

Ocugen's product candidates and the activities associated with their development and commercialization, including their design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, marketing, promotion, sale, and distribution, are subject to comprehensive regulation by the FDA, other regulatory agencies in the United States and similar regulatory authorities outside the United States. Failure to obtain marketing approval for a product candidate will prevent Ocugen from commercializing the product candidate. Ocugen has no experience in filing and supporting the applications necessary to gain marketing approvals and expect to rely on third-parties to assist it in this process. Securing marketing approval requires the submission of extensive preclinical and clinical data and supporting information to regulatory authorities for each therapeutic indication to establish the product candidate's safety and efficacy for that indication. Securing



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marketing approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities and clinical trial sites by the regulatory authorities. The FDA or other similar regulatory authorities may determine that its product candidates are not effective, only moderately effective or have undesirable or unintended side effects, toxicities or other characteristics that preclude Ocugen from obtaining marketing approval or prevent or limit commercial use.

Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. This is especially true for rare and/or complicated diseases. Failure can occur at any time during the clinical trial process. Ocugen has limited experience in designing clinical trials and may be unable to design and execute a clinical trial to support marketing approval.

The results of preclinical studies, preliminary study results, and early clinical trials of Ocugen's product candidates may not be predictive of the results of later-stage clinical trials or the ultimately completed trial. Preliminary and final results from such studies may not be representative of study results that are found in larger, controlled, blinded, and more long-term studies. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and initial clinical trials. Preclinical and early clinical studies may also reveal unfavorable product candidate characteristics, including safety concerns. A number of companies have suffered significant setbacks in advanced clinical trials, notwithstanding promising results in earlier trials. In some instances, there can be significant variability in safety or efficacy results between different clinical trials of the same product candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient populations, changes in and adherence to the clinical trial protocols and the rate of dropout among clinical trial participants.

Ocugen's future clinical trial results may not be successful. Moreover, should there be a flaw in a clinical trial, it may not become apparent until the clinical trial is well advanced.

Ocugen may also experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent its ability to receive marketing approval or commercialize its product candidates, including:

- regulators, including the FDA and the National Institutes of Health, or IRBs or Institutional Biosafety Committees ("IBCs") may not authorize Ocugen or its investigators to commence or continue a clinical trial, conduct a clinical trial at a prospective trial site, or amend trial protocols, or regulators, IRBs or IBCs may require that it modify or amend its clinical trial protocols;
- Ocugen may experience delays in reaching, or fail to reach, agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites and its contract research organizations ("CROs");
- regulators may require it to perform additional or unanticipated clinical trials to obtain approval or it may be subject to additional post-marketing testing, surveillance, or REMS requirements to maintain regulatory approval;
- clinical trials of its product candidates may produce negative or inconclusive results, or its studies may fail to reach the necessary level of statistical significance, and it may decide, or regulators may require it, to conduct additional clinical trials or abandon product development programs;
- clinical trials of its product candidates may not produce the necessary results on all study endpoints. By example, for OCU310, the FDA has advised Ocugen that it will be required to demonstrate efficacy on its primary endpoints for marketing approval for the indication of relief of the signs and symptoms of DED. Ocugen expects that it will also be required to demonstrate effectiveness of both of the co-primary endpoints for marketing approval of OCU300 for the indication of treatment of ocular redness and discomfort in patients with oGVHD. If Ocugen's product candidates do not achieve statistical significance in both primary endpoints in its Phase 3 clinical trials, the FDA may require it to conduct additional clinical trials to support the approval of its proposed indications;

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- the number of patients required for clinical trials of its product candidates may be larger than it anticipates, enrollment in these clinical trials may be slower than it anticipates, or participants may drop out of these clinical trials or be lost to follow-up at a higher rate than it anticipates. By example, the Phase 1/2 clinical study of brimonidine tartrate in patients with oGVHD was discontinued early due to slow enrollment;
- Ocugen's third-party contractors may fail to comply with regulatory requirements or the clinical trial protocol, or meet their contractual obligations to it in a timely manner, or at all, or it may be required to engage in additional clinical trial site monitoring;
- Ocugen, the regulators, IRBs or IBCs may require the suspension or termination of clinical research for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks, undesirable side effects, or other unexpected characteristics (alone or in combination with other products) of the product candidate, or due to findings of undesirable effects caused by a chemically or mechanistically similar therapeutic or therapeutic candidate;
- changes in marketing approval policies during the development period rendering its data insufficient to obtain marketing approval;
- changes in or the enactment of additional statutes or regulations;
- changes in regulatory review for submitted product applications;
- the cost of clinical trials of its product candidates may be greater than it anticipates or it may have insufficient funds for a clinical trial or to pay the substantial user fees required by the FDA upon the filing of a marketing application;
- the supply or quality of its product candidates or other materials necessary to conduct clinical trials of its product candidates may be insufficient or inadequate;
- Ocugen may decide, or regulators may require it, to conduct or gather, as applicable, additional clinical trials, analyses, reports, data, or preclinical trials, or it may abandon product development programs;
- it may fail to reach an agreement with regulators, IRBs or IBCs regarding the scope, design, or implementation of its clinical trials. For instance, the FDA or comparable foreign regulatory authorities may require changes to its study design that make further study impractical or not financially prudent;
- it may have delays in adding new investigators or clinical trial sites, or it may experience a withdrawal of clinical trial sites;
- patients that enroll in its studies may misrepresent their eligibility or may otherwise not comply with the clinical trial protocol, resulting in the need to drop the patients from the study, increase the needed enrollment size for the study or extend the study's duration;
- there may be regulatory questions or disagreements regarding interpretations of data and results, or new information may emerge regarding its product candidates;
- the FDA or comparable foreign regulatory authorities may disagree with its study design, including endpoints, or its interpretation of data from preclinical studies and clinical trials or find that a product candidate's benefits do not outweigh its safety risks;
- the FDA or comparable foreign regulatory authorities may not accept data from studies with clinical trial sites in foreign countries;
- the FDA or comparable foreign regulatory authorities may disagree with its intended indications;
- the FDA or comparable foreign regulatory authorities may fail to approve or subsequently find fault with the manufacturing processes or its contract manufacturer's manufacturing facility for clinical and future commercial supplies;

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- the data collected from clinical trials of its product candidates may not be sufficient to the satisfaction of the FDA or comparable foreign regulatory authorities to support the submission of a marketing application, or other comparable submissions in foreign jurisdictions or to obtain regulatory approval in the United States or elsewhere;
- the FDA or comparable foreign regulatory authorities may take longer than it anticipates to make a decision on its product candidates; and
- it may not be able to demonstrate that a product candidate provides an advantage over current standards of care or current or future competitive therapies in development.

Ocugen's product candidate development costs will also increase if it experiences delays in testing or approvals, and it may not have sufficient funding to complete the testing and approval process for any of its product candidates. Ocugen may be required to obtain additional funds to complete clinical trials and prepare for possible commercialization of its product candidates. Ocugen does not know whether any preclinical tests or clinical trials above what it currently has planned will be required, will begin as planned, will need to be restructured, or will be completed on schedule, or at all. Significant delays relating to any preclinical or clinical trials also could shorten any periods during which it may have the exclusive right to commercialize its product candidates or allow its competitors to bring products to market before it does. This may prevent Ocugen from receiving marketing approvals and impair its ability to successfully commercialize its product candidates and may harm its business and results of operations. In addition, many of the factors that cause, or lead to, delays in clinical trials may ultimately lead to the denial of marketing approval of any of its product candidates. If any of this occurs, its business, financial condition, results of operations, and prospects will be materially harmed.

Regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that Ocugen's data are insufficient for approval and require additional preclinical, clinical or other studies. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent marketing approval of a product candidate. The number and types of preclinical studies and clinical trials that will be required for regulatory approval also varies depending on the product candidate, the disease or condition that the product candidate is designed to address, and the regulations applicable to any particular product candidate. Approval policies, regulations or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. The foregoing may cause delays or limitations in the approval or the decision not to approve an application. It is possible that its product candidates will never obtain the appropriate regulatory approvals necessary for Ocugen to commence product sales.

Finally, even if Ocugen was to obtain approval, regulatory authorities may approve any of its product candidates for fewer or more limited indications, populations, or uses than it requests, may contain significant safety warnings, including black box warnings, contraindications, and precautions, may grant approval contingent on the performance of costly post-marketing clinical trials, surveillance, or other requirements, including REMS to monitor the safety or efficacy of the product, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Any of these scenarios could compromise the commercial prospects for Ocugen's product candidates.

If Ocugen experiences delays in obtaining approval, if it fails to obtain approval of a product candidate or if the label for a product candidate does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate, the commercial prospects for such product candidate may be harmed and Ocugen's ability to generate revenues from that product candidate will be materially impaired.

### ***The FDA may determine that Ocugen's product candidates have undesirable side effects that could delay or prevent their regulatory approval or commercialization.***

Undesirable side effects caused by Ocugen's product candidates could cause it, IRBs, and other reviewing entities or regulatory authorities to interrupt, delay, or halt clinical trials and could result in a more restrictive

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label or the delay or denial of regulatory approval by the FDA or other comparable foreign authorities. For example, if concerns are raised regarding the safety of one of Ocugen's product candidates as a result of undesirable side effects identified during clinical or preclinical testing, the FDA may order it to cease further development, decline to approve such product candidate or issue a letter requesting additional data or information prior to making a final decision regarding whether or not to approve the product candidate. FDA requests for additional data or information can result in substantial delays in the approval of a new product candidate.

Undesirable side effects caused by or any unexpected characteristics (alone or in combination with other products) for any of Ocugen's product candidates could also result in denial of regulatory approval by the FDA or other comparable foreign authorities for any or all targeted indications or the inclusion of unfavorable information in Ocugen's product labeling, such as limitations on the indicated uses or populations for which the products may be marketed or distributed, a label with significant safety warnings, including boxed warnings, contraindications, and precautions, a label without statements necessary or desirable for successful commercialization, or may result in requirements for costly post-marketing testing and surveillance, or other requirements, including REMS, to monitor the safety or efficacy of the products. These could prevent Ocugen from commercializing and generating revenues from the sale of its product candidates.

While there have been a few adverse events that have occurred in the investigator-led clinical studies of brimonidine tartrate for the treatment of ocular redness and discomfort in patients with oGVHD and Ocugen's clinical trials of brimonidine tartrate for relief from the signs and symptoms of dry eye disease, overall brimonidine tartrate was well-tolerated. Ocugen does not have any studies exploring long term exposure in these patient populations to brimonidine tartrate or its product candidates. Ocugen's understanding of the relationship between its product candidates and any adverse effects may change as it gathers more information, and unexpected adverse effects may occur.

Many compounds that initially showed promise in clinical or earlier stage testing have later been found to cause side effects that prevented further development of the compound. In addition, adverse events which had initially been considered unrelated to the study treatment may later be found to be caused by the study treatment. Moreover, incorrect or improper use of Ocugen's product candidates (including use more frequently than is prescribed) by patients could cause unexpected side effects or adverse events. There can be no assurance that Ocugen's product candidates will be used correctly, and if used incorrectly, such misuse could prevent its receipt or maintenance of marketing authorization, resulting in label changes or regulatory authority safety communications or warnings, or hamper commercial adoption of its product candidate, if approved, at the rate it currently expects.

For those product candidates that are based on previously approved products, such as OCU300 and OCU310, subjects and patients may also experience adverse events that are included on the label for the FDA approved products.

If any of Ocugen's product candidates is associated with serious adverse events or undesirable side effects or have properties that are unexpected, Ocugen may need to abandon development or limit development of that product candidate to certain uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. The therapeutic-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may significantly harm Ocugen's business, financial condition, results of operations, and prospects.

***If Ocugen experiences delays or difficulties in the enrollment of patients in clinical trials, its completion of clinical trials and receipt of necessary regulatory approvals could be delayed or prevented.***

Ocugen may not be able to initiate or continue conducting clinical trials for its product candidates if it is unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or

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similar regulatory authorities outside the United States. Competitors may also have ongoing clinical trials for product candidates that are intended to treat the same indications as its product candidates, and patients who would otherwise be eligible for Ocugen's clinical trials may instead enroll in clinical trials of its competitors' product candidates. Patient enrollment is affected by other factors including:

- the size and nature of the patient population (for instance, Ocugen is pursuing clinical trials for certain orphan indications, for which the size of the patient population is limited);
- the severity of the disease under investigation;
- the existence of current treatments for the indications for which it is conducting clinical trials;
- the eligibility criteria for and design of the clinical trial in question, including factors such as frequency of required assessments, length of the study and ongoing monitoring requirements;
- the perceived risks and benefits of the product candidate, including the potential advantages or disadvantages of the product candidate being studied in relation to other available therapies;
- competition in recruiting and enrolling patients in clinical trials;
- efforts to facilitate timely enrollment in clinical trials;
- patient referral practices of physicians;
- effectiveness of publicity created by clinical trial sites regarding the trial;
- patients' ability to comply with the specific instructions related to the trial protocol, proper documentation, and use of the product candidate;
- an inability to obtain or maintain patient informed consents;
- the risk that enrolled patients will drop out before completion or not return for post-treatment follow-up;
- the ability to monitor patients adequately during and after treatment;
- the ability to compensate patients for their time and effort; and
- the proximity and availability of clinical trial sites for prospective patients.

Ocugen's inability to enroll a sufficient number of patients for its clinical trials would result in significant delays and could require it to abandon one or more clinical trials altogether. In particular, there may be low or slow enrollment, and the studies may enroll subjects that do not meet the inclusion criteria, requiring the erroneously enrolled subjects to be excluded and the trial population to be increased. By example, the Phase 1/2 clinical study examining the use of brimonidine tartrate eye drops in patients with oGVHD was discontinued early due to slow enrollment. Moreover, patients in Ocugen's clinical trials, especially patients in its control groups, may be at risk for dropping out of its studies if they are not experiencing relief of their disease. A significant number of withdrawn patients would compromise the quality of its data.

Enrollment delays in Ocugen's clinical trials may result in increased development costs for its product candidates, or the inability to complete development of its product candidates, which would cause the value of its company to decline, limit its ability to obtain additional financing, and materially impair its ability to generate revenues.

***Ocugen's development and commercialization strategy for OCU300 and OCU310 depends, in part, on published scientific literature and the FDA's prior findings regarding the safety and efficacy of approved products. If Ocugen is not able to pursue this strategy, it will need to conduct additional development activities beyond what it currently plans, its development costs will increase, and it may be delayed in receiving regulatory authority approval. The submission of 505(b)(2) New Drug Applications may also subject it to the risk of patent infringement lawsuits or regulatory actions that would delay or prevent its submission of a marketing application to the FDA, or the FDA's review and approval of its marketing applications.***

The Hatch-Waxman Act added Section 505(b)(2) to the Federal Food, Drug and Cosmetic Act, or FDCA. Section 505(b)(2) permits the filing of a New Drug Application, or NDA, where at least some of the information required for approval comes from investigations that were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted. The FDA interprets Section 505(b)(2) of the FDCA, for purposes of approving an NDA, to permit the applicant to rely, in part, upon published literature and/or the FDA's previous findings of safety and efficacy for an approved product. The FDA also requires companies to perform additional clinical trials or measurements to support any deviation from the previously approved product and to support the reliance on the applicable published literature or referenced product, referred to as bridging. The FDA may then approve the new product candidate for all or some of the label indications for which the referenced product has been approved, as well as for any new indication sought by the Section 505(b)(2) applicant, if such approval is supported by study data. The label, however, may require all or some of the limitations, contraindications, warnings or precautions included in the reference product's label, including a black box warning, or may require additional limitations, contraindications, warnings or precautions.

Ocugen currently plans to pursue marketing approval for OCU300 in the United States through 505(b)(2) NDAs and will be completing bridging analyses prior to NDA submission. If the FDA disagrees with its conclusions regarding the appropriateness of its reliance on a reference listed drug or published literature or if it is not otherwise able to bridge to the reference listed drug or published literature to demonstrate that its reliance is scientifically appropriate, it could be required to conduct additional clinical trials or other studies to support its NDA, which could lead to unanticipated costs and delays or to the termination of its development program. If Ocugen is unable to obtain approval for its pharmaceutical formulations through the 505(b)(2) NDA process, it may be required to pursue the more expensive and time consuming 505(b)(1) approval process, which consists of full reports of investigations of safety and effectiveness conducted by or for the applicant.

There may also be circumstances under which the FDA would not allow Ocugen to pursue a 505(b)(2) application. For instance, should the FDA approve a pharmaceutically equivalent product to its product candidates, Ocugen would no longer be able to use the 505(b)(2) regulatory pathway. In that case, it is the FDA's policy that the appropriate submission would be an Abbreviated New Drug Application, or ANDA, for a generic version of the approved product. Ocugen may, however, not be able to immediately submit an ANDA or have an ANDA approval made effective, as it could be blocked by others' periods of patent and regulatory exclusivity protection.

Notwithstanding the approval of a number of products by the FDA under Section 505(b)(2), pharmaceutical companies and others have objected to the FDA's interpretation of Section 505(b)(2). If the FDA's interpretation of Section 505(b)(2) is successfully challenged, the FDA may change its policies and practices with respect to Section 505(b)(2) regulatory approvals, which could delay or even prevent the FDA from approving any NDA that Ocugen submits pursuant to the 505(b)(2) process. It is also not uncommon for a sponsor of an approved product to file a citizen petition with the FDA seeking to delay approval of, or impose additional approval requirements for, pending competing products. If successful, such petitions can significantly delay, or even prevent, the approval of the new product. However, even if the FDA ultimately denies such a petition, the FDA may substantially delay approval while it considers and responds to the petition.

If Ocugen cannot seek approval for OCU300 and OCU310 through the 505(b)(2) regulatory pathway, it may need to conduct additional clinical trials, provide additional data and information and meet additional standards

for regulatory approval. If this were to occur, the time and financial resources required to obtain FDA approval for OCU300 and OCU310, and the complications and risks associated with approval of OCU300 and OCU310, would likely substantially increase. Even if Ocugen is allowed to pursue the 505(b)(2) regulatory pathway to FDA approval, it cannot assure you that OCU300 and/or OCU310 will receive the requisite approvals for commercialization. Moreover, Ocugen's inability to pursue a 505(b)(2) application could result in new competitive products reaching the market more quickly than its product candidates, which could hurt its competitive position and its business prospects.

Ocugen's use of the 505(b)(2) regulatory pathway may also subject it to the risk of patent infringement lawsuits or other regulatory actions that could prevent its submission of a marketing application for OCU300 and OCU310, or prevent the FDA making the approval of a marketing application effective. Applicants submitting NDAs under Section 505(b)(2) of the FDCA must provide a patent certification for the patents listed in FDA's list of Approved Drug Products with Therapeutic Equivalence Evaluations, commonly referred to as the Orange Book, for all reference listed drugs and for all brand name products identified in published literature upon which the 505(b)(2) application relies. The possible certifications are that (1) no patent information has been submitted to the FDA; (2) such patent has expired; (3) the date on which such patent expires; or (4) such patent is invalid or will not be infringed upon by the manufacture, use or sale of the drug product for which the application is submitted. If there are any listed patents for the reference listed or brand name products that Ocugen relies upon for its 505(b)(2) applications, the FDA may not approve its 505(b)(2) product candidates until all listed patents have expired, unless Ocugen challenges the listed patents through the last type of certification, also known as a paragraph IV certification, or otherwise indicates that it is not seeking approval of a patented method of use.

If Ocugen does challenge a listed patent through a paragraph IV certification, under the Hatch Waxman Act, the holder of the patents or NDAs that the 505(b)(2) application references may file a patent infringement lawsuit after receiving notice of the paragraph IV certification. Filing of a patent infringement lawsuit against the filer of the 505(b)(2) application within 45 days of the patent or NDA owner's receipt of notice triggers a one time, automatic, 30-month stay of the FDA's ability to make the 505(b)(2) NDA approval effective. In such a case, the FDA may not make the 505(b)(2) NDA approval effective until the earlier of 30 months from the receipt of the notice of the paragraph IV certification, the expiration of the patent, when the infringement case concerning each such patent was favorably decided in the applicant's favor or settled, or such shorter or longer period as may be ordered by a court. Accordingly, Ocugen may invest a significant amount of time and expense in the development of one or more product candidates only to be subject to significant delay and patent litigation before such product candidates may be commercialized, if at all. In addition, a 505(b)(2) application approval may, in some cases, not be submitted, or may, in other cases, not be made effective until any existing non-patent regulatory exclusivities have expired or, if possible, are carved out from the label.

Companies that produce branded reference listed drugs routinely bring litigation against applicants that seek regulatory approval to manufacture and market new forms of their branded products. These companies often allege patent infringement or other violations of intellectual property rights as the basis for filing suit. Likewise, patent holders may bring patent infringement suits against companies that are currently marketing and selling such products. Litigation to enforce or defend intellectual property rights is often complex and often involves significant expense and can delay or prevent introduction or sale of Ocugen's product candidates. If patents are held to be valid and infringed by Ocugen's product candidates in a particular jurisdiction, it may be required to cease selling, relinquish or destroy existing stock, or pay monetary damages in that jurisdiction unless it can obtain a license from the patent holder. There may also be situations where Ocugen uses its business judgment and decides to market and sell its approved products, notwithstanding the fact that allegations of patent infringement(s) have not been finally resolved by the courts, which is known as an "at risk launch." The risk involved in doing so can be substantial because the remedies available to the owner of a patent for infringement may include, among other things, damages measured by the profits lost by the patent owner which may be greater than the profits earned by the infringer. In the case of willful infringement, such damages may be increased up to three times. An adverse decision in patent litigation could have a material adverse effect on Ocugen's business, financial position, and results of operations and could cause the market value of its common stock to decline.

***Changes in product candidate manufacturing or formulation may result in additional costs or delay.***

As product candidates are developed through preclinical studies to late-stage clinical trials toward approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods, manufacturing sites, and formulation, are altered along the way in an effort to optimize processes and results. Any of these changes could cause Ocugen's product candidates to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with the altered materials. Such changes may also require additional testing, FDA notification, or FDA approval. For instance, the FDA may require that Ocugen conducts a comparability study that evaluates the potential differences in the product candidate resulting from the change. Delays in designing and completing such a study to the satisfaction of the FDA could delay or preclude its development and commercialization plans, and the regulatory approval of its product candidates. It may also require the repetition of one or more clinical trials, increase clinical trial costs, delay approval of Ocugen's product candidates and jeopardize its ability to commence product sales and generate revenue. Any of the foregoing could limit its future revenues and growth. Any changes would also require that Ocugen devote time and resources to manufacturing development and would also likely require additional testing and regulatory actions on its part, which may delay the development of its product candidates.

***Ocugen may not be successful in its efforts to develop product candidates based on its OcuNanoE™ nanoemulsion formulation or expand the use of its OcuNanoE™ nanoemulsion formulation for treating additional diseases and conditions.***

Ocugen is currently directing some of its development efforts towards developing its product candidate based on its OcuNanoE™ nanoemulsion formulation and applying its OcuNanoE™ nanoemulsion formulation to support therapeutic interventions of ocular diseases with the potential of improving the tear film stability and targeting of drug molecules to the specialized tissues. Ocugen has product candidates at various stages of development for treatment of eye diseases and is exploring the potential use of its OcuNanoE™ nanoemulsion formulation in other diseases. Ocugen's existing product candidates and any other potential product candidates that it identifies may not be suitable for continued preclinical or clinical development, including as a result of being shown to have harmful side effects, a lack of efficacy or other characteristics that indicate that such product candidates are unlikely to be products that will receive marketing approval and achieve market acceptance. If Ocugen does not successfully develop and commercialize its product candidates based upon its OcuNanoE™ nanoemulsion formulation, it will not be able to obtain substantial product revenues in future periods.

***Ocugen may expend its limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.***

Because Ocugen has limited financial and managerial resources, it focuses on research programs and product candidates that it identifies for specific indications. As a result, it may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential. Ocugen's resource allocation decisions may cause it to fail to capitalize on viable commercial products or profitable market opportunities. Ocugen's spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable products. If it does not accurately evaluate the commercial potential or target market for a particular product candidate, it may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for Ocugen to retain sole development and commercialization rights to such product candidate.

***Ocugen may in the future conduct clinical trials for product candidates at sites outside the United States, and the FDA may not accept data from trials conducted in such locations.***

Ocugen may in the future choose to conduct one or more of its clinical trials outside the United States. Although the FDA may accept data from clinical trials conducted outside the United States, acceptance of these data is subject to



conditions imposed by the FDA. For example, the clinical trial must be well designed and conducted and be performed by qualified investigators in accordance with ethical principles. The trial population must also adequately represent the U.S. population, and the data must be applicable to the U.S. population and U.S. medical practice in ways that the FDA deems clinically meaningful. If the FDA does not accept the data from any trial that Ocugen conducts outside the United States, it would likely result in the need for additional trials, which would be costly and time-consuming and could delay or permanently halt Ocugen's development of the applicable product candidates. Moreover, trials conducted outside the United States would be subject to the laws of the applicable foreign jurisdiction. Failure to comply with such laws could result in regulatory enforcement action.

***Failure to obtain marketing approval in international jurisdictions would prevent Ocugen's product candidates from being marketed abroad.***

In order to market and sell its products in jurisdictions outside the United States, Ocugen must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The approval procedures vary among countries and can involve additional testing. The time required to obtain approval may differ substantially from that required to obtain FDA approval. The regulatory approval process outside the United States generally includes all of the risks associated with obtaining FDA approval. In addition, in many countries outside the United States, it is required that the product be approved for reimbursement before the product can be approved for sale in that country. Ocugen's clinical trials of its product candidates may not be sufficient to support an application for marketing approval outside the United States.

Ocugen, or any eventual collaborators, may not obtain approvals from regulatory authorities outside the United States on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one regulatory authority outside the United States does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA. However, the failure to obtain approval in one jurisdiction may compromise Ocugen's ability to obtain approval elsewhere. Ocugen may not be able to file for marketing approvals and may not receive necessary approvals to commercialize its products in any market.

Additionally, on June 23, 2016, the electorate in the United Kingdom voted in favor of leaving the European Union, commonly referred to as Brexit. On March 29, 2017, the United Kingdom formally notified the European Union of its intention to withdraw pursuant to Article 50 of the Lisbon Treaty. Since a significant proportion of the regulatory framework in the United Kingdom is derived from European Union directives and regulations, the withdrawal could materially impact the regulatory regime with respect to the approval of Ocugen's product candidates in the United Kingdom or the European Union. Any delay in obtaining, or an inability to obtain, any marketing approvals, as a result of Brexit or otherwise, would prevent Ocugen from commercializing its product candidates in the United Kingdom and/or the European Union and restrict its ability to generate revenue and achieve and sustain profitability. If any of these outcomes occur, Ocugen may be forced to restrict or delay efforts to seek regulatory approval in the United Kingdom and/or European Union for its product candidates, which could significantly and materially harm its business.

***Regulatory approval is limited by the FDA to those specific indications and conditions for which approval has been granted, and Ocugen may be subject to fines, penalties, injunctions, or other enforcement actions if it is determined to be promoting the use of its products for unapproved or "off-label" uses, resulting in damage to Ocugen's reputation and business.***

Ocugen must comply with requirements concerning advertising and promotion for any product candidates for which it obtains marketing approval. Promotional communications with respect to therapeutics are subject to a variety of legal and regulatory restrictions and continuing review by the FDA, Department of Justice, Department of Health and Human Services' Office of Inspector General, state attorneys general, members of Congress, and the public. When the FDA or comparable foreign regulatory authorities issue regulatory approval for a product candidate, the regulatory approval is limited to those specific uses and indications for which a product is

approved. If Ocugen is not able to obtain FDA approval for desired uses or indications for its product candidates, it may not market or promote them for those indications and uses, referred to as off-label uses, and Ocugen's business may be adversely affected. Ocugen further must be able to sufficiently substantiate any claims that it makes for its products including claims comparing its products to other companies' products and must abide by the FDA's strict requirements regarding the content of promotion and advertising.

While physicians may choose to prescribe products for uses that are not described in the product's labeling and for uses that differ from those tested in clinical studies and approved by the regulatory authorities, Ocugen is prohibited from marketing and promoting the products for indications and uses that are not specifically approved by the FDA. These off-label uses are common across medical specialties and may constitute an appropriate treatment for some patients in varied circumstances. Regulatory authorities in the United States generally do not restrict or regulate the behavior of physicians in their choice of treatment within the practice of medicine. Regulatory authorities do, however, restrict communications by companies concerning off-label use.

If Ocugen is found to have impermissibly promoted any of its product candidates, it may become subject to significant liability and government fines. The FDA and other agencies actively enforce the laws and regulations regarding product promotion, particularly those prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted a product may be subject to significant sanctions. The federal government has levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees of permanent injunctions under which specified promotional conduct is changed or curtailed. Thus, Ocugen will not be able to promote any products it develops for indications or uses for which they are not approved.

In the United States, engaging in the impermissible promotion of Ocugen's products, following approval, for off-label uses can also subject Ocugen to false claims and other litigation under federal and state statutes, including fraud and abuse and consumer protection laws. Such litigation can lead to civil and criminal penalties and fines, agreements with governmental authorities that materially restrict the manner in which it promotes or distributes therapeutic products and does business through, for example, corporate integrity agreements, suspension or exclusion from participation in federal and state healthcare programs, suspension and debarment from government contracts, and refusal of orders under existing government contracts. These false claims statutes include the federal civil False Claims Act, which allows any individual to bring a lawsuit against a company on behalf of the federal government alleging submission of false or fraudulent claims, or causing others to present such false or fraudulent claims, for payment by a federal program such as Medicare or Medicaid. If the government decides to intervene and prevails in the lawsuit, the individual will share in the proceeds from any fines or settlement funds. If the government declines to intervene, the individual may pursue the case alone. These False Claims Act lawsuits against sponsors of drugs and biologics have increased significantly in volume and breadth, leading to several substantial civil and criminal settlements, up to \$3.0 billion, pertaining to certain sales practices and promoting off-label uses. In addition, False Claims Act lawsuits may expose sponsors to follow-on claims by private payers based on fraudulent marketing practices. This growth in litigation has increased the risk that companies will have to defend a false claim action, and pay settlements fines or restitution, as well as criminal and civil penalties, agree to comply with burdensome reporting and compliance obligations, and be excluded from Medicare, Medicaid, or other federal and state healthcare programs. If Ocugen does not lawfully promote its approved products, if any, it may become subject to such litigation and, if it does not successfully defend against such actions, those actions may have a material adverse effect on its business, financial condition, results of operations and prospects.

In the United States, the distribution of product samples to physicians must further comply with the requirements of the U.S. Prescription Drug Marketing Act, and the promotion of biologic and pharmaceutical products are subject to additional FDA requirements and restrictions on promotional statements. If the FDA determines that Ocugen's promotional activities violate its regulations and policies pertaining to product promotion, it could request that Ocugen modify its promotional materials or subject it to regulatory or other enforcement actions,

including issuance of warning letters or untitled letters, suspension or withdrawal of an approved product from the market, requests for recalls, payment of civil fines, disgorgement of money, imposition of operating restrictions, injunctions or criminal prosecution, and other enforcement actions. These regulatory and enforcement actions could significantly harm Ocugen's business, financial condition, results of operations, and prospects.

***Even if Ocugen's product candidates receive regulatory approval, it will be subject to ongoing obligations and continued regulatory review, which may result in significant additional expense. Additionally, any of Ocugen's product candidates, if approved, could be subject to labeling and other restrictions and market withdrawal, and Ocugen may be subject to penalties if it fails to comply with regulatory requirements or experiences unanticipated problems with its products.***

Any product candidate for which Ocugen obtains marketing approval will be subject to extensive and ongoing requirements of and review by the FDA and other regulatory authorities, including requirements related to the manufacturing processes, post-approval clinical data, labeling, packaging, distribution, adverse event reporting, storage, recordkeeping, export, import, advertising, marketing, and promotional activities for such product. These requirements further include submissions of safety and other post-marketing information, including manufacturing deviations and reports, registration and listing requirements, the payment of annual fees, continued compliance with current good manufacturing practices ("cGMPs"), or cGMP-requirements relating to manufacturing, quality control, quality assurance, and corresponding maintenance of records and documents, requirements regarding the distribution of samples to physicians and good clinical practices, or GCPs, for any clinical trials that Ocugen conducts post-approval.

Even if marketing approval of a product candidate is granted, the approval may be subject to limitations on the indicated uses and populations for which the product may be marketed or to the conditions of approval, including significant safety warnings, such as boxed warnings, contraindications, and precautions that are not desirable for successful commercialization. Any approved products may also be subject to a REMS that render the approved product not commercially viable or other post-market requirements, such as Phase 4 studies, or restrictions. Moreover, the FDA and comparable foreign regulatory authorities will continue to closely monitor the safety profile of any product even after approval. If the FDA or comparable foreign regulatory authorities become aware of new safety information after approval of any of Ocugen's product candidates, they may, among other actions, withdraw approval, require labeling changes or establishment of a REMS or similar strategy, impose significant restrictions on a product's indicated uses or marketing, or impose ongoing requirements for potentially costly post-approval studies or post-market surveillance. Any such restrictions could limit sales of the product.

Ocugen and any of its collaborators, including its contract manufacturer, could be subject to periodic unannounced inspections by the FDA to monitor and ensure compliance with cGMPs and other FDA regulatory requirements. Application holders must further notify the FDA, and depending on the nature of the change, obtain FDA pre-approval for product and manufacturing changes.

In addition, later discovery of previously unknown adverse events or that the product is less effective than previously thought or other problems with Ocugen's products, manufacturers or manufacturing processes, or failure to comply with regulatory requirements both before and after approval, may yield various results, including:

- restrictions on manufacturing, distribution, or marketing of such products;
- restrictions on the labeling, including restrictions on the indication or approved patient population, and required additional warnings, such as black box warnings, contraindications, and precautions;
- modifications to promotional pieces;
- issuance of corrective information;

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- requirements to conduct post-marketing studies or other clinical trials;
- clinical holds or termination of clinical trials;
- requirements to establish or modify a REMS or a comparable foreign authority may require that Ocugen establish or modify a similar strategy;
- changes to the way the product is administered;
- liability for harm caused to patients or subjects;
- reputational harm;
- the product becoming less competitive;
- warning, untitled, or cyber letters;
- suspension of marketing or withdrawal of the products from the market;
- regulatory authority issuance of safety alerts, Dear Healthcare Provider letters, press releases, or other communications containing warnings or other safety information about the product;
- refusal to approve pending applications or supplements to approved applications that Ocugen submits;
- recalls of products;
- fines, restitution or disgorgement of profits or revenues;
- suspension or withdrawal of marketing approvals;
- refusal to permit the import or export of Ocugen's products;
- product seizure or detention;
- FDA debarment, suspension and debarment from government contracts, and refusal of orders under existing government contracts, exclusion from federal healthcare programs, consent decrees, or corporate integrity agreements; or
- injunctions or the imposition of civil or criminal penalties, including imprisonment.

Non-compliance with any foreign jurisdictions' requirements, including requirements regarding the protection of personal information, can also lead to significant penalties and sanctions.

Any of these events could prevent Ocugen from achieving or maintaining market acceptance of the particular product candidate, if approved, or could substantially increase the costs and expenses of developing and commercializing such product, which in turn could delay or prevent Ocugen from generating significant revenues from its sale. Any of these events could further have other material and adverse effects on its operations and business and could adversely impact its stock price and could significantly harm its business, financial condition, results of operations, and prospects.

The FDA's policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of Ocugen's product candidates, that could limit the marketability of its product candidates, or that could impose additional regulatory obligations on it. Changes in medical practice and standard of care may also impact the marketability of its product candidates.

If Ocugen is slow or unable to adapt to changes in existing requirements, standards of care, or the adoption of new requirements or policies, or if it is not able to maintain regulatory compliance, it may lose any marketing approval that it may have obtained and be subject to regulatory enforcement action.

Should any of the above actions take place, they could adversely affect Ocugen's ability to achieve or sustain profitability. Further, the cost of compliance with post-approval regulations may have a negative effect on Ocugen's operating results and financial condition.

***Ocugen will need to obtain FDA approval of any proposed product names, and any failure or delay associated with such approval may adversely affect its business.***

Any name Ocugen intends to use for its product candidates will require approval from the FDA regardless of whether it has secured a formal trademark registration from the U.S. Patent and Trademark Office (the “USPTO”). The FDA typically conducts a review of proposed product names, including an evaluation of the potential for confusion with other product names. The FDA may also object to a product name if it believes the name inappropriately implies medical claims or contributes to an overstatement of efficacy. If the FDA objects to any of Ocugen’s proposed product names, it may be required to adopt alternative names for its product candidates. If Ocugen adopts alternative names, it would lose the benefit of any existing trademark applications for such product candidate and may be required to expend significant additional resources in an effort to identify a suitable product name that would qualify under applicable trademark laws, not infringe the existing rights of third-parties, and be acceptable to the FDA. Ocugen may be unable to build a successful brand identity for a new trademark in a timely manner or at all, which would limit its ability to commercialize its product candidates.

***In the future Ocugen may seek FDA designations to facilitate product candidate development, such as fast track or breakthrough designation. Ocugen may not receive any such designations or if it receives such designations they may not lead to faster development or regulatory review or approval and it does not increase the likelihood that Ocugen’s product candidates will receive marketing approval.***

In the future, Ocugen may seek product designations, such as fast track or breakthrough designation, which are intended to facilitate the development or regulatory review or approval process for product candidates. Receipt of such a designation is within the discretion of the FDA. Accordingly, even if Ocugen believes one of its product candidates meets the criteria for a designation, the FDA may disagree. In any event, the receipt of such a designation for a product candidate may not result in a faster development process, review, or approval compared to product candidates considered for approval under conventional FDA procedures and does not assure ultimate marketing approval by the FDA. In addition, the FDA may later decide that the product candidates no longer meet the designation conditions, in which case any granted designations may be revoked.

***OCU300, OCU400 and OCU100 have received Orphan Drug Designation from the FDA. However, there is no guarantee that Ocugen will be able to maintain this designation, receive this designation for any of its other product candidates, or receive or maintain any corresponding benefits, including periods of exclusivity.***

Ocugen has obtained from the FDA Office of Orphan Products Orphan Drug Designations (“ODD”) for OCU300 for oGVHD, OCU400 for NR2E3 mutation-associated retinal degenerative disease and OCU100 for RP. Ocugen was the first company to receive ODD for oGVHD from the FDA. It has obtained orphan medical product designation from the European Commission for OCU100 for RP in the European Union. Ocugen may also seek ODD for its other product candidates, as appropriate. While ODD does provide Ocugen with certain advantages, it neither shortens the development time or regulatory review time of a product candidate nor gives the product candidate any advantage in the regulatory review or approval process.

Generally, if a product candidate with ODD subsequently receives marketing approval before another product considered by the FDA to be the same, for the same orphan indication, the product is entitled to a period of marketing exclusivity, which precludes the EMA or the FDA from approving another marketing application for the same drug or biologic for the same indication for a specified time period. The applicable period is seven years in the United States and ten years in Europe. The European exclusivity period can be reduced to six years if a product no longer meets the criteria for ODD or if the product is sufficiently profitable so that market exclusivity is no longer justified.

Ocugen may not be able to obtain any future ODDs that it applies for, ODDs do not guarantee that Ocugen will be able to successfully develop its product candidates, and there is no guarantee that Ocugen will be able to maintain any ODDs that it receives. For instance, ODDs may be revoked if the FDA finds that the request for designation contained an untrue statement of material fact or omitted material information, or if the FDA finds that the product candidate was not eligible for designation at the time of the submission of the request.

Moreover, even if Ocugen is able to receive and maintain ODDs, it may ultimately not receive any period of regulatory exclusivity if its product candidates are approved. For instance, Ocugen may not receive orphan product regulatory exclusivity if the indication for which it receives FDA approval is broader than the ODD. Orphan exclusivity may also be lost for the same reasons that ODD may be lost. Orphan exclusivity may further be lost if Ocugen is unable to assure a sufficient quantity of the product to meet the needs of patients with the rare disease or condition.

Even if Ocugen obtains orphan exclusivity for any of its current or future product candidates, that exclusivity may not effectively protect the product from competition as different products can be approved for the same condition or products that are the same as Ocugen's can be approved for different conditions. Even after an orphan product is approved, the FDA can also subsequently approve a product containing the same principal molecular features for the same condition if the FDA concludes that the later product is clinically superior. The FDA may further grant ODD to multiple sponsors for the same compound or active molecule and for the same indication. If another sponsor receives FDA approval for such product before Ocugen does, Ocugen would be prevented from launching its product in the United States for the orphan indication for a period of at least seven years unless it can demonstrate clinical superiority. Moreover, third-party payors may reimburse for products off-label even if not indicated for the orphan condition.

#### **Risks Related to the Commercialization of Ocugen's Product Candidates**

***Ocugen faces significant competition from other biologic, pharmaceutical and biotechnology companies, academic institutions, government agencies, and other research organizations. Ocugen's operating results will suffer if it fails to compete effectively.***

The development and commercialization of new therapeutic products is highly competitive. Ocugen faces competition with respect to its current product candidates and will face competition with respect to any product candidates that Ocugen may seek to develop or commercialize in the future, from major biologic and pharmaceutical companies, specialty biologic and pharmaceutical companies, and biotechnology companies worldwide. Potential competitors also include academic institutions, government agencies, and other public and private research organizations that conduct research, seek patent protection, and establish collaborative arrangements for research, development, manufacturing, and commercialization.

Ocugen's product candidates will target markets that are already served by a variety of competing products. Many of these existing products have achieved widespread acceptance among clinicians, patients and payors. In addition, many of these products are available on a generic basis, and Ocugen's product candidates may not demonstrate sufficient additional clinical benefits to clinicians, patients or payors to justify a higher price compared to generic products. In many cases, insurers or other third-party payors, particularly Medicare, seek to encourage the use of generic products.

Ocugen is developing OCU300 for the treatment of ocular redness and discomfort in patients with oGVHD. Any product that is developed for the treatment of ocular redness and ocular discomfort in patients with oGVHD could directly compete with OCU300. There are several product candidates in preclinical and clinical development in the United States for oGVHD. If any of these product candidates is approved, it could reduce the overall market opportunity for OCU300. These product candidates are being developed by pharmaceutical companies, biotechnology companies, and specialty pharmaceutical and generic drug companies of various sizes, such as Genentech, Inc., in co-development with the University of Illinois at Chicago and the National Eye Institute, Michigan Cornea Consultants, PC in collaboration with Kresge Eye Institute, and the University of Utah. There are also other product candidates for the treatment of ocular redness and ocular discomfort in patients with oGVHD in the United States in earlier stage development.

Ocugen is developing OCU310 for the relief of the signs and symptoms of dry eye disease. Any product that is developed for dry eye disease could directly compete with OCU310. Current disease management approaches for

dry eye disease in the United States include the following: over-the-counter artificial tear eye drops, which are used on an intermittent or chronic basis to provide short term symptomatic relief of dryness and irritation; off-label prescription drugs, including topical steroid drops and/or other similar products, which are prescribed on occasion for treatment of dry eye disease; and on-label prescription drugs, including Restasis® and Xiidra®. Restasis® is approved for increasing tear production in patients whose tear production is presumed to be suppressed due to ocular inflammation associated with keratoconjunctivitis sicca and Xiidra® is approved for treatment of the signs and symptoms of dry eye disease. Both are typically used chronically as part of the dry eye management regimen, which also includes artificial tears and other palliative therapies, such as hot compresses for the eye and lid hygiene management. Devices, such as punctal plugs that are inserted into the tear ducts to inhibit tear drainage, resulting in more moisture on the surface of the eye may also be used.

Moreover, there are several product candidates in preclinical and clinical development in the United States for the treatment of dry eye disease. If any of these product candidates is approved, it could reduce the overall market opportunity for OCU310. These product candidates are being developed by pharmaceutical companies, biotechnology companies, and specialty pharmaceutical and generic drug companies of various sizes, such as Mimetogen Pharmaceuticals, Inc., Sun Pharmaceuticals (Seciera™), ReGenTree LLC (TGN-259), Allergan plc, Kala Pharmaceuticals (KPI-121 1.0% and KPI-121 0.25%), Aldeyra Therapeutics, Inc. (reproxalap) and Kissei Pharmaceutical Co., Ltd (KCT-0809). There are also other product candidates for dry eye disease in the United States in earlier stage development.

See “Ocugen Business—Competition” for additional information regarding competing products and product candidates.

Ocugen’s ability to compete may also be affected by whether competing products are available over-the-counter. As stated above, there are competing products for dry eye disease that are currently available over-the-counter. Competitors may seek to switch products that are currently only available with a prescription to over-the-counter use. Moreover, in view of legislative efforts to modify FDA’s over-the-counter monograph system, it may become easier for competitors to market products for over-the-counter use, increasing competition.

Ocugen’s ability to compete may further be affected in many cases by insurers or other third-party payors, particularly Medicare, seeking to encourage the use of generic or biosimilar products. Generic products are currently being used for certain of the indications that Ocugen is pursuing, and additional products are expected to become available on a generic basis over the coming years.

Ocugen’s commercial opportunities could be reduced or eliminated if its competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any products that Ocugen may develop. Ocugen’s competitors also may obtain FDA or other regulatory approval for their products more rapidly than Ocugen may obtain approval for its products, which could result in Ocugen’s competitors establishing a strong market position before Ocugen is able to enter the market. In addition, Ocugen’s ability to compete may be affected in many cases by insurers or other third-party payors coverage decisions.

Many of the companies against which Ocugen is competing or against which it may compete in the future have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals, and marketing approved products than Ocugen does. Mergers and acquisitions in the biologic, pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of Ocugen’s competitors. Early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third-parties compete with Ocugen in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, Ocugen’s programs.

***If Ocugen is unable to establish effective marketing and sales, capabilities or enter into agreements with third-parties to market and sell its product candidates, if they are approved, Ocugen may be unable to generate product revenues.***

Ocugen currently does not have a commercial infrastructure for the marketing, sale, and distribution of biologic and pharmaceutical products. If approved, in order to commercialize its products, Ocugen must build its marketing, sales, and distribution capabilities or make arrangements with third-parties to perform these services. Ocugen may not be successful in doing so. Should Ocugen decide to develop its own marketing capabilities, it may incur expenses prior to product launch or even approval in order to recruit a sales force and develop a marketing and sales infrastructure. If a commercial launch is delayed as a result of FDA requirements non-approval or other reasons, Ocugen would incur these expenses prior to being able to realize any revenue from sales of its product candidates. Even if Ocugen is able to effectively hire a sales force and develop a marketing and sales infrastructure, its sales force and marketing teams may not be successful in commercializing its product candidates.

Subject to successful results of Ocugen's ongoing and anticipated Phase 3 clinical trials and FDA approval of any of its product candidates, Ocugen may build a commercial team of specialty sales and marketing representatives in support of OCU300 and possibly other preclinical product candidates that Ocugen develops in the United States, if and when they are approved, as well as distribution capabilities. As discussed below, Ocugen may also partner with third parties to commercialize and distribute OCU300, OCU310, or its other product candidates.

There are risks involved with Ocugen establishing its own sales, marketing and distribution capabilities. For example, recruiting and training a sales force is expensive, time-consuming, and could delay any product launch. Further, Ocugen may underestimate the size of the sales force required for a successful product launch and may need to expand its sales force earlier and at a higher cost than it anticipated. If the commercial launch of Ocugen's product candidates for which it recruits a sales force and establish marketing capabilities is delayed or does not occur for any reason, Ocugen would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and Ocugen's investment would be lost if it cannot retain or reposition its sales and marketing personnel.

Ocugen may also seek marketing approval and explore commercialization of OCU300 and OCU310 in certain markets outside the United States. It may also consider seeking marketing approval outside the United States for other preclinical product candidates in future. If Ocugen decides to seek regulatory approval for any of its product candidates outside the United States (including OCU300 and OCU310), it may need to seek additional patent approvals, licenses to patents held by third parties and/or face claims of infringing third-party patent rights.

Ocugen may also or alternatively decide to collaborate with a third-party or contract sales organization to commercialize any approved product candidates, in which event, its ability to generate product revenues may be limited. By example, as further described in "Ocugen Business—Our Strategy," Ocugen may retain commercialization rights to OCU300 or OCU310 or utilize a variety of collaboration, distribution and other marketing arrangements with one or more third parties to commercialize OCU300 or OCU310. Ocugen's product revenues and its profitability, if any, under any such third-party collaboration, distribution or other marketing arrangements are likely to be lower than if Ocugen were to market, sell and distribute OCU300 or OCU310 entirely itself.

Ocugen may not be successful in entering into arrangements with third parties to sell, market and distribute its product candidates or may be unable to do so on terms that are favorable to it. In addition, Ocugen would have less control over the sales efforts of any other third-parties involved in its commercialization efforts and any of them may fail to devote the necessary resources and attention to sell and market its product candidates effectively. Ocugen could also be held liable if they failed to comply with applicable legal or regulatory requirements.



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If Ocugen does not establish sales, marketing and distribution capabilities successfully, either on its own or in collaboration with third parties, it will not be successful in commercializing any product candidates for which it receives marketing approval.

Ocugen has no prior experience in the marketing, sale, and distribution of biologic and pharmaceutical products, and there are significant risks involved in the building and managing of a commercial infrastructure. The establishment and development of commercial capabilities, including compliance plans, to market any products Ocugen may develop will be expensive and time consuming and could delay any product launch, and Ocugen may not be able to successfully develop this capability. Ocugen will have to compete with other biologic, pharmaceutical and biotechnology companies to recruit, hire, train, manage, and retain marketing and sales personnel. In the event Ocugen is unable to develop a team of marketing and sales representatives, it may not be able to commercialize its product candidates, which would limit Ocugen's ability to generate product revenues. Factors that may inhibit Ocugen's efforts to commercialize its product candidates include:

- the inability to recruit, train, manage, and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to physicians or persuade adequate numbers of physicians to prescribe its product candidates;
- Ocugen's inability to effectively oversee a geographically dispersed sales and marketing team;
- the costs associated with training sales and marketing personnel on legal and regulatory compliance matters and monitoring their actions;
- an inability to secure adequate coverage and reimbursement by government and private health plans;
- reduced realization on government sales from mandatory discounts, rebates and fees, and from price concessions to private health plans and pharmacy benefit managers necessitated by competition for access to managed formularies;
- the clinical indications for which the products are approved and the claims that Ocugen may make for the products;
- limitations or warnings, including distribution or use restrictions, contained in the products' approved labeling;
- any distribution and use restrictions imposed by the FDA or to which Ocugen agrees as part of a mandatory REMS or voluntary risk management plan;
- liability for sales or marketing personnel who fail to comply with the applicable legal and regulatory requirements;
- the lack of complementary products to be offered by sales personnel, which may put Ocugen at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization or engaging a contract sales organization.

Should any of the foregoing occur, Ocugen may not be successful in commercializing any product candidates for which it receives marketing approval.

***If Ocugen's product candidates do not achieve broad market acceptance, the revenues that it generates from their sales will be limited.***

Ocugen has never commercialized a product candidate for any indication. Even if Ocugen's product candidates are approved by the appropriate regulatory authorities for marketing and sale, they may not gain acceptance among physicians, patients, third-party payors, and others in the medical community. If any product candidates

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for which Ocugen obtains regulatory approval do not gain an adequate level of market acceptance, it may not generate significant product revenues or become profitable. Market acceptance of Ocugen's product candidates by the medical community, patients, and third-party payors will depend on a number of factors, some of which are beyond Ocugen's control. For example, physicians are often reluctant to switch their patients and patients may be reluctant to switch from existing therapies even when new and potentially more effective or safer treatments enter the market.

While there are no drugs currently approved in the United States for treatment of oGVHD, there are several product candidates in clinical development for treatment of oGVHD in the United States. It is possible that doctors may rely on these treatments rather than OCU300, if and when it is approved for marketing by the FDA.

Current treatments used in the United States for dry eye disease include over-the-counter artificial tears, Restasis®, Xiidra® and off-label use of corticosteroids. There are also several product candidates in clinical development by third parties for dry eye disease. It is possible that doctors may rely or continue to rely on these treatments rather than OCU310, if and when it is approved for marketing by the FDA.

If generic or biosimilar versions of any products that compete with any of Ocugen's product candidates are approved for marketing by the FDA, they would likely be offered at a substantially lower price than Ocugen expects to offer for its product candidates, if approved. In the case of OCU300 and OCU310, it is also possible that physicians may prescribe other less expensive brimonidine tartrate products off label rather than prescribe OCU300 or OCU310. As a result, clinicians, patients and third-party payors may choose to rely on products other than Ocugen's product candidates for the treatment of ocular redness and discomfort in patients with oGVHD or for the treatment of the signs and symptoms of dry eye disease.

Efforts to educate the medical community and third-party payors on the benefits of Ocugen's product candidates may require significant resources and may not be successful. If any of Ocugen's product candidates is approved but does not achieve an adequate level of market acceptance, Ocugen may not generate significant revenues and it may not become profitable. The degree of market acceptance of any of Ocugen's product candidates will depend on a number of factors, including:

- the efficacy of its product candidates;
- the prevalence and severity of adverse events associated with such product candidates;
- interactions of its products with other medicines patients are taking and any restrictions on the use of its products together with other medications;
- the clinical indications for which the products are approved and the approved claims that Ocugen may make for the products;
- limitations or warnings contained in the product's FDA-approved labeling, including potential limitations or warnings for such product candidates that may be more restrictive than other competitive products;
- changes in the standard of care for the targeted indications for such product candidates, which could reduce the marketing impact of any claims that Ocugen could make following FDA approval, if obtained;
- the relative convenience and ease of administration of such product candidates;
- cost of treatment versus economic and clinical benefit in relation to alternative treatments or therapies;
- the availability of third-party formulary coverage and adequate coverage or reimbursement by third-parties, such as insurance companies and other healthcare payors, and by government healthcare programs, including Medicaid and particularly by Medicare in light of the prevalence of dry eye disease in persons over age 55;

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- the price concessions required by third party payors to obtain coverage;
- the extent and strength of Ocugen’s marketing and distribution of such product candidates;
- the safety, efficacy, and other potential advantages over, and availability of, alternative treatments already used or that may later be approved;
- distribution and use restrictions imposed by the FDA with respect to such product candidates or to which Ocugen agrees as part of a REMS or voluntary risk management plan;
- the timing of market introduction of such product candidates, as well as competitive products;
- its ability to offer such product candidates for sale at competitive prices;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the extent and strength of its third-party manufacturer and supplier support;
- the approval of other new products;
- adverse publicity about the product or favorable publicity about competitive products; and
- potential product liability claims.

The potential market opportunities for Ocugen’s product candidates are difficult to precisely estimate. Ocugen’s estimates of the potential market opportunities are predicated on many assumptions, which may include industry knowledge and publications, third-party research reports, and other surveys, some of which Ocugen may have commissioned. Industry publications and third-party research, surveys and studies generally indicate that their information has been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. While Ocugen believes these industry publications and third-party research, surveys and studies are reliable, it has not independently verified such data. In addition, while Ocugen believes that its internal assumptions are reasonable, these assumptions involve the exercise of significant judgment on the part of its management, are inherently uncertain, and the reasonableness of these assumptions has not been assessed by an independent source. If any of the assumptions proves to be inaccurate, the actual markets for Ocugen’s product candidates could be smaller than its estimates of the potential market opportunities, and as a result its product revenue may be limited, and it may be more difficult for it to achieve or maintain profitability.

### ***Ocugen’s product candidates may face competition sooner than anticipated.***

Both Ocugen’s drug and biologic product candidates, if approved, may face competition from other products that are the same as or similar to its product candidates. If the FDA or comparable foreign regulatory authorities approve generic or similar versions of any of Ocugen’s product candidates that receive marketing approval, or such authorities do not grant its products appropriate periods of regulatory exclusivity before approving generic or similar versions of Ocugen’s products, the sales of its products could be adversely affected.

In the case of Ocugen’s drug product candidates, once an NDA is approved, the product will become a “reference listed drug” in the FDA’s Orange Book. Other applicants may then seek approval of generic versions of Ocugen’s products through submission of ANDAs in the United States. In support of an ANDA, a generic applicant would not need to conduct full clinical studies. Rather, the applicant generally must show that its product has the same active ingredient(s), dosage form, strength, route of administration, conditions of use and labeling, among other commonalities, as the reference listed drug and that the generic version is bioequivalent to the reference listed drug, meaning it is available at the site of action at the same rate and to the same extent as the reference listed drug. Generic products may be significantly less costly to bring to market than the reference listed drug and companies that produce generic products are generally able to offer them at lower prices and are generally preferred by third party payors. As a result, the FDA, the administration and Congress have recently taken steps to encourage increased generic drug competition in the market in an effort to bring down drug costs.

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Following the introduction of a generic drug, a significant percentage of the sales of any branded product or reference listed drug is typically lost to the generic product. Moreover, in addition to generic competition, Ocugen could face competition from other companies seeking approval of drug products that are similar to its products using the 505(b)(2) regulatory pathway. Such applicants may be able to rely on Ocugen's product candidates, if approved, or other approved drug products or published literature to develop drug products that are similar to Ocugen's. The introduction of a drug product similar to Ocugen's product candidates could expose it to increased competition.

Any ANDA or 505(b)(2) applicants seeking to rely upon any of Ocugen's product candidates, if such product candidates are approved, would need to submit patent certification statements with their applications for any of Ocugen's patents that are listed in the FDA's Orange Book. There are detailed rules and requirements regarding the patents that may be submitted to the FDA for listing in the Orange Book. Ocugen may be unable to obtain patents covering its product candidates that contain one or more claims that satisfy the requirements for listing in the Orange Book. If one of Ocugen's product candidates is approved and a patent covering that product candidate is not listed in the Orange Book, an ANDA or 505(b)(2) applicant would not have to submit a patent certification with regard to such patent to the FDA, in which case, Ocugen would not receive the protections provided by the Hatch Waxman Act, as further described in this prospectus.

Moreover, if an ANDA or 505(b)(2) applicant files a paragraph IV challenge to any patents that Ocugen may list in the FDA's Orange Book and if Ocugen does not file a patent infringement lawsuit within 45 days of receiving notice of a paragraph IV certification, the ANDA or 505(b)(2) applicant would not be subject to a 30-month stay. If Ocugen did file such an action, the litigation or other proceedings to enforce or defend its intellectual property rights would likely be complex in nature, may be expensive and time consuming, may divert its management's attention from its core business, and may result in unfavorable results that could adversely impact its ability to prevent third parties from competing with its products. Accordingly, upon approval of its product candidates Ocugen may be subject to generic competition or competition from similar products, or may need to commence patent infringement proceedings, which would divert its resources.

Ocugen currently anticipates that it may be eligible for three years of non-patent marketing exclusivity in the United States for OCU300 and OCU310 if they are approved. These three years, however, would only protect Ocugen's modifications in formulation or approved uses in comparison to the reference listed drug, would not prevent other companies from submitting full NDAs, and would not prevent physicians from prescribing other products off-label or third-party payors from reimbursing for them. By example, even if Ocugen receives approval for OCU300 and OCU310, physicians may prescribe other brimonidine tartrate products off-label for the treatment of ocular discomfort and ocular redness in patients with oGVHD or the treatment of the signs and symptoms of dry eye disease. Moreover, applicants may be able to rely on a reference listed drug that is not one of Ocugen's product candidates, or, in the case of 505(b)(2) applicants, published literature, in which case any periods of patent or non-patent protection that it may have may not prevent FDA from making an approval effective.

Similarly, if the FDA licenses OCU400, OCU200 or OCU100, Ocugen may face competition from biosimilar products. The enactment of the Biologics Price Competition and Innovation Act of 2009, or BPCIA, as part of the Affordable Care Act, or ACA, created an abbreviated pathway for the approval of biosimilar and interchangeable biological products. The abbreviated regulatory pathway establishes legal authority for the FDA to review and approve biosimilar biologics, including the possible designation of a biosimilar as "interchangeable" based on its similarity to an existing brand product. As in the generic drug product space, the FDA and the administration are taking steps to encourage increased biosimilar competition in the market in an effort to bring down the cost of biologic products. If another company pursues approval of a product that is biosimilar to any biologic product for which Ocugen receives FDA approval, it may need to pursue costly and time-consuming patent infringement actions, which may include certain statutorily specified regulatory steps before an infringement action may be brought. Biosimilar applicants may also be able to bring an action for declaratory judgment concerning Ocugen's patents, requiring that it spend time and money defending the action.

Under the BPCIA, an application for a biosimilar product cannot be approved by the FDA until 12 years after the original branded product was approved under a BLA. Certain changes, however, and supplements to an approved BLA, and certain subsequent applications filed by the same sponsor, manufacturer, licensor, predecessor in interest, or other related entity do not qualify for the 12-year exclusivity period. Moreover, there have been efforts to decrease this period of exclusivity to a shorter timeframe. Future proposed budgets, international trade agreements and other arrangements or proposals may affect periods of exclusivity. Ocugen's biologic product candidates may qualify for the BPCIA's 12-year period of exclusivity, however, there is a risk that the FDA will not consider Ocugen's product candidates to be reference products for competing products, potentially creating the opportunity for biosimilar competition sooner than anticipated. Additionally, this period of regulatory exclusivity does not apply to companies pursuing regulatory approval via their own traditional BLA, rather than via the abbreviated pathway. Moreover, the extent to which a biosimilar, once approved, will be substituted for any one of Ocugen's reference products in a way that is similar to traditional generic substitution for non-biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing. It is also possible that payers will give reimbursement preference to biosimilars, even over reference biologics, absent a determination of interchangeability.

For certain of Ocugen's drug and biologic product candidates, it may seek pediatric exclusivity, which is another type of non-patent marketing exclusivity in the United States, as further described in this prospectus. This is not a patent term extension, but it effectively extends the regulatory period during which the FDA cannot approve another application. Ocugen cannot provide any assurance that pediatric exclusivity will be obtained for any of its product candidates.

To the extent Ocugen does not receive any anticipated periods of regulatory exclusivity or to the extent FDA or foreign regulatory authorities approve any biosimilar, interchangeable, generic, similar, or other competing products, its business would be adversely impacted. Competition that Ocugen's products may face from generic, biosimilar, interchangeable, similar, or other competing products could materially and adversely impact Ocugen's future revenue, profitability, and cash flows and substantially limit its ability to obtain a return on the investments it has made in those product candidates.

***Ocugen faces potential product liability exposure, and if successful claims are brought against it, Ocugen may incur substantial liability for its product candidates and may have to limit their commercialization.***

The use of Ocugen's product candidates in clinical trials, and the sale of any of its product candidates for which it obtains regulatory approval, exposes Ocugen to the risk of product liability claims. Ocugen faces inherent risk of product liability related to the testing of its product candidates in human clinical trials and will face an even greater risk if Ocugen commercially sells any product candidates that it may develop. For example, Ocugen may be sued if any product candidate it develops allegedly causes injury or is found to be otherwise unsuitable during clinical testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability or a breach of warranties. Claims could also be asserted under state consumer protection acts. Product liability claims might be brought against Ocugen by consumers, healthcare providers or others using, administering or selling its products. If Ocugen cannot successfully defend itself against these claims, it will incur substantial liabilities or be required to limit development or commercialization of its product candidates. Even successful defense would require significant financial and management resources. Regardless of merit or eventual outcome, liability claims may result in:

- loss of revenue from decreased demand for Ocugen's products and/or product candidates;
- impairment of Ocugen's business reputation or financial stability;
- costs of related litigation;
- substantial monetary awards to patients or other claimants;
- diversion of management attention;

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- withdrawal of clinical trial participants and potential termination of clinical trial sites or entire clinical programs;
- the inability to commercialize Ocugen's product candidates;
- significant negative media attention;
- decrease in Ocugen's stock price; or
- initiation of investigations, and enforcement actions by regulators; and product recalls, withdrawals, revocation of approvals, or labeling, marketing or promotional restrictions.

Ocugen currently holds \$5.0 million in product liability insurance coverage in the aggregate, with a per incident limit of \$3.0 million, which may not be adequate to cover all liabilities that it may incur. Ocugen may need to increase its insurance coverage as it expands its clinical trials. Ocugen will need to further increase its insurance coverage if it commences commercialization of any of its product candidates for which it obtains marketing approval. Insurance coverage is increasingly expensive. Ocugen may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise. On occasion, large judgments have been awarded in class action lawsuits based on therapeutics that had unanticipated side effects. A successful product liability claim or series of claims brought against Ocugen could cause its stock price to fall and, if judgments exceed its insurance coverage, could decrease its cash and adversely affect its business and its prospects.

### **Risks Related to Ocugen's Dependence On Third Parties**

***Ocugen relies, and expects to continue to rely, on third parties to conduct, supervise, and monitor its preclinical studies and clinical trials, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials or failing to comply with regulatory requirements.***

Ocugen relies on third parties, study sites, and others to conduct, supervise, and monitor its preclinical and clinical trials for its product candidates and does not currently plan to independently conduct clinical or preclinical trials of any other potential product candidates. Ocugen expects to continue to rely on third parties, such as CROs clinical data management organizations, medical and scientific institutions, and clinical and preclinical investigators, to conduct its preclinical studies and clinical trials. For example, for the clinical studies completed to date concerning the use of brimonidine tartrate for the treatment of ocular discomfort and ocular redness in patients with oGVHD, Ocugen relied on an investigator to sponsor and conduct the studies. For the clinical study concerning the use of brimonidine tartrate for the treatment of the signs and symptoms of dry eye disease, while Ocugen sponsored the study, it relied on third-party vendors and investigators for the conduct of the study.

While Ocugen has agreements governing the activities of such third parties, it has limited influence and control over their actual performance and activities. For instance, Ocugen's third-party service providers are not its employees, and except for remedies available to it under its agreements with such third parties Ocugen cannot control whether or not they devote sufficient time and resources to its ongoing clinical, non-clinical, and preclinical programs. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct Ocugen's preclinical studies or clinical trials in accordance with regulatory requirements or its stated protocols, if they need to be replaced or if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to Ocugen's protocols, regulatory requirements or for other reasons, Ocugen's trials may be repeated, extended, delayed, or terminated, it may not be able to obtain, or may be delayed in obtaining, marketing approvals for its product candidates, it may not be able to, or may be delayed in its efforts to, successfully commercialize its product candidates, or it or they may be subject to regulatory enforcement actions. As a result, Ocugen's results of operations and the commercial prospects for its product candidates would be harmed, its costs could increase and its ability to generate revenues could be delayed. To the extent Ocugen is unable to successfully identify and manage the performance of third-party service providers in

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the future, its business may be materially and adversely affected. Ocugen's third-party service providers may also have relationships with other entities, some of which may be its competitors, for whom they may also be conducting trials or other therapeutic development activities that could harm Ocugen's competitive position.

Ocugen's reliance on these third-parties for development activities will reduce its control over these activities. Nevertheless, Ocugen is responsible for ensuring that each of its studies is conducted in accordance with the applicable protocol, legal, regulatory, and scientific standards and its reliance on third parties does not relieve it of its regulatory responsibilities. For example, Ocugen will remain responsible for ensuring that each of its trials is conducted in accordance with the general investigational plan and protocols for the trial. Ocugen must also ensure that its preclinical trials are conducted in accordance with good laboratory practices ("GLPs"), as appropriate. Moreover, the FDA and comparable foreign regulatory authorities require Ocugen to comply with GCPs for conducting, recording, and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity, and confidentiality of trial participants are protected. Regulatory authorities enforce these requirements through periodic inspections of trial sponsors, clinical and preclinical investigators, and trial sites. If Ocugen or any of its third-party service providers fail to comply with applicable GCPs or other regulatory requirements, it or they may be subject to enforcement or other legal actions, the data generated in its trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require it to perform additional studies.

In addition, Ocugen will be required to report certain financial interests of its third-party investigators if these relationships exceed certain financial thresholds or meet other criteria. The FDA or comparable foreign regulatory authorities may question the integrity of the data from those clinical trials conducted by investigators who may have conflicts of interest.

Ocugen cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of its trials complies with the applicable regulatory requirements. In addition, Ocugen's clinical trials must be conducted with product candidates that were produced under cGMP conditions. Failure to comply with these regulations may require it to repeat clinical trials, which would delay the regulatory approval process. Ocugen is also required to register certain clinical trials and post the results of certain completed clinical trials on a government-sponsored database, ClinicalTrials.gov, within specified timeframes. Failure to do so can result in enforcement actions and adverse publicity.

Agreements with third parties conducting or otherwise assisting with Ocugen's clinical or preclinical studies might terminate for a variety of reasons, including a failure to perform by the third parties. If any of Ocugen's relationships with these third parties terminate, it may not be able to enter into arrangements with alternative providers or to do so on commercially reasonable terms. Switching or adding additional third parties involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new third party commences work. As a result, if Ocugen needs to enter into alternative arrangements, it could delay its product development activities and adversely affect its business. Though Ocugen carefully manages its relationships with its third parties, there can be no assurance that it will not encounter challenges or delays in the future or that these delays or challenges will not have a material adverse impact on its business, financial condition and prospects, and results of operations.

Ocugen also relies on other third parties to store and distribute its products for the clinical and preclinical trials that it conducts. Any performance failure on the part of its distributors could delay development, marketing approval, or commercialization of its product candidates, producing additional losses and depriving it of potential product revenue.

***If the manufacturers upon whom Ocugen relies fail to produce its product candidates or components in the volumes that it requires on a timely basis, or fail to comply with stringent regulations applicable to biologic and pharmaceutical manufacturers, Ocugen may face delays in the development and commercialization of, or be unable to meet demand for, its product candidates and may lose potential revenues.***

Ocugen does not manufacture any of its product candidates or any product components, and it does not currently plan to develop any capacity to do so. Ocugen expects to rely on a qualified supplier to manufacture and supply to it a minimum amount of brimonidine tartrate (the drug substance used in the manufacture of OCU300 and OCU310) for use in process validation campaigns and future commercial needs. Ocugen expects to rely on another third-party manufacturer (U.S. based) to supply commercial drug products of OCU300 and OCU310 if and when approved for marketing by applicable regulatory authorities. Ocugen expects to rely on its qualified supplier and other third parties to manufacture clinical supplies of other product candidates and commercial supplies of all of its products, if and when approved for marketing by applicable regulatory authorities, as well as for packaging, serialization, storage, distribution and other production logistics.

Ocugen's current and anticipated future dependence upon others for the manufacture of its product candidates or any product that it develops may adversely affect its future profit margins and its ability to commercialize any products that receive marketing approval on a timely and competitive basis. In addition, any performance failure on the part of its existing or future manufacturers could delay clinical development or marketing approval.

If these third-party manufacturers do not successfully carry out their contractual duties, meet expected deadlines or manufacture Ocugen's product candidates in accordance with regulatory requirements, if there are disagreements between Ocugen and such parties, or if such parties are unable to expand capacities to support commercialization of any of Ocugen's product candidates for which it obtains marketing approval, Ocugen may not be able to produce, or may be delayed in producing sufficient product candidates to meet its supply requirements. Any delays in obtaining adequate supplies with respect to Ocugen's product candidates and components may delay the development or commercialization of its product candidates.

Ocugen may not succeed in its efforts to establish manufacturing relationships or other alternative arrangements for any of its product candidates, components, and programs. Ocugen's product candidates may compete with other products and product candidates for access to manufacturing facilities. There are a limited number of manufacturers that operate under cGMP regulations and that are both capable of manufacturing for Ocugen and willing to do so. Moreover, because Ocugen's product candidates must be manufactured under sterile conditions, the number of manufacturers who can meet this requirement are even more limited. If Ocugen's existing third-party manufacturers, or the third parties that it engages in the future to manufacture a product or component for commercial sale or for its clinical trials should cease to continue to do so for any reason, Ocugen would likely experience delays in obtaining sufficient quantities of its product candidates for it to meet commercial demand or to advance its clinical trials while it identifies and qualifies replacement suppliers. These third-party facilities may also be affected by natural disasters, such as floods or fire, or such facilities could face manufacturing issues, such as contamination or regulatory findings following a regulatory inspection of such facility. In such instances, Ocugen may need to locate an appropriate replacement third-party relationship, which may not be readily available or on acceptable terms, which would cause additional delay and increased expense. The addition of a new or alternative manufacturer may also require FDA approvals and may have a material adverse effect on Ocugen's business.

If for any reason Ocugen is unable to obtain adequate supplies of its product candidates or the components used to manufacture them, it will be more difficult for it to develop its product candidates and compete effectively. Further, even if Ocugen does establish such collaborations or arrangements, its third-party manufacturers may breach, terminate, or not renew these agreements.

Ocugen or its third-party manufacturers may also encounter shortages in the raw materials, therapeutic substances, or active pharmaceutical ingredients necessary to produce its product candidates in the quantities



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needed for its clinical trials or, if its product candidates are approved, in sufficient quantities for commercialization or to meet an increase in demand. Such shortages may occur for a variety of reasons, including capacity constraints, delays or disruptions in the market, and shortages caused by the purchase of such materials by Ocugen's competitors or others. Ocugen's or its third-party manufacturers' failure to obtain the raw materials, therapeutic substances, or active pharmaceutical ingredients necessary to manufacture sufficient quantities of its product candidates may have a material adverse effect on its business.

Any problems or delays Ocugen experiences in preparing for commercial-scale manufacturing of a product candidate or component, including manufacturing validation, may result in a delay in FDA approval or commercial launch of the product candidate or may impair its ability to manufacture commercial quantities or such quantities at an acceptable cost, which could result in the delay, prevention, or impairment of commercialization of its product candidates and could adversely affect its business. Furthermore, if Ocugen's commercial manufacturers fail to deliver the required commercial quantities of its product candidates on a timely basis and at commercially reasonable prices, it would likely be unable to meet demand for its products and it would lose potential revenues.

While Ocugen has a commercial supply arrangement with a supplier, if its supplier does not perform as it expects or if Ocugen is not able to enter into a final contractual agreement, it may be required to replace its supplier with one or more other suppliers. If this were to occur, Ocugen may incur added costs and delays in identifying and qualifying any such replacements. Additional manufacturers and testing laboratories for its product candidates will be considered for long-term commercial supply if and when such product candidates are approved for marketing by applicable regulatory authorities.

The manufacture of biologic and pharmaceutical products requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Manufacturers of therapeutics often encounter difficulties in production, particularly in scaling up initial production. These problems include difficulties with production costs and yields, quality control, including stability of the product candidate and quality assurance testing, shortages of qualified personnel, and compliance with strictly enforced federal, state, and foreign regulations. If Ocugen's manufacturers were to encounter any of these difficulties and were unable to perform as agreed, its ability to provide product candidates to patients in its clinical trials and for commercial use, if approved, would be jeopardized. Reliance on third-party manufacturers entails exposure to risks to which it would not be subject if it manufactured the product candidate itself, including:

- inability to negotiate manufacturing agreements with third parties under commercially reasonable terms;
- competition with other product candidates and products for access to a limited number of suitable manufacturing facilities that operate under cGMP regulations;
- reliance on the third party for regulatory compliance and quality assurance;
- reduced day-to-day control over the manufacturing process for Ocugen's product candidates as a result of using third-party manufacturers for all aspects of manufacturing activities;
- reduced control over the protection of its trade secrets and know-how from misappropriation or inadvertent disclosure;
- termination, breach or nonrenewal of manufacturing agreements with third parties in a manner or at a time that may be costly or damaging to Ocugen or result in delays in the development or commercialization of its product candidates; and
- disruptions to the operations of Ocugen's third-party manufacturers or suppliers caused by conditions unrelated to its business or operations, including the bankruptcy of the manufacturer or supplier.

In addition, all manufacturers of Ocugen's product candidates and therapeutic substances must comply with cGMP requirements enforced by the FDA that are applicable to both finished products and their active

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components used both for clinical and commercial supply. The FDA enforces these requirements through its facilities inspection program. Ocugen's manufacturers must be approved by the FDA pursuant to inspections that will be conducted after it submits its marketing applications to the agency. Ocugen manufacturers will also be subject to continuing FDA and other regulatory authority inspections should it receive marketing approval. Further, Ocugen, in cooperation with its contract manufacturers, must supply all necessary chemistry, manufacturing, and control documentation to the FDA in support of a marketing application on a timely basis.

The cGMP requirements include quality control, quality assurance, and the maintenance of records and documentation. Manufacturers of Ocugen's product candidates and the therapeutic substances and active pharmaceutical ingredients necessary to produce its product candidates may be unable to comply with its specifications, cGMP requirements and with other FDA, state, and foreign regulatory requirements. Poor control of production processes can lead to the introduction of adventitious agents or other contaminants, or to inadvertent changes in the properties or stability of a product candidate that may not be detectable in final product testing. If Ocugen's contract manufacturers cannot successfully manufacture material that conforms to its specifications and the strict regulatory requirements of the FDA or other regulatory authorities, they will not be able to secure or maintain regulatory approval for their manufacturing facilities. Any such deviations may also require remedial measures that may be costly and/or time-consuming for Ocugen or a third party to implement and that may include the temporary or permanent suspension of a clinical trial or commercial sales or the temporary or permanent closure of a facility. Any such remedial measures imposed upon or by Ocugen or third parties with whom Ocugen contracts could materially harm its business. Any delays in obtaining products or product candidates that comply with the applicable regulatory requirements may result in delays to clinical trials, product approvals, and commercialization. It may also require that Ocugen conduct additional studies.

While Ocugen is ultimately responsible for the manufacture of its product candidates, other than through its contractual arrangements, Ocugen has little control over its manufacturers' compliance with these regulations and standards. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of its product candidates or if it withdraws any such approval in the future, Ocugen may need to find alternative manufacturing facilities, which would significantly impact its ability to develop, obtain and maintain regulatory approval for or market its product candidates, if approved. Any new manufacturers would need to either obtain or develop the necessary manufacturing know-how, and obtain the necessary equipment and materials, which may take substantial time and investment. Ocugen must also receive FDA approval for the use of any new manufacturers for commercial supply.

A failure to comply with the applicable regulatory requirements may result in regulatory enforcement actions against Ocugen's manufacturers or Ocugen, including fines and civil and criminal penalties, including imprisonment, suspension or restrictions of production, injunctions, delay, withdrawal or denial of product approval or supplements to approved products, clinical holds or termination of clinical studies, warning or untitled letters, regulatory authority communications warning the public about safety issues with the product, refusal to permit the import or export of the products, product seizure, detention, or recall, operating restrictions, suits under the civil False Claims Act, corporate integrity agreements, or consent decrees. Depending on the severity of any potential regulatory action, Ocugen's clinical or commercial supply could be interrupted or limited, which could have a material adverse effect on its business.

Ocugen does not currently have arrangements in place for redundant supply for bulk pharmaceutical and biologic substances and finished products. Any change in Ocugen's manufacturers could be costly because the commercial terms of any new arrangement could be less favorable and because the expenses relating to the transfer of necessary technology and processes could be significant.

***Ocugen may rely on third parties to perform many essential services for any products that it commercializes, including services related to warehousing and inventory control, distribution, government price reporting, customer service, accounts receivable management, cash collection, and pharmacovigilance and adverse event reporting. If these third parties fail to perform as expected or to comply with legal and regulatory requirements, Ocugen's ability to commercialize its product candidates will be significantly impacted and it may be subject to regulatory sanctions.***

Ocugen may retain third-party service providers to perform a variety of functions related to the sale and distribution of its product candidates, key aspects of which will be out of its direct control. These service providers may provide key services related to warehousing and inventory control, distribution, customer service, accounts receivable management, and cash collection. If Ocugen retains a service provider, it would substantially rely on it as well as other third-party providers that perform services for it, including entrusting its inventories of products to their care and handling. If these third-party service providers fail to comply with applicable laws and regulations, fail to meet expected deadlines, or otherwise do not carry out their contractual duties to Ocugen, or encounter physical or natural damage at their facilities, Ocugen's ability to deliver product to meet commercial demand would be significantly impaired and it may be subject to regulatory enforcement action.

In addition, Ocugen may engage third parties to perform various other services for it relating to pharmacovigilance and adverse event reporting, safety database management, fulfillment of requests for medical information regarding its product candidates and related services. If the quality or accuracy of the data maintained by these service providers is insufficient, or these third parties otherwise fail to comply with regulatory requirements, Ocugen could be subject to regulatory sanctions.

Additionally, Ocugen may contract with a third party to calculate and report pricing information mandated by various government programs. If a third party fails to timely report or adjust prices as required, or errors in calculating government pricing information from transactional data in its financial records, it could impact Ocugen's discount and rebate liability, and potentially subject it to regulatory sanctions or False Claims Act lawsuits.

***Ocugen may collaborate with third parties for the development or commercialization of its product candidates. Ocugen may not be successful in establishing or maintaining collaborative relationships, which could adversely affect its ability to develop and commercialize its product candidates.***

In the future Ocugen may seek collaboration arrangements with biologic, pharmaceutical or biotechnology companies for the development or commercialization of its product candidates. Ocugen may utilize a variety of types of collaboration, distribution and other marketing arrangements with third parties to develop and commercialize its product candidates outside the United States. Ocugen may also enter into arrangements with third parties to perform these services in the United States if it does not establish its own sales, marketing and distribution capabilities in the United States or if it determines that such third-party arrangements are otherwise beneficial. For example, Ocugen may utilize a variety of collaboration, distribution and other marketing arrangements with one or more third parties to facilitate commercialization of OCU300. Ocugen may also consider potential collaborative partnership opportunities for sales, marketing, distribution, development, or licensing or broader collaboration arrangements, including with large and mid-size pharmaceutical companies, regional and national pharmaceutical companies and biotechnology companies. Ocugen is not currently party to any such arrangement.

The success of future collaboration arrangements that Ocugen may enter into will depend heavily on the efforts and activities of its collaborators. Collaborators generally have significant discretion in determining the efforts and resources that they will apply to collaboration arrangements. Accordingly, if Ocugen does enter into any such arrangements with any third parties in the future, it will likely have limited control over the amount and timing of resources that its collaborators dedicate to the development or commercialization of its product candidates. Ocugen's ability to generate revenues from these arrangements will depend on its collaborators'

abilities and efforts to successfully perform the functions assigned to them in these arrangements. Disagreements between parties to a collaboration arrangement regarding clinical development and commercialization matters can lead to delays in the development process or commercializing the applicable product candidate and, in some cases, termination of the collaboration arrangement. These disagreements can be difficult to resolve if neither of the parties has final decision-making authority. Moreover, collaborations with biologic and pharmaceutical companies and other third parties are often terminated or allowed to expire. Any such termination or expiration would adversely affect Ocugen financially and could harm its business reputation.

Ocugen may also license the right to market and sell its product candidates under its collaborators' labeler codes. Alternatively, Ocugen may enter into agreements with collaborators to market and sell its product candidates under its own labeler code, in which case errors and omissions by collaborators in capturing and transmitting transactional data may impact the accuracy of its government price reporting.

Any future collaborations Ocugen might enter into may pose a number of risks, including the following:

- collaborators may not perform their obligations as expected;
- collaborators have significant discretion in determining the amount and timing of efforts and resources that they will apply to these collaborations;
- collaborators may not pursue development of product candidates and commercialization of any product candidates that achieve regulatory approval or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborators' strategic focus or available funding, or external factors, such as an acquisition, that divert resources or create competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- collaborators could fail to make timely regulatory submissions for a product candidate;
- collaborators may not comply with all applicable regulatory requirements or may fail to report safety data in accordance with all applicable regulatory requirements, which could subject them or Ocugen to regulatory enforcement actions;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with Ocugen's product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than Ocugen's;
- product candidates discovered in collaboration with Ocugen may be viewed by its collaborators as competitive with their own product candidates or products, which may cause collaborators to cease to devote resources to the commercialization of Ocugen's product candidates;
- a collaborator with marketing and distribution rights to one or more of Ocugen's product candidates that achieve regulatory approval may not commit sufficient resources to the marketing and distribution of such product candidate or product;
- disagreements with collaborators, including disagreements over proprietary rights, contract interpretation or the preferred course of development, might cause delays or termination of the research, development or commercialization of product candidates, might lead to additional responsibilities for Ocugen with respect to product candidates, or might result in litigation or arbitration, any of which would be time consuming and expensive;
- collaborators may not properly maintain or defend Ocugen's intellectual property rights or may use its proprietary information in such a way as to invite litigation that could jeopardize or invalidate Ocugen's intellectual property or proprietary information or expose it to potential litigation;

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- collaborators may infringe the intellectual property rights of third parties, which may expose Ocugen to litigation and potential liability; and
- collaborations may be terminated for the convenience of the collaborator and, if terminated, Ocugen could be required to raise additional capital to pursue further development or commercialization of the applicable product candidates.

Collaboration agreements may not lead to development or commercialization of product candidates in the most efficient manner, or at all. If any collaborations Ocugen might enter into in the future do not result in the successful development and commercialization of product candidates or if one of Ocugen's collaborators subsequently terminates its agreement with it, Ocugen may not receive any future research funding or milestone or royalty payments under the collaboration. If Ocugen does not receive the funding it expects under the agreements, its development of its product candidates could be delayed, and Ocugen may need additional resources to develop its product candidates and its product platform. All of the risks relating to product development, regulatory approval and commercialization described in this prospectus also apply to the activities of Ocugen's collaborators.

Additionally, if any future collaborator of Ocugen's is involved in a business combination, the collaborator might deemphasize or terminate development or commercialization of any product candidate licensed to it by Ocugen. If one of Ocugen's collaborators terminates its agreement with Ocugen, Ocugen may find it more difficult to attract new collaborators and its reputation in the business and financial communities could be adversely affected.

***Should Ocugen desire to pursue a collaboration agreement but is not able to establish collaborations, it may have to alter its development and commercialization plans and its business could be adversely affected.***

For some of Ocugen's product candidates, Ocugen may decide to collaborate with pharmaceutical or biotechnology companies for the development and potential commercialization of those product candidates. Ocugen faces significant competition in seeking appropriate collaborators and whether it reaches a definitive agreement for a collaboration will depend, among other things, upon its assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Those factors may include the design or results of clinical trials, the likelihood of approval by the FDA or similar regulatory authorities outside the United States, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing products, the existence of uncertainty with respect to Ocugen's ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge, and industry and market conditions generally. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with Ocugen for its product candidate. Ocugen may also be restricted under future license agreements from entering into agreements on certain terms with potential collaborators. Collaborations are complex and time-consuming to negotiate and document. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators.

Should Ocugen desire to pursue a collaboration agreement but is unable to reach agreements with suitable collaborators on a timely basis, on acceptable terms, or at all, it may have to curtail the development of a product candidate, reduce or delay its development program or one or more of its other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase its expenditures and undertake development or commercialization activities at its own expense. If Ocugen elects to fund and undertake development or commercialization activities on its own, it may need to obtain additional expertise and additional capital, which may not be available to it on acceptable terms or at all. If Ocugen fails to enter into collaborations and does not have sufficient funds or expertise to undertake the necessary development and

commercialization activities, it may not be able to further develop its product candidates or bring them to market or continue to develop its product platform and its business may be materially and adversely affected.

#### **Risks Related to Legal and Compliance Matters**

***If Ocugen fails to comply with federal and state healthcare laws, including fraud and abuse and health and other information privacy and security laws, it could face substantial penalties and its business, financial condition, results of operations, and prospects could be adversely affected.***

As a biologic and pharmaceutical company, Ocugen is subject to many federal and state healthcare laws, including those described in the section entitled “Business-Government Regulation and Product Approval” of this prospectus, such as the federal Anti-Kickback Statute, the federal civil and criminal False Claims Acts, the civil monetary penalties statute, the Medicaid Drug Rebate statute and other price reporting requirements, the Veterans Health Care Act of 1992, the federal Health Insurance Portability and Accountability Act of 1996 (as amended by the Health Information Technology for Economics and Clinical Health Act), the Foreign Corrupt Practices Act of 1977, the Patient Protection and Affordable Care Act of 2010, and similar state laws. Ocugen may also be subject to laws regarding transparency and patient privacy. Even though Ocugen does not and will not control referrals of healthcare services or bill directly to Medicare, Medicaid or other third-party payors, certain federal and state healthcare laws, and regulations pertaining to fraud and abuse, reimbursement programs, government procurement, and patients’ rights are and will be applicable to its business. Ocugen would be subject to healthcare fraud and abuse and patient privacy regulation by both the federal government and the states in which it conducts its business.

Efforts to ensure that Ocugen’s business arrangements with third parties will comply with applicable healthcare laws and regulations may involve substantial costs. It is possible that governmental authorities will conclude that Ocugen’s business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If Ocugen or its operations are found to be in violation of any federal or state healthcare law, or any other governmental laws or regulations that applies to it, Ocugen may be subject to penalties, including civil, criminal, and administrative penalties, damages, fines, imprisonment, disgorgement, suspension and debarment from government contracts, and refusal of orders under existing government contracts, exclusion from participation in U.S. federal or state health care programs, corporate integrity agreements, and the curtailment or restructuring of its operations, any of which could materially adversely affect its ability to operate its business and its financial results. If any of the physicians or other healthcare providers or entities with whom Ocugen expects to do business is found not to be in compliance with applicable laws, it may be subject to criminal, civil or administrative sanctions, including but not limited to, exclusions from participation in government healthcare programs, which could also materially affect its business.

Although an effective compliance program can mitigate the risk of investigation and prosecution for violations of these laws, the risks cannot be entirely eliminated. Moreover, achieving and sustaining compliance with applicable federal and state privacy, security, reimbursement, and fraud laws may prove costly. Any action against Ocugen for violation of these laws, even if Ocugen successfully defends against it, could cause it to incur significant legal expenses and divert its management’s attention from the operation of its business.

***Ocugen is subject to new legislation, regulatory proposals and healthcare payor initiatives that may increase its costs of compliance, and adversely affect its ability to market its products, obtain collaborators, and raise capital.***

In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of Ocugen’s product candidates, restrict or regulate post-approval activities and affect its ability to profitably sell any products for which it obtains marketing approval. The biopharmaceutical industry has been a particular focus of these efforts and has been significantly affected by legislative initiatives. Ocugen expects that current laws, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that it may receive for any approved products.

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In 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or the ACA, included provisions of importance to Ocugen's business, including, without limitation, its ability to commercialize and the prices it may obtain for any of its product candidates that are approved for sale. These provisions include:

- an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic agents, including products approved through the 505(b)(2) regulatory pathway;
- an increase in the statutory minimum rebates a sponsor must pay under the Medicaid Drug Rebate Program;
- a Medicare Part D coverage gap discount program, in which participating sponsors must agree to offer 50% point-of-sale discounts off negotiated drug prices of drugs and biologics approved under an NDA or BLA (including drugs approved pursuant to the 505(b)(2) regulatory pathway) during the coverage gap period as a condition for the sponsors' outpatient drugs to be covered under Medicare Part D;
- expansion of healthcare fraud and abuse laws, including the federal False Claims Act and the federal Anti-Kickback Statute, and the addition of new government investigative powers, and enhanced penalties for noncompliance;
- extension of sponsor's Medicaid rebate liability to managed Medicaid plans;
- expansion of eligibility criteria for Medicaid programs;
- expansion of the entities eligible for discounts under the Public Health Service Acts or the PHSA, pharmaceutical pricing program; and
- creation of a special Medicare Part B payment methodology for biosimilars approved under PHSA Section 351(k) in which providers are paid the ASP of the biosimilar plus the margin based on ASP of the reference biologic.

The ACA was recently amended to repeal the individual insurance mandate, and efforts to repeal and replace portions of the law may continue. It remains to be seen, however, whether new legislation will be enacted and, if so, precisely what any new legislation could provide and what impact it will have on the availability of healthcare and containing or lowering the cost of healthcare. For example, it is possible that any repeal and replacement initiatives, if enacted into law, could ultimately result in fewer individuals having health insurance coverage or in individuals having insurance coverage with less generous benefits. Accordingly, such reforms, if enacted, could have an adverse effect on anticipated revenue from product candidates that Ocugen may successfully develop and for which it may obtain marketing approval and may affect its overall financial condition and ability to develop or commercialize product candidates. The timing and scope of any potential future legislation to repeal and replace ACA provisions is highly uncertain in many respects.

Since the ACA was enacted in 2010, other legislative and regulatory changes have been proposed and adopted. These changes include, among other things, aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, which went effective on April 1, 2013 and will remain in effect through 2024 unless additional Congressional action is taken. More recently, the Bipartisan Budget Act increased sponsor responsibility for prescription costs in the Medicare Part D coverage gap, and also extended sponsor responsibility for prescription costs in the Medicare Part D coverage gap to biosimilars, which had previously been exempt. In addition, the American Taxpayer Relief Act of 2012, among other things, further reduced Medicare payments to several providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. CMS promulgated regulations governing sponsors' obligations and reimbursement under the Medicaid Drug Rebate Program, and recently promulgated a regulation that limited Medicare Part B payment to certain hospitals for outpatient drugs purchased under the 340B program. To the extent that Ocugen licenses the right to sell a product to another entity under that entity's labeler code, the licensee would further have healthcare reimbursement and pricing regulatory responsibilities.

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Ocugen expects that current law and federal and state healthcare reform measures that may be adopted in the future, may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, increased regulatory burdens and operating costs, decreased net revenue from its biologic and pharmaceutical products, decreased potential returns from its development efforts, new payment methodologies and in additional downward pressure on the price that Ocugen receives for any approved product and/or the level of reimbursement physicians receive for administering any approved product it might bring to market. Reductions in reimbursement levels may negatively impact the prices Ocugen receives or the frequency with which any products it may develop are prescribed or administered. Any reduction in reimbursement from Medicare or other government healthcare programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent it from being able to generate revenue, attain profitability or commercialize its products.

The costs of prescription pharmaceuticals and biologics in the United States has also been the subject of considerable discussion in the United States, and members of Congress and the Trump Administration have stated that they will address such costs through new legislative and administrative measures. The pricing of prescription pharmaceuticals and biologics is also subject to governmental control outside the United States. In certain countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, Ocugen may be required to conduct a clinical trial that compares the cost-effectiveness of its product candidates to other available therapies. If reimbursement of its products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, Ocugen's ability to generate revenues and become profitable could be impaired.

Legislative and regulatory proposals may also be made to expand post-approval requirements and restrict sales and promotional activities. Ocugen cannot be sure whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of its product candidates, if any, may be. In addition, increased scrutiny by the U.S. Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject Ocugen to more stringent product labeling and post-marketing testing and other requirements.

In addition, there have been a number of other legislative and regulatory proposals aimed at changing the biologic and pharmaceutical industry. For instance, the Drug Quality and Security Act (the "DQSA"), imposes obligations on sponsors of biologic and pharmaceutical products related to product tracking and tracing. Among the requirements of this legislation, sponsors are required to provide certain information regarding the product to individuals and entities to which product ownership is transferred, will be required to label products with a product identifier, and are required keep certain records regarding the product. The transfer of information to subsequent product owners by manufacturers is also required to be done electronically. Sponsors are also required to verify that purchasers of the sponsors' products are appropriately licensed. Further, manufacturers have product investigation, quarantine, disposition, and FDA and trading partner notification responsibilities related to counterfeit, diverted, stolen, and intentionally adulterated products that would result in serious adverse health consequences of death to humans, as well as products that are the subject of fraudulent transactions or which are otherwise unfit for distribution such that they would be reasonably likely to result in serious health consequences or death. Future licensees or affiliates may also have responsibilities under DQSA.

Compliance with the federal track and trace requirements may increase Ocugen's operational expenses and impose significant administrative burdens. As a result of these and other new proposals, Ocugen may determine to change its current manner of operation, provide additional benefits or change its contract arrangements, any of which could have a material adverse effect on its business, financial condition, and results of operations.



***Ocugen’s employees, independent contractors, consultants, commercial partners, principal investigators, or CROs may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could have a material adverse effect on its business.***

Ocugen is exposed to the risk of employee fraud or other misconduct. Misconduct by employees, independent contractors, consultants, commercial partners, manufacturers, investigators, or CROs could include intentional, reckless, negligent, or unintentional failures to comply with FDA regulations, comply with applicable fraud and abuse laws, provide accurate information to the FDA, properly calculate pricing information required by federal programs, comply with federal procurement rules or contract terms, report financial information or data accurately or disclose unauthorized activities to Ocugen. This misconduct could also involve the improper use or misrepresentation of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to Ocugen’s reputation. It is not always possible to identify and deter this type of misconduct, and the precautions Ocugen takes to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting it from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. Moreover, it is possible for a whistleblower to pursue a False Claims Act case against Ocugen even if the government considers the claim unmeritorious and declines to intervene, which could require Ocugen to incur costs defending against such a claim. Further, due to the risk that a judgment in a False Claims Act case could result in exclusion from federal health programs or debarment from government contracts, whistleblower cases often result in large settlements. If any such actions are instituted against Ocugen, and it is not successful in defending itself or asserting its rights, those actions could have a significant impact on its business, financial condition, and results of operations, including the imposition of significant fines or other sanctions.

***Ocugen’s business and operations would suffer in the event of system failures.***

Ocugen’s internal computer systems and those of its CROs and other contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war, and telecommunication and electrical failures. If such an event were to occur and cause interruptions in its operations, it could result in a material disruption of its product candidate development and, if such product candidates are approved, commercialization programs. For example, the loss of clinical trial data from completed, ongoing or planned clinical trials could result in delays in its regulatory approval efforts and significantly increase its costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of or damage to its data or applications, or inappropriate disclosure of personal, confidential or proprietary information, Ocugen could incur liability and regulatory enforcement actions, and the further development of any of its product candidates could be delayed.

***Ocugen is subject to anti-corruption laws, as well as export control laws, customs laws, sanctions laws and other laws governing its operations. If it fails to comply with these laws, it could be subject to civil or criminal penalties, other remedial measures and legal expenses, be precluded from developing manufacturing and selling certain products outside the United States or be required to develop and implement costly compliance programs, which could adversely affect its business, results of operations and financial condition.***

Ocugen’s operations are subject to anti-corruption laws, including the U.K. Bribery Act 2010 (the “Bribery Act”), the U.S. Foreign Corrupt Practices Act (the “FCPA”), and other anti-corruption laws that apply in countries where it does business and may do business in the future. The Bribery Act, FCPA and these other laws generally prohibit Ocugen, its officers, and its employees and intermediaries from bribing, being bribed or making other prohibited payments to government officials or other persons to obtain or retain business or gain some other business advantage. Compliance with the FCPA, in particular, is expensive and difficult, particularly in countries in which corruption is a recognized problem. In addition, the FCPA presents particular challenges in the pharmaceutical industry, because, in many countries, hospitals are operated by the government, and doctors and other hospital employees are considered foreign officials. Certain payments to hospitals in connection with clinical trials and other work have been deemed to be improper payments to government officials and have led to FCPA enforcement actions.

Ocugen may in the future operate in jurisdictions that pose a high risk of potential Bribery Act or FCPA violations, and it may participate in collaborations and relationships with third parties whose actions could potentially subject it to liability under the Bribery Act, FCPA or local anti-corruption laws. In addition, Ocugen cannot predict the nature, scope or effect of future regulatory requirements to which its international operations might be subject or the manner in which existing laws might be administered or interpreted. If Ocugen expands its operations outside of the United States, it will need to dedicate additional resources to comply with numerous laws and regulations in each jurisdiction in which it plans to operate.

Ocugen is also subject to other laws and regulations governing its international operations, including regulations administered by the governments of the United Kingdom and the United States, and authorities in the European Union, including applicable export control regulations, economic sanctions on countries and persons, customs requirements and currency exchange regulations, collectively referred to as the Trade Control laws. In addition, various laws, regulations and executive orders also restrict the use and dissemination outside of the United States, or the sharing with certain non-U.S. nationals, of information classified for national security purposes, as well as certain products and technical data relating to those products. If Ocugen expands its presence outside of the United States, it will require Ocugen to dedicate additional resources to comply with these laws, and these laws may preclude Ocugen from developing, manufacturing, or selling certain products and product candidates outside of the United States, which could limit Ocugen's growth potential and increase its development costs.

There is no assurance that Ocugen will be completely effective in ensuring its compliance with all applicable anti-corruption laws, including the Bribery Act, the FCPA or other legal requirements, including Trade Control laws. If Ocugen is not in compliance with the Bribery Act, the FCPA and other anti-corruption laws or Trade Control laws, it may be subject to criminal and civil penalties, disgorgement and other sanctions and remedial measures, and legal expenses, which could have an adverse impact on its business, financial condition, results of operations and liquidity. The Securities and Exchange Commission also may suspend or bar issuers from trading securities on U.S. exchanges for violations of the FCPA's accounting provisions. Any investigation of any potential violations of the Bribery Act, the FCPA, other anti-corruption laws or Trade Control laws by U.K., U.S. or other authorities could also have an adverse impact on Ocugen's reputation, its business, results of operations and financial condition.

### **Risks Related to Ocugen's Intellectual Property**

***Ocugen may be unable to obtain and maintain patent protection for its technology and product candidates, or the scope of the patent protection obtained may not be sufficiently broad or enforceable, such that its competitors could develop and commercialize technology and products similar or identical to Ocugen's, and Ocugen's ability to successfully commercialize its technology and product candidates may be impaired.***

Ocugen's success depends in large part on its ability to obtain and maintain patent protection in the United States and other countries with respect to its proprietary technology and product candidates. Ocugen has sought to protect its proprietary position by filing in the United States and in certain foreign jurisdictions patent applications related to its novel technologies and product candidates.

The patent prosecution process is expensive and time-consuming, and Ocugen may not have filed, maintained or prosecuted and may not be able to file, maintain and prosecute all necessary or desirable patents or patent applications at a reasonable cost or in a timely manner. Ocugen may also fail to identify patentable aspects of its research and development output before it is too late to obtain patent protection.

The patent position of pharmaceutical and biotechnology companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of its patent rights are highly uncertain. Ocugen's pending and future patent applications may fail to result in issued patents in the United States or in other foreign countries which protect its technology or product candidates, or which effectively prevent others from

commercializing competitive technologies and products. In addition, the laws of foreign countries may not protect Ocugen's rights to the same extent as the laws of the United States, and the standards applied by the USPTO and foreign patent offices in granting patents are not always applied uniformly or predictably. For example, unlike patent law in the United States, European patent law precludes the patentability of methods of treatment of the human body and imposes substantial restrictions on the scope of claims it will grant of broader than specifically disclosed embodiments. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, Ocugen cannot be certain whether it or its licensors were the first to make the inventions claimed in its owned or licensed patents or pending patent applications, or that it or its licensors were the first to file for patent protection of such inventions. Databases for patents and publications, and methods for searching them, are inherently limited so Ocugen may not know the full scope of all issued and pending patent applications. As a result, the issuance, scope, validity, enforceability and commercial value of Ocugen's patent rights are uncertain. Ocugen's pending and future patent applications may not result in patents being issued which protect its technology or product candidates, in whole or in part, or which effectively prevent others from commercializing competitive technologies and products. In particular, during prosecution of any patent application, the issuance of any patents based on the application may depend upon Ocugen's ability to generate additional preclinical or clinical data that support the patentability of its proposed claims. Ocugen may not be able to generate sufficient additional data on a timely basis, or at all. Moreover, changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of its patents or narrow the scope of its patent protection.

Even if Ocugen's owned and licensed patent applications issue as patents, they may not issue in a form that will provide Ocugen with any meaningful protection for its proprietary technology and product candidates, prevent competitors from competing with it, or otherwise provide it with any competitive advantage. Ocugen's competitors may be able to circumvent its owned or licensed patents by developing similar or alternative technologies or products in a non-infringing manner. In particular, a competitor may develop an approach to deliver drugs through the mucus layer to the underlying target tissue that uses a different approach than Ocugen's OcuNanoE™ nanoemulsion formulation, and therefore may not infringe on its patent rights.

The issuance of a patent is not conclusive as to its inventorship, ownership, scope, validity or enforceability, and Ocugen's owned and licensed patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in loss of exclusivity or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit its ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of its technology and product candidates. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, Ocugen's patent portfolio may not provide it with sufficient rights to exclude others from commercializing products similar or identical to Ocugen's.

***Patent reform legislation could increase the uncertainties and costs surrounding the prosecution of Ocugen's patent applications and the enforcement or defense of its issued patents.***

On September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to United States patent law. These include provisions that affect the way patent applications are prosecuted and may also affect patent litigation. The USPTO developed new regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first to file provisions, became effective on March 16, 2013. The first to file provisions limit the rights of an inventor to patent an invention if not the first to file an application for patenting that invention, even if such invention was the first invention. The Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of Ocugen's patent applications and the enforcement or defense of its issued patents, which could have a material adverse effect on its business, financial condition, results of operations and

prospects. For example, the Leahy-Smith Act created a new administrative tribunal known as the Patent Trial and Appeals Board, or PTAB, that provides a venue for companies to challenge the validity of competitor patents at a cost that is much lower than district court litigation and on timelines that are much faster. Although it is not clear what, if any, long term impact the PTAB proceedings will have on the operation of Ocugen's business, the outcome of patent challenge proceedings before the PTAB since its inception in 2013 have resulted in the invalidation of many U.S. patent claims. The availability of the PTAB as a lower-cost, faster and potentially more potent tribunal for challenging patents could therefore increase the likelihood that Ocugen's own patents will be challenged, thereby increasing the uncertainties and costs of maintaining, defending and enforcing them.

***If Ocugen is not able to obtain patent term extension in the United States under the Hatch-Waxman Act and in foreign countries under similar legislation, thereby potentially extending the term of its marketing exclusivity for its product candidates, its business may be materially harmed.***

Depending upon the timing, duration and specifics of FDA marketing approval of its product candidates, one of the U.S. patents covering each of such product candidates or the use thereof may be eligible for up to five years of patent term extension under the Hatch-Waxman Act. The Hatch-Waxman Act allows a maximum of one patent to be extended per FDA approved product to account for the patent term lost during the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval and only those claims covering such approved drug product, a method for using it or a method for manufacturing it may be extended. Patent term extension also may be available in certain foreign countries upon regulatory approval of Ocugen's product candidates. Nevertheless, Ocugen may not be granted patent term extension either in the United States or in any foreign country because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the term of extension, as well as the scope of patent protection during any such extension, afforded by the governmental authority could be less than Ocugen requests.

If Ocugen is unable to obtain patent term extension or restoration, or the term of any such extension is less than it requests, the period during which it will have the right to exclusively market its product may be shortened and its competitors may obtain approval of competing products following its patent expiration sooner, and its revenue could be reduced, possibly materially.

It is possible that Ocugen will not obtain patent term extension under the Hatch-Waxman Act for a U.S. patent covering one of its product candidates even where that patent is eligible for patent term extension, or if Ocugen obtains such an extension, it may be for a shorter period than it had sought. Further, for Ocugen's licensed patents, it does not have the right to control prosecution, including filing with the USPTO, a petition for patent term extension under the Hatch-Waxman Act. Thus, if one of Ocugen's licensed patents is eligible for patent term extension under the Hatch-Waxman Act, it may not be able to control whether a petition to obtain a patent term extension is filed, or obtained, from the USPTO.

***Ocugen may become involved in lawsuits to protect or enforce its patents or other intellectual property, which could be expensive, time-consuming and unsuccessful.***

Competitors and other third parties may infringe, misappropriate or otherwise violate its owned and licensed patents, trade secrets, or other intellectual property. As a result, to counter infringement, misappropriation or unauthorized use, Ocugen may be required to file infringement or misappropriation claims or other intellectual property related proceedings, which can be expensive and time-consuming. Any claims Ocugen asserts against perceived infringers could provoke such parties to assert counterclaims against it alleging that it infringes their patents or that its asserted patents are invalid. In addition, in a patent infringement or other intellectual property related proceeding, a court may decide that a patent of Ocugen's is invalid or unenforceable, in whole or in part, construe the patent's claims narrowly or refuse to stop the other party from using the technology at issue on the grounds that Ocugen's patents do not cover the technology in question. An adverse result in any litigation

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proceeding could put one or more of Ocugen's patents at risk of being invalidated, held unenforceable or interpreted narrowly, and could put any of its patent applications at risk of not yielding an issued patent. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of Ocugen's confidential information or trade secrets could be compromised by disclosure during this type of litigation.

Ocugen may be subject to a third-party preissuance submission of prior art to the USPTO, or become involved in other contested proceedings such as opposition, derivation, reexamination, inter partes review, post-grant review or interference proceedings in the United States or elsewhere, challenging its patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, Ocugen's patent rights, allow third parties to commercialize its technology or product candidates and compete directly with it, without payment to it, or result in Ocugen's inability to manufacture or commercialize products without infringing third-party patent rights. In addition, if the breadth or strength of protection provided by Ocugen's patents and patent applications is threatened, it could dissuade companies from collaborating with it to license, develop or commercialize current or future product candidates.

In the United States, the FDA does not prohibit clinicians from prescribing an approved product for uses that are not described in the product's labeling. Although use of a product directed by off-label prescriptions may infringe Ocugen's method-of-treatment patents, the practice is common across medical specialties, particularly in the United States, and such infringement is difficult to detect, prevent or prosecute.

***Third parties may initiate legal proceedings alleging that Ocugen is infringing, misappropriating or otherwise violating their intellectual property rights, the outcome of which would be uncertain and could have a material adverse effect on the success of Ocugen's business.***

Ocugen's commercial success depends upon its ability to develop, manufacture, market and sell OCU300, OCU310, and other product candidates and use its proprietary technologies without infringing, misappropriating or otherwise violating the intellectual property and other proprietary rights of third parties. There is a considerable amount of intellectual property litigation in the biotechnology and pharmaceutical industries. Ocugen may become party to, or threatened with, infringement litigation claims regarding its products and technology, including claims from competitors or from non-practicing entities that have no relevant product revenue and against whom its own patent portfolio may have no deterrent effect. Moreover, Ocugen may become party to future adversarial proceedings or litigation regarding its patent portfolio or the patents of third parties. Such proceedings could also include contested post-grant proceedings such as oppositions, inter partes review, reexamination, interference or derivation proceedings before the USPTO or foreign patent offices.

The legal threshold for initiating litigation or contested proceedings is low, so even lawsuits or proceedings with a low probability of success might be initiated and require significant resources to defend. Litigation and contested proceedings can also be expensive and time-consuming, and Ocugen's adversaries in these proceedings may have the ability to dedicate substantially greater resources to prosecuting these legal actions than Ocugen does. The risks of being involved in such litigation and proceedings may increase as Ocugen's product candidates near commercialization and as it gains the greater visibility associated with being a public company. Third parties may assert infringement claims against it based on existing patents or patents that may be granted in the future. Ocugen may not be aware of all such intellectual property rights potentially relating to its product candidates and their uses. Thus, it does not know with certainty that OCU300, OCU310, or any of its other product candidates, or its development and commercialization thereof, do not and will not infringe or otherwise violate any third party's intellectual property.

If Ocugen is found to infringe, misappropriate or otherwise violate a third party's intellectual property rights, it could be required to obtain a license from such third party to continue developing and marketing its products and technology. However, Ocugen may not be able to obtain any required license on commercially reasonable terms or at all. Even if Ocugen was able to obtain a license, it could be non-exclusive, thereby giving its competitors

access to the same technologies licensed to it and could require it to make substantial licensing and royalty payments. Ocugen could be forced, including by court order, to cease commercializing the infringing technology or product. In addition, it could be found liable for monetary damages, including treble damages and attorneys' fees if it is found to have willfully infringed a patent, and could be forced to indemnify its customers or collaborators. A finding of infringement could also result in an injunction that prevents Ocugen from commercializing its product candidates or forces it to cease some of its business operations, which could materially harm its business. In addition, Ocugen may be forced to redesign its product candidates, seek new regulatory approvals and indemnify third parties pursuant to contractual agreements. Claims that Ocugen has misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on its business.

***Obtaining and maintaining patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and Ocugen's patent protection could be reduced or eliminated for non-compliance with these requirements.***

Periodic maintenance, renewal and annuity fees on any issued patent must be paid to the USPTO and foreign patent agencies in several stages or annually over the lifetime of Ocugen's owned and licensed patents and patent applications. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. In certain circumstances, Ocugen relies on its licensing partners to pay these fees to, or comply with the procedural and documentary rules of, the relevant patent agency. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If Ocugen or its licensors fail to maintain the patents and patent applications covering its product candidates, it would have a material adverse effect on its business.

***Certain aspects of OCU300, OCU310 and Ocugen's other product candidates, and certain aspects of its OcuNanoE™ nanoemulsion formulation, are protected by patents exclusively licensed from other companies or institutions. If these third parties terminate their agreements with Ocugen or fail to maintain or enforce the underlying patents, or Ocugen otherwise loses its rights to these patents, its competitive position and its market share in the markets for any of its approved products will be harmed.***

A substantial portion of Ocugen's patent portfolio is in-licensed. As such, Ocugen is a party to license agreements and certain aspects of its business depend on patents and/or patent applications owned by other companies or institutions. In particular, Ocugen holds exclusive licenses for patent families relating to OCU300, OCU310, other of its product candidates, and some aspects of its OcuNanoE™ nanoemulsion formulation.

Pursuant to Ocugen's license arrangement with University of Illinois at Chicago ("UIC"), which relates to OCU300 and OCU310, Ocugen is responsible for and control patent prosecution of licensed patent families developed jointly pursuant to the license arrangement with UIC, while Ocugen and UIC are each responsible for and control patent prosecution of licensed patent families developed or held individually by Ocugen or UIC, respectively.

Pursuant to Ocugen's license arrangement with University of Colorado ("CU"), which relates to OCU200 and OCU100, Ocugen is responsible for and control patent prosecution of all patent families licensed under the CU license arrangement.

Pursuant to Ocugen's license arrangement with The Schepens Eye Research Institute ("SERI"), which relates to nuclear hormone receptor ("NHR") genes *NR1D1*, *NR2E3*, *RORA*, *NUPR1*, and *NR2C1*, from and after

December 19, 2017, Ocugen has the right to assume responsibility and control patent prosecution of licensed patent families relating to these NHR genes. Additionally, Ocugen is responsible for and control patent prosecution for any patent applications developed in connection with the SERI licensing arrangement filed after December 19, 2017 that are owned jointly by Ocugen and SERI or solely by Ocugen.

Ocugen's rights with respect to in-licensed patents and patent applications may be lost if the applicable license agreement expires or is terminated. Ocugen is likely to enter into additional license agreements to in-license patents and patent applications as part of the development of its business in the future, under which it may not retain control of the preparation, filing, prosecution, maintenance, enforcement and defense of such patents. If Ocugen is unable to maintain these patent rights for any reason, its ability to develop and commercialize its product candidates could be materially harmed.

Ocugen's licensors may not successfully prosecute certain patent applications, the prosecution of which they control, under which Ocugen is licensed and on which its business depends. Even if patents issue from these applications, Ocugen's licensors may fail to maintain these patents, may decide not to pursue litigation against third-party infringers, may fail to prove infringement, or may fail to defend against counterclaims of patent invalidity or unenforceability.

Risks with respect to parties from whom Ocugen has obtained intellectual property rights may also arise out of circumstances beyond Ocugen's control. In spite of Ocugen's best efforts, its licensors might conclude that it has materially breached its intellectual property agreements and might therefore terminate the intellectual property agreements, thereby removing its ability to market products covered by these intellectual property agreements. If Ocugen's intellectual property agreements are terminated, or if the underlying patents fail to provide the intended market exclusivity, competitors would have the freedom to seek regulatory approval of, and to market, products similar or identical to Ocugen's. Moreover, if its intellectual property agreements are terminated, Ocugen's former licensors and/or assignors may be able to prevent it from utilizing the technology covered by the licensed or assigned patents and patent applications. This could have a material adverse effect on Ocugen's competitive business position and its business prospects.

***Some intellectual property which Ocugen owns or has licensed may have been discovered through government funded programs and thus may be subject to federal regulations such as "march-in" rights, certain reporting requirements, and a preference for U.S. industry. Compliance with such regulations may limit Ocugen's exclusive rights, subject it to expenditure of resources with respect to reporting requirements, and limit its ability to contract with non-U.S. manufacturers.***

Some of the intellectual property rights that Ocugen owns or licenses have been generated through the use of United States government funding and may therefore be subject to certain federal regulations under the Bayh-Dole Act. To the best of Ocugen's knowledge, Ocugen's intellectual property for OCU400 for the treatment of *NR2E3* mutation-associated retinal degenerative disease is subject to the Bayh-Dole Act. As a result, the United States government may have certain rights to intellectual property embodied in these patents and patent applications. In general, the Bayh-Dole Act provides the U.S. government certain rights in inventions developed using a government funded program, such as U.S. government's right to a non-exclusive, non-transferable, irrevocable worldwide license to use inventions for any governmental purpose. In addition, under the Bayh-Dole Act the U.S. government has the right to require any invention developed using U.S. government funding to be granted exclusive, partially exclusive, or non-exclusive licenses to any of these inventions to a third party if it determines that: (i) adequate steps have not been taken to commercialize the invention; (ii) government action is necessary to meet public health or safety needs; or (iii) government action is necessary to meet requirements for public use under federal regulations (also referred to as "march-in rights"). Under the Bayh-Dole Act, the U.S. government also has the right to take title to inventions developed using a U.S. government funded program, if one fails to disclose the invention to the government and fail to file an application to register the intellectual property within specified time limits. In addition, the U.S. government may acquire title to these inventions in any country in which a patent application is not filed within specified time limits. Intellectual property generated

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under a government funded program is also subject to certain reporting requirements. In addition, the Bayh-Dole Act requires that any products subject to the Bayh-Dole Act be manufactured substantially in the United States. However, under the Bayh-Dole Act, this manufacturing preference requirement can be waived if the owner of the intellectual property can show that reasonable efforts to manufacture the product substantially in the United States were unsuccessful or that under the circumstances domestic manufacture is not commercially feasible. Any exercise by the government of any of the foregoing rights under the Bayh-Dole Act may affect Ocugen's competitive position, business, financial condition, results of operations and prospects.

***If Ocugen fails to comply with its obligations in its intellectual property licenses and funding arrangements with third parties, it could lose rights that are important to its business.***

Ocugen's license agreements with CU, UIC, and SERI under which Ocugen licenses certain of its patent rights and a significant portion of the technology for OCU300, OCU310, and other product candidates, impose royalty and other financial obligations on it and other substantial performance obligations. Ocugen may also enter into additional licensing and funding arrangements with third parties that may impose diligence, development and commercialization timelines and milestone payment, royalty, insurance and other obligations on it. If Ocugen fails to comply with its obligations under current or future license and collaboration agreements, its counterparties may have the right to terminate these agreements, in which event Ocugen might not be able to develop, manufacture or market any product that is covered by these agreements or may face other penalties under the agreements. Such an occurrence could diminish the value of Ocugen's products and product candidates. Termination of these agreements or reduction or elimination of Ocugen's rights under these agreements may result in Ocugen having to negotiate new or reinstated agreements with less favorable terms or cause it to lose its rights under these agreements, including its rights to important intellectual property or technology.

In addition, it is possible that CU, UIC or SERI may conclude that Ocugen has materially breached the applicable license agreement and might therefore terminate the agreement, thereby removing its ability to market products covered by its license agreements with CU, UIC, or SERI, respectively. If any license agreement is terminated, or if the underlying patents fail to provide the intended market exclusivity, competitors would have the freedom to seek regulatory approval of, and to market, products similar or identical to Ocugen's. Moreover, if any of Ocugen's license agreements is terminated, the counterparty and/or its assignors may be able to prevent it from utilizing the technology covered by the licensed or assigned patents and patent applications. This could have a material adverse effect on Ocugen's competitive business position and its business prospects.

In addition, the agreements under which Ocugen currently licenses intellectual property or technology from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what Ocugen believes to be the scope of its rights to the relevant intellectual property or technology or increase what Ocugen believes to be its financial or other obligations under the relevant agreement, either of which could have a material adverse effect on its business, financial condition, results of operations, and prospects. Moreover, if disputes over intellectual property that Ocugen has licensed prevent or impair its ability to maintain its current licensing arrangements on commercially acceptable terms, Ocugen may be unable to successfully develop and commercialize the affected product candidates, which could have a material adverse effect on its business, financial conditions, results of operations, and prospects.

***Ocugen may not be able to protect its intellectual property and proprietary rights throughout the world.***

Filing, prosecuting, and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and the laws of foreign countries may not protect Ocugen's rights to the same extent as the laws of the United States. Consequently, Ocugen may not be able to prevent third parties from practicing its inventions in all countries outside the United States, or from selling or importing products made using its inventions in and into the United States or other jurisdictions. Competitors may use Ocugen's technologies in



jurisdictions where it has not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where Ocugen has patent protection or licenses, but enforcement is not as strong as that in the United States. These products may compete with Ocugen's products, and its patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets, and other intellectual property protection, particularly those relating to biotechnology products, which could make it difficult for Ocugen to stop the infringement of its patents or marketing of competing products in violation of Ocugen's intellectual property and proprietary rights generally. Proceedings to enforce its intellectual property and proprietary rights in foreign jurisdictions could result in substantial costs and divert its efforts and attention from other aspects of its business, could put its patents at risk of being invalidated or interpreted narrowly, could put its patent applications at risk of not issuing, and could provoke third parties to assert claims against it. Ocugen may not prevail in any lawsuits that it initiates, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, Ocugen's efforts to enforce its intellectual property and proprietary rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that it develops or licenses.

Many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If Ocugen or any of its licensors is forced to grant a license to third parties with respect to any patents relevant to its business, its competitive position may be impaired, and its business, financial condition, results of operations, and prospects may be adversely affected.

***Ocugen may be subject to claims by third parties asserting that its employees or it has misappropriated their intellectual property or claiming ownership of what Ocugen regards as its own intellectual property.***

Many of Ocugen's and its licensors' employees and contractors were previously employed at other biotechnology, medical device or pharmaceutical companies, including its competitors or potential competitors. Although Ocugen tries to ensure that its employees and contractors do not use the proprietary information or know-how of others in their work for it, Ocugen may be subject to claims that these individuals or it has used or disclosed intellectual property, including trade secrets or other proprietary information, of any such employee's former employer. Litigation may be necessary to defend against these claims.

In addition, while it is Ocugen's policy to require its employees and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to it, Ocugen may be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that it regards as its own. Furthermore, Ocugen is unable to control whether its licensors have obtained similar assignment agreements from their own employees and contractors. Ocugen's and their assignment agreements may not be self-executing or may be breached, and Ocugen or its licensors may be forced to bring claims against third parties, or defend claims they may bring against Ocugen, to determine the ownership of what Ocugen regards as its intellectual property.

If Ocugen or its licensors fail in prosecuting or defending any such claims, in addition to paying monetary damages, Ocugen may lose valuable intellectual property rights or personnel which could have a material adverse effect on its competitive business position and prospects. Such intellectual property rights could be awarded to a third party, and Ocugen could be required to obtain a license from such third party to commercialize its technology or products, which may not be available on commercially reasonable terms or at all. Even if Ocugen is successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to management.

***Intellectual property litigation or other legal proceedings relating to intellectual property could cause Ocugen to spend substantial resources and distract its personnel from their normal responsibilities.***

Even if resolved in Ocugen's favor, litigation or other legal proceedings relating to intellectual property claims may cause it to incur significant expenses and could distract Ocugen's technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of Ocugen common stock. Such litigation or proceedings could substantially increase Ocugen's operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. Ocugen may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of Ocugen's competitors may be able to sustain the costs of such litigation or proceedings more effectively than Ocugen can because of their greater financial resources and may also have an advantage in such proceedings due to their more mature and developed intellectual property portfolios. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have an adverse effect on Ocugen's ability to compete in the marketplace.

***If Ocugen is unable to protect the confidentiality of its trade secrets, its business and competitive position would be harmed.***

In addition to seeking patents for Ocugen's technology and product candidates, Ocugen also relies on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain its competitive position. Ocugen seeks to protect these trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as its employees, corporate collaborators, outside scientific collaborators, contract manufacturers, consultants, advisors and other third parties. Ocugen also enters into confidentiality and invention or patent assignment agreements with its employees and consultants. Despite these efforts, any of these parties may breach the agreements and disclose Ocugen's proprietary information, including its trade secrets, and Ocugen may not be able to obtain adequate remedies for such breaches. Detecting the disclosure or misappropriation of a trade secret and enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. If any of Ocugen's trade secrets were to be lawfully obtained or independently developed by a competitor, Ocugen would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with Ocugen. If any of Ocugen's trade secrets were to be disclosed to or independently developed by a competitor, its competitive position would be harmed.

**Risks Related to Employee Matters and Managing Growth**

***Ocugen's future success depends on its ability to retain key executives and to attract, retain and motivate qualified personnel.***

Ocugen is highly dependent on the research and development, clinical and business development expertise of Shankar Musunuri, Ph.D., MBA, its Chief Executive Officer, Chairman of the Board and Co-Founder, Daniel Jorgensen, M.D., M.P.H., MBA, its Chief Medical Officer, Rasappa Arumugham, Ph.D., its Chief Scientific Officer, as well as the other principal members of its management, scientific and clinical team. Although Ocugen has entered into employment agreements with its executive officers, each of them may terminate their employment with Ocugen at any time. Ocugen does not maintain "key person" insurance for any of its executives or other employees.

Recruiting and retaining qualified scientific, clinical, manufacturing, legal and sales and marketing personnel will also be critical to Ocugen's success. The loss of the services of Ocugen's executive officers or other key employees could impede the achievement of its research, development and commercialization objectives and seriously harm its ability to successfully implement its business strategy. Furthermore, replacing executive

officers and key employees may be difficult and may take an extended period of time because of the limited number of individuals in its industry with the breadth of skills and experience required to successfully develop, gain regulatory approval of and commercialize products. Competition to hire from this limited pool is intense, and Ocugen may be unable to hire, train, retain or motivate these key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. Ocugen also experiences competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition, Ocugen relies on consultants and advisors, including scientific and clinical advisors, to assist Ocugen in formulating its research and development and commercialization strategy. Ocugen's consultants and advisors may be employed by employers other than it and may have commitments under consulting or advisory contracts with other entities that may limit their availability to Ocugen. If Ocugen unable to continue to attract and retain high quality personnel, its ability to pursue its growth strategy will be limited.

***Ocugen expects to expand its development, regulatory and manufacturing capabilities and potentially implement sales, marketing and distribution capabilities, and as a result, Ocugen may encounter difficulties in managing its growth, which could disrupt its operations.***

Ocugen expects to experience significant growth in the number of its employees and the scope of its operations, particularly in the areas of drug development, clinical, regulatory affairs, manufacturing, sales, marketing and distribution. To manage its anticipated future growth, Ocugen must continue to implement and improve its managerial, operational and financial systems, expand its facilities and continue to recruit and train additional qualified personnel. Due to Ocugen's limited financial resources and its limited experience in managing such anticipated growth, it may not be able to effectively manage the expansion of its operations or recruit and train additional qualified personnel. The expansion of Ocugen's operations may lead to significant costs and may divert its management and business development resources. Any inability to manage growth could delay the execution of its business plans or disrupt its operations.

### **Risks Related to Ocugen Common Stock**

***An active, liquid and orderly market for the combined company's common stock may not develop, and you may not be able to resell your common stock at or above the purchase price.***

There has been no public market for Ocugen common stock. Although Histogenics common stock is listed on Nasdaq, and Ocugen and Histogenics have applied to have the combined company's common stock listed on Nasdaq, an active trading market for the combined company's common stock may never develop or be sustained following the merger. Ocugen, Histogenics and their financial advisors will set the final reverse split ratio to target a trading price to provide for sufficient liquidity. The price that the combined company trades at immediately after the merger may not necessarily reflect the price at which investors in the market will be willing to buy and sell the shares on a sustained basis. In addition, an active trading market may not develop following the consummation of the merger or, if it is developed, may not be sustained. The lack of an active market may impair your ability to sell your shares at the time you wish to sell them or at a price that you consider reasonable. An inactive market may also impair the combined company's ability to raise capital by selling shares and may impair the combined company's ability to acquire other businesses or technologies using the combined company's shares as consideration, which, in turn, could materially adversely affect the combined company's business.

***The trading price of the shares of the combined company's common stock could be highly volatile, and purchasers of the combined company's common stock after the merger could incur substantial losses.***

The combined company's stock price is likely to be volatile. The stock market in general and the market for stock of biopharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, investors may not be able to sell their common stock at or above their purchase price. The market price for the combined company's

common stock may be influenced by those factors discussed in this “Risk Factors” section and many others, including:

- the combined company’s ability to enroll subjects in its ongoing and planned clinical trials;
- results of the combined company’s clinical trials and preclinical studies, and the results of trials of the combined company’s competitors or those of other companies in the combined company’s market sector;
- regulatory approval of the combined company’s product candidates, or limitations to specific label indications or patient populations for its use, or changes or delays in the regulatory review process;
- regulatory developments in the United States and foreign countries;
- changes in the structure of healthcare payment systems, especially in light of current reforms to the U.S. healthcare system;
- the success or failure of the combined company’s efforts to acquire, license or develop additional product candidates;
- innovations or new products developed by the combined company’s or its competitors;
- announcements by the combined company or its competitors of significant acquisitions, strategic partnerships, joint ventures or capital commitments;
- manufacturing, supply or distribution delays or shortages;
- any changes to the combined company’s relationship with any manufacturers, suppliers, licensors, future collaborators or other strategic partners;
- achievement of expected product sales and profitability;
- variations in the combined company’s financial results or those of companies that are perceived to be similar to the combined company;
- market conditions in the biopharmaceutical sector and issuance of securities analysts’ reports or recommendations;
- trading volume of the combined company’s common stock;
- an inability to obtain additional funding;
- sales of the combined company’s stock by insiders and stockholders;
- general economic, industry and market conditions other events or factors, many of which are beyond the combined company’s control;
- additions or departures of key personnel; and
- intellectual property, product liability or other litigation against the combined company.

In addition, in the past, stockholders have initiated class action lawsuits against biopharmaceutical companies following periods of volatility in the market prices of these companies’ stock. Such litigation, if instituted against the combined company, could cause Ocugen to incur substantial costs and divert management’s attention and resources, which could have a material adverse effect on the combined company’s business, financial condition and results of operations.

***The combined company’s failure to meet the continued listing requirements of the Nasdaq could result in a delisting of the combined company’s common stock.***

If, after listing, the combined company fails to satisfy the continued listing requirements of the Nasdaq, such as the corporate governance requirements or the minimum closing bid price requirement, Nasdaq may take steps to

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delist the combined company's common stock. Such a delisting would likely have a negative effect on the price of the combined company's common stock and would impair your ability to sell or purchase the combined company's common stock when you wish to do so. In the event of a delisting, the combined company can provide no assurance that any action taken by the combined company to restore compliance with listing requirements would allow the combined company's common stock to become listed again, stabilize the market price or improve the liquidity of the combined company's common stock, prevent the combined company's common stock from dropping below the Nasdaq minimum bid price requirement or prevent future non-compliance with Nasdaq's listing requirements.

***After the merger, the combined company's executive officers, directors and principal stockholders, if they choose to act together, will continue to control or significantly influence all matters submitted to stockholders for approval.***

Following the completion of the merger, the combined company's executive officers, directors and greater than 5% stockholders will own, in the aggregate, approximately 47.42% of Ocugen's outstanding common stock (assuming no exercise of outstanding options). As a result, such persons or their appointees to the combined company's board of directors, acting together, will have the ability to control or significantly influence all matters submitted to the combined company's board of directors or stockholders for approval, including the appointment of the combined company's management, the election and removal of directors and approval of any significant transaction, as well as the combined company's management and business affairs. This concentration of ownership may have the effect of delaying, deferring or preventing a change in control, impeding a merger, consolidation, takeover or other business combination involving the combined company, or discouraging a potential acquiror from making a tender offer or otherwise attempting to obtain control of the combined company's business, even if such a transaction would benefit other stockholders.

***Ocugen does not currently intend to pay dividends on the combined company's common stock, and, consequently, your ability to achieve a return on your investment will depend on appreciation, if any, in the price of the combined company's common stock.***

Ocugen has never declared or paid any cash dividend on Ocugen common stock. Ocugen currently anticipates that it will retain future earnings for the development, operation and expansion of the combined company's business and does not anticipate declaring or paying any cash dividends for the foreseeable future. In addition, the terms of any future debt agreements may preclude the combined company from paying dividends. Any return to stockholders will therefore be limited to the appreciation of their stock. There is no guarantee that shares of the combined company's common stock will appreciate in value or even maintain the price at which stockholders have purchased their shares.

***Sales of a substantial number of shares of the combined company's common stock by the combined company's stockholders in the public market could cause the combined company's stock price to fall.***

Sales of a substantial number of shares of the combined company's common stock in the public market or the perception that these sales might occur could significantly reduce the market price of the combined company's common stock and impair the combined company's ability to raise adequate capital through the sale of additional equity securities.

Based on the exchange ratio of 28.7650, upon the closing of the merger, the combined company will have outstanding a total of 600,817,865 shares of common stock after the merger, assuming no exercise of outstanding options or warrants (including the Investor Warrants). Of these shares, only 252,364,307 shares of common stock will be freely tradable, without restriction, in the public market immediately following the merger, unless they are purchased by one of the combined company's affiliates.

Ocugen's directors and executive officers and holders of approximately 93% of Ocugen's outstanding shares of common stock (excluding securities issued to the Investors pursuant to the Securities Purchase Agreement) have

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entered into lock-up agreements with Histogenics pursuant to which they may not, with limited exceptions, for a period of 180 days from the date of the Effective Time, offer, sell or otherwise transfer or dispose of any of the Histogenics' securities, without the prior written consent of Histogenics, subject to certain exceptions. Sales of these shares, or perceptions that they will be sold, could cause the trading price of the combined company's common stock to decline. After the lock-up agreements expire, up to an additional 348,453,558 shares of common stock will be eligible for sale in the public market.

Additionally, in connection with the Pre-Merger Financing, Histogenics and Ocugen will enter into lock-up agreements with each officer, director or other person that will be subject to Section 16 of the Exchange Act, with respect to Histogenics immediately following the consummation of the merger, and each holder of greater than 3% of Ocugen common stock (excluding the shares of Ocugen common stock issuable pursuant to the Securities Purchase Agreement) immediately prior to the consummation of the merger (the "Financing Lock-Up Parties"), pursuant to which each of the Financing Lock-Up Parties will agree that until the date that is 30 calendar days after the Trigger Date (as defined in the section entitled "Agreements Related to the Merger—Securities Purchase Agreement" in this proxy statement/prospectus/information statement), subject to certain customary exceptions, such Financing Lock-Up Party will not and will cause its affiliates not to (i) offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, make any short sale or otherwise transfer or dispose of or lend, directly or indirectly, any shares of Histogenics common stock or any securities convertible into, exercisable or exchangeable for or that represent the right to receive Histogenics common stock, (ii) enter into any swap or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of any of the Financing Lock-Up Party's shares of Histogenics common stock or such other securities, in cash or otherwise, (iii) make any demand for or exercise any right or cause to be filed a registration statement, including any amendments thereto, with respect to the registration of any shares of Histogenics common stock or such other securities, in cash or otherwise, (iv) grant any proxies or powers of attorney with respect to any shares of Histogenics common stock or such other securities, deposit any shares of Histogenics common stock or such other securities into a voting trust or enter into a voting agreement or similar arrangement or commitment with respect to any shares of Histogenics common stock or such other securities, or (v) publicly disclose the intention to do any of the foregoing.

After the merger, the holders of 1,827,666 shares of Histogenics' outstanding common stock, or approximately 1.9% of Histogenics' total outstanding common stock as of March 31, 2019, will be entitled to rights with respect to the registration of their shares under the Securities Act, subject to vesting and the 180-day lock-up agreements described above. See "Description of Histogenics' Capital Stock—Registration Rights." Registration of these shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act, except for shares held by affiliates, as defined in Rule 144 under the Securities Act. Any sales of securities by these stockholders could have a material adverse effect on the trading price of the combined company's common stock.

***Ocugen will incur significant increased costs as a result of operating as a public company, and its management will be required to devote substantial time to new compliance initiatives.***

As a public company, Ocugen will incur significant legal, accounting and other expenses that Ocugen did not incur as a private company. Ocugen will be subject to the reporting requirements of the Exchange Act, which will require, among other things, that Ocugen files with the U.S. Securities and Exchange Commission, or SEC, annual, quarterly and current reports with respect to Ocugen's business and financial condition. In addition, Sarbanes-Oxley, as well as rules subsequently adopted by the SEC and Nasdaq to implement provisions of Sarbanes-Oxley, impose significant requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. Further, pursuant to the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010, the SEC has adopted additional rules and regulations in these areas, such as mandatory "say on pay" voting requirements that will apply to Ocugen when it ceases to be an emerging growth company. Stockholder activism, the current

political environment and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact the manner in which Ocugen operates its business in ways Ocugen cannot currently anticipate.

Ocugen expects the rules and regulations applicable to public companies to substantially increase Ocugen's legal and financial compliance costs and to make some activities more time consuming and costly. If these requirements divert the attention of Ocugen's management and personnel from other business concerns, they could have a material adverse effect on Ocugen's business, financial condition and results of operations. The increased costs will increase Ocugen's net loss, and may require Ocugen to reduce costs in other areas of its business or increase the prices of its products or services. For example, Ocugen expects these rules and regulations to make it more difficult and more expensive for Ocugen to obtain director and officer liability insurance, and Ocugen may be required to incur substantial costs to maintain the same or similar coverage. Ocugen cannot predict or estimate the amount or timing of additional costs Ocugen may incur to respond to these requirements. The impact of these requirements could also make it more difficult for Ocugen to attract and retain qualified persons to serve on its board of directors, its board committees or as executive officers.

***If securities or industry analysts do not publish research or reports or publish unfavorable research or reports about the combined company's business, the combined company's stock price and trading volume could decline.***

The trading market for the combined company's common stock will depend in part on the research and reports that securities or industry analysts publish about the combined company, its business, its market or its competitors. Ocugen does not currently have and may never obtain research coverage by securities and industry analysts. If no securities or industry analysts commence coverage of the combined company, the trading price for the combined company's stock would be negatively impacted. In the event the combined company obtains securities or industry analyst coverage, if one or more of the analysts who covers the combined company downgrades its stock, the combined company's stock price would likely decline. If one or more of these analysts ceases to cover the combined company or fails to regularly publish reports on the combined company, interest in the combined company's stock could decrease, which could cause the combined company's stock price or trading volume to decline.

***If the combined company fails to maintain proper and effective internal control over financial reporting, Ocugen's ability to produce accurate and timely financial statements could be impaired, investors may lose confidence in the combined company's financial reporting and the trading price of the combined company's common stock may decline.***

Pursuant to Section 404 of Sarbanes-Oxley, the combined company's management will be required to report upon the effectiveness of the combined company's internal control over financial reporting beginning with the annual report for the combined company's fiscal year ending December 31, 2019. Additionally, if the combined company reaches an accelerated filer threshold, the combined company's independent registered public accounting firm will be required to attest to the effectiveness of the combined company's internal control over financial reporting. The rules governing the standards that must be met for management to assess the combined company's internal control over financial reporting are complex and require significant documentation, testing and possible remediation. To comply with the requirements of being a reporting company under the Exchange Act, the combined company will need to upgrade its information technology systems; implement additional financial and management controls, reporting systems and procedures; and hire additional accounting and finance staff. If the combined company or, if required, its auditors are unable to conclude that the combined company's internal control over financial reporting is effective, investors may lose confidence in the combined company's financial reporting and the trading price of the combined company's common stock may decline.

The combined company cannot assure you that there will not be material weaknesses or significant deficiencies in the combined company's internal control over financial reporting in the future. Any failure to maintain internal

control over financial reporting could severely inhibit the combined company's ability to accurately report its financial condition, results of operations or cash flows. If the combined company is unable to conclude that its internal control over financial reporting is effective, or if the combined company's independent registered public accounting firm determines the combined company has a material weakness or significant deficiency in the combined company's internal control over financial reporting once that firm begins its Section 404 reviews, investors may lose confidence in the accuracy and completeness of the combined company's financial reports, the market price of the combined company's common stock could decline, and the combined company could be subject to sanctions or investigations by Nasdaq, the SEC or other regulatory authorities. Failure to remedy any material weakness in the combined company's internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also restrict the combined company's future access to the capital markets.

***Provisions in the combined company's charter documents and under Delaware law could discourage a takeover that stockholders may consider favorable and may lead to entrenchment of management.***

The anticipated amended and restated certificate of incorporation and amended and restated bylaws of the combined company that will be in effect immediately after consummation of the merger will contain provisions that could significantly reduce the value of the combined company's shares to a potential acquiror or delay or prevent changes in control or changes in the combined company's management without the consent of the combined company's board of directors. The provisions in the combined company's charter documents are expected to include the following:

- a classified board of directors with three-year staggered terms, which may delay the ability of stockholders to change the membership of a majority of the combined company's board of directors;
- no cumulative voting in the election of directors, which limits the ability of minority stockholders to elect director candidates;
- the exclusive right of the combined company's board of directors, unless the board of directors grants such right to the stockholders, to elect a director to fill a vacancy created by the expansion of the board of directors or the resignation, death or removal of a director, which prevents stockholders from being able to fill vacancies on the combined company's board of directors;
- the prohibition on removal of directors without cause due to the classified board of directors;
- the ability of the combined company's board of directors to authorize the issuance of shares of preferred stock and to determine the price and other terms of those shares, including preferences and voting rights, without stockholder approval, which could be used to significantly dilute the ownership of a hostile acquiror;
- the ability of the combined company's board of directors to alter Ocugen's amended and restated bylaws without obtaining stockholder approval;
- the required approval of at least 66-2/3% of the shares entitled to vote to adopt, amend or repeal the combined company's amended and restated bylaws or repeal certain provisions of the combined company's amended and restated certificate of incorporation;
- a prohibition on stockholder action by written consent, which forces stockholder action to be taken at an annual or special meeting of Ocugen's stockholders;
- an exclusive forum provision providing that the Court of Chancery of the State of Delaware will be the exclusive forum for certain actions and proceedings;
- the requirement that a special meeting of stockholders may be called only by the chairman of the board of directors, the chief executive officer or the board of directors, which may delay the ability of the combined company's stockholders to force consideration of a proposal or to take action, including the removal of directors; and



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- advance notice procedures that stockholders must comply with in order to nominate candidates to the combined company's board of directors or to propose matters to be acted upon at a stockholders' meeting, which may discourage or deter a potential acquiror from conducting a solicitation of proxies to elect the acquiror's own slate of directors or otherwise attempting to obtain control of the combined company.

The combined company is also subject to the anti-takeover provisions contained in Section 203 of the Delaware General Corporation Law. Under Section 203, a corporation may not, in general, engage in a business combination with any holder of 15% or more of its capital stock unless the holder has held the stock for three years or, among other exceptions, the board of directors has approved the transaction.

***The combined company's amended and restated bylaws will provide that the Court of Chancery of the State of Delaware will be the exclusive forum for substantially all disputes between the combined company and its stockholders, which could limit the combined company's stockholders' ability to obtain a favorable judicial forum for disputes with the combined company or its directors, officers or employees.***

The combined company's amended and restated bylaws will provide that the Court of Chancery of the State of Delaware is the exclusive forum for any derivative action or proceeding brought on the combined company's behalf, any action asserting a breach of fiduciary duty, any action asserting a claim against the combined company arising pursuant to the Delaware General Corporation Law, the combined company's amended and restated certificate of incorporation or the combined company's amended and restated bylaws, or any action asserting a claim against the combined company that is governed by the internal affairs doctrine. These choice of forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with the combined company or its directors, officers or other employees, which may discourage such lawsuits against the combined company and its directors, officers and other employees. By agreeing to this provision, however, stockholders will not be deemed to have waived the combined company's compliance with the federal securities laws and the rules and regulations thereunder. Furthermore, the enforceability of similar choice of forum provisions in other companies' certificates of incorporation has been challenged in legal proceedings, and it is possible that a court could find these types of provisions to be inapplicable or unenforceable. If a court were to find the choice of forum provisions in the combined company's amended and restated bylaws to be inapplicable or unenforceable in an action, the combined company may incur additional costs associated with resolving such action in other jurisdictions, which could adversely affect the combined company's business and financial condition.

***If the merger does not qualify as a "reorganization" for U.S. federal income tax purposes, U.S. Holders of Ocugen common stock will be required to recognize gain or loss for U.S. federal income tax purposes upon the exchange of their Ocugen common stock for Histogenics common stock in the merger.***

The U.S. federal income tax consequences of the merger to U.S. Holders (as defined under the heading "The Merger—Material U.S. Federal Income Tax Consequences of the Merger") will depend on whether the merger qualifies as a "reorganization" for U.S. federal income tax purposes. Histogenics' and Ocugen's obligations to effect the merger are subject to the satisfaction, or waiver, at or prior to the effective time of the merger, of the condition that each company receive an opinion of counsel, dated as of the closing date of the merger, to the effect that the merger will qualify as a "reorganization" within the meaning of Section 368(a) of the Code. If, contrary to the opinions from counsel, the merger fails to qualify as a reorganization within the meaning of Section 368(a) of the Code, a U.S. Holder of Ocugen common stock would recognize gain or loss for U.S. federal income tax purposes on each share of Ocugen common stock surrendered in the merger for Histogenics common stock and any cash received in lieu of a fractional share. For a more complete discussion of the material U.S. federal income tax consequences of the merger, please carefully review the information set forth in the section entitled "The Merger—Material U.S. Federal Income Tax Consequences of the Merger."

***Ocugen's ability to use net operating loss carryforwards and other tax attributes may be limited in connection with the merger and other ownership changes.***

Ocugen has incurred substantial losses during its history and does not expect to become profitable in the near future, and Ocugen may never achieve profitability. To the extent that Ocugen continues to generate taxable losses, unused losses will carry forward to offset future taxable income, if any, until such unused losses expire (if at all). At December 31, 2018, Ocugen had federal and state NOL carryforwards of approximately \$47.4 million. Such federal and state NOL carryforwards will begin to expire in 2033, unless previously utilized. At December 31, 2018, Ocugen had federal and state research and development credit available carryforwards of approximately \$0.5 million and less than \$0.1 million, respectively. The federal research and development credit carryforwards will begin expiring in 2034, unless previously utilized. The state research and development credits do not expire.

Under the Tax Act, federal NOLs generated in taxable years ending after December 31, 2017, may be carried forward indefinitely but federal NOLs generated in taxable years beginning after December 31, 2017 may only be used to offset 80% of Ocugen's taxable income annually. Ocugen's NOL carryforwards are subject to review and possible adjustment by the IRS and state tax authorities. Under Sections 382 and 383 of the Code, Ocugen's federal NOL and research and development tax credit carryforwards may become subject to an annual limitation in the event of certain cumulative changes in the ownership interest of significant stockholders over a three-year period in excess of 50 percentage points. Ocugen's ability to utilize its NOL carryforwards and other tax attributes to offset future taxable income or tax liabilities may be limited as a result of ownership changes, including in connection with the merger. Similar rules may apply under state tax laws. Ocugen has not yet determined the amount of the cumulative change in its ownership resulting from the merger, the Pre-Merger Financing or other transactions, or any resulting limitations on its ability to utilize its NOL carryforwards and other tax attributes. If Ocugen earns taxable income, such limitations could result in increased future tax liability to Ocugen and its future cash flows could be adversely affected. Ocugen has recorded a full valuation allowance related to its NOLs and other deferred tax assets due to the uncertainty of the ultimate realization of the future benefits of those assets.

***The combined company could be subject to securities class action litigation.***

In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for the combined company, because biotechnology and pharmaceutical companies have experienced significant stock price volatility in recent years. If the combined company faces such litigation, it could result in substantial costs and a diversion of management's attention and resources, which could harm the combined company's business.

***The combined organization may never pay dividends on the combined organization's common stock so any returns would be limited to the appreciation of the combined organization's stock.***

Ocugen and Histogenics currently anticipate that the combined organization will retain future earnings for the development, operation and expansion of the combined organization's business and do not anticipate it will declare or pay any cash dividends for the foreseeable future. Any return to stockholders will therefore be limited to the appreciation of their stock.

***Certain of the Investor Warrants contain price-based adjustment provisions which, if triggered, may cause substantial additional dilution to the combined organization's stockholders.***

The Investor Warrants will be issued on the fifth trading day following the merger and will be exercisable immediately upon issuance. Certain of the Investor Warrants contain price-based adjustment provisions, pursuant to which the number of shares of the combined organization's common stock that are issuable upon exercise of such Investor Warrants may be adjusted upward based upon the volume weighted average trading price of the

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combined organization's common stock after closing and in the event of certain dilutive issuances by the combined organization. Even if the combined organization's stock increases in value after the merger, the number of shares of the combined organization's common stock issuable upon exercise of the Investor Warrants may still increase. The circumstances under which the number of shares of the combined organization's common stock issuable upon exercise of the Investor Warrants may be adjusted upward are set forth in the Investor Warrants and described in the sections entitled "Agreements Related to the Merger-Series A Warrants," "Agreements Related to the Merger-Series B Warrants" and "Agreements Related to the Merger-Series C Warrants" in this proxy statement/prospectus/information statement.

If the Investor Warrants are exercised, additional shares of the combined organization's common stock will be issued, which will result in dilution to our then-existing stockholders and increase the number of shares eligible for resale in the public market. Assuming (i) the merger is effected, (ii) an exchange ratio of 28.7650 shares of pre-reverse stock split Histogenics common stock for each outstanding share of Ocugen common stock as of immediately prior to the merger, (iii) a total of 13,024,138 shares of Ocugen common stock issued and outstanding as of immediately prior to the merger, (iv) the issuance of the maximum number of Converted Additional Shares and (v) ignoring restrictions in the Securities Purchase Agreement preventing exercises of Investor Warrants if the exercising Investor would beneficially own in excess of 4.99% or 9.99% of the outstanding common stock of Histogenics (including the shares of common stock issuable upon such exercise), following the issuance of the maximum number of shares issuable upon exercise of the Investor Warrants, the Investors would hold an aggregate of approximately 89.7% of Histogenics' total outstanding common stock following such issuance. Sales of substantial numbers of such shares in the public market could depress the market price of the combined organization's common stock. If the adjustment provisions in the Investor Warrants are triggered, a substantial number of additional shares of the combined organization's common stock may become issuable upon exercise of the Investor Warrants, potentially increasing the impact of any subsequent exercise of the Investor Warrants and resale of the shares issuable pursuant thereto.

## FORWARD-LOOKING STATEMENTS

This proxy statement/prospectus/information statement and the documents incorporated by reference into this proxy statement/prospectus/information statement contain forward-looking statements (including within the meaning of Section 21E of the United States Securities Exchange Act of 1934, as amended (the “Exchange Act”), and Section 27A of the United States Securities Act of 1933, as amended (the “Securities Act”)) concerning Histogenics, Ocugen, the merger and other matters. These statements may discuss goals, intentions and expectations as to future plans, trends, events, results of operations or financial condition, or otherwise, based on current beliefs of the management of Histogenics, as well as assumptions made by, and information currently available to, management. Forward-looking statements generally include statements that are predictive in nature and depend upon or refer to future events or conditions, and include words such as “may,” “will,” “should,” “would,” “expect,” “plan,” “believe,” “intend,” “look forward,” and other similar expressions among others. Statements that are not historical facts are forward-looking statements. Forward-looking statements are based on current beliefs and assumptions that are subject to risks and uncertainties and are not guarantees of future performance. Actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of these risks and uncertainties, which include, without limitation: (i) the risk that the conditions to the closing of the merger are not satisfied, including the failure to timely obtain stockholder approval for the transaction, if at all; (ii) uncertainties as to the timing of the consummation of the merger and the ability of each of Histogenics and Ocugen to consummate the merger; (iii) risks related to Histogenics’ ability to manage its operating expenses and its expenses associated with the merger pending closing; (iv) risks related to the failure or delay in obtaining required approvals from any governmental or quasi-governmental entity necessary to consummate the merger; (v) the risk that as a result of adjustments to or exercise of the Investor Warrants, stockholders of the combined company could be substantially and materially diluted; (vi) risks related to the market price of Histogenics common stock relative to the exchange ratio; (vii) unexpected costs, charges or expenses resulting from the transaction; (viii) potential adverse reactions or changes to business relationships resulting from the announcement or completion of the merger; (ix) the uncertainties associated with the clinical development and regulatory approval of product candidates, including potential delays in the commencement, enrollment and completion of clinical trials; (x) risks related to the inability of the combined company to obtain sufficient additional capital to continue to advance these product candidates and its preclinical programs; (xi) uncertainties in obtaining successful clinical results for product candidates and unexpected costs that may result therefrom; (xii) risks related to the failure to realize any value from product candidates and preclinical programs being developed and anticipated to be developed in light of inherent risks and difficulties involved in successfully bringing product candidates to market; and (xiii) risks associated with the possible failure to realize certain anticipated benefits of the merger, including with respect to future financial and operating results. Actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of these risks and uncertainties. Except as required by applicable law, Histogenics undertakes no obligation to revise or update any forward-looking statement, or to make any other forward-looking statements, whether as a result of new information, future events or otherwise.

For a discussion of the factors that may cause Histogenics, Ocugen or the combined organization’s actual results, performance or achievements to differ materially from any future results, performance or achievements expressed or implied in such forward-looking statements, or for a discussion of risk associated with the ability of Histogenics and Ocugen to complete the merger and the effect of the merger on the business of Histogenics, Ocugen and the combined organization, see the section entitled “Risk Factors” beginning on page 30.

Additional factors that could cause actual results to differ materially from those expressed in the forward-looking statements are discussed in reports filed with the SEC by Histogenics including the risk factors included in Histogenics’ most recent Annual Report on Form 10-K, Quarterly Reports on Form 10-Q and Current Reports on Form 8-K filed with the SEC. See the section entitled “Where You Can Find More Information” beginning on page 382.

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**If any of these risks or uncertainties materialize or any of these assumptions prove incorrect, the results of Histogenics, Ocugen or the combined organization could differ materially from the forward-looking statements. All forward-looking statements in this proxy statement/prospectus/information statement are current only as of the date on which the statements were made. Histogenics and Ocugen do not undertake any obligation to publicly update any forward-looking statement to reflect events or circumstances after the date on which any statement is made or to reflect the occurrence of unanticipated events.**

## THE SPECIAL MEETING OF HISTOGENICS' STOCKHOLDERS

### Date, Time and Place

The Histogenics special meeting will be held on September 12, 2019, at the offices of Gunderson Dettmer Stough Villeneuve Franklin & Hachigian, LLP located at One Marina Park Drive, Suite 900, Boston, MA 02210 commencing at 9:00 am local time. Histogenics is sending this proxy statement/prospectus/information statement to its stockholders in connection with the solicitation of proxies by the Histogenics Board for use at the Histogenics special meeting and any adjournments or postponements of the Histogenics special meeting. This proxy statement/prospectus/information statement is first being furnished to Histogenics' stockholders on or about August , 2019.

### Purpose of the Histogenics Special Meeting

The purpose of the Histogenics special meeting is:

1. To approve the Merger Agreement, and the transactions contemplated thereby, including the merger, the issuance of Histogenics common stock to Ocugen's stockholders in accordance with the Merger Agreement and the change of control resulting from the merger.
2. To approve an amendment to the sixth amended and restated certificate of incorporation of Histogenics to effect the Histogenics Reverse Stock Split, in the form attached as *Annex D* to this proxy statement/prospectus/information statement.
3. To approve the amendment to the sixth amended and restated certificate of incorporation of Histogenics to effect the Histogenics Name Change in the form attached as *Annex E* to this proxy statement/prospectus/information statement.
4. To approve the amendment to the sixth amended and restated certificate of incorporation of Histogenics to increase the number of authorized shares of Histogenics common stock to a total number of 200,000,000 shares, in the form attached as *Annex F* to this proxy statement/prospectus/information statement.
5. To approve the issuance of: (a) shares of Histogenics common stock upon the exercise of the Investor Warrants to be issued in the Pre-Merger Financing, and (b) additional shares of Histogenics common stock that may be issued following the closing of the Pre-Merger Financing, in each case pursuant to the Securities Purchase Agreement and as required by and in accordance with Nasdaq Listing Rule 5635.
6. To consider and vote upon an adjournment of the Histogenics special meeting, if necessary, to solicit additional proxies if there are not sufficient votes in favor of Proposal Nos. 1 and 2.
7. To transact such other business as may properly come before the Histogenics special meeting or any adjournment or postponement thereof.

### Recommendation of The Histogenics Board

- The Histogenics Board has determined that the transactions contemplated by the Merger Agreement, including the merger, the issuance of shares of Histogenics common stock to Ocugen's stockholders pursuant to the Merger Agreement and the change of control resulting from the merger are fair to, advisable and in the best interest of Histogenics and its stockholders and has approved and declared advisable the Merger Agreement and such transactions. The Histogenics Board recommends that Histogenics' stockholders vote "FOR" Proposal No. 1 to approve the Merger Agreement and the transactions contemplated thereby, including the merger, the issuance of shares of Histogenics common stock to Ocugen's stockholders and the change of control resulting from the merger.
- The Histogenics Board has determined that the Histogenics Reverse Stock Split is fair to, advisable and in the best interest of Histogenics and its stockholders and has approved and declared advisable the

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Histogenics Reverse Stock Split. The Histogenics Board recommends that Histogenics' stockholders vote "FOR" Proposal No. 2 to approve an amendment to the sixth amended and restated certificate of incorporation of Histogenics effecting the Histogenics Reverse Stock Split.

- The Histogenics Board has determined that the Histogenics Name Change is fair to, advisable and in the best interest of Histogenics and its stockholders and has approved and declared advisable the Histogenics Name Change. The Histogenics Board recommends that Histogenics' stockholders vote "FOR" Proposal No. 3 to approve an amendment to the sixth amended and restated certificate of incorporation of Histogenics effecting the Histogenics Name Change.
- The Histogenics Board has determined that the amendment to Histogenics' sixth amended and restated certificate of incorporation to increase the number of authorized shares of Histogenics common stock to a total number of 200,000,000 shares is fair to, advisable and in the best interest of Histogenics and its stockholders and has approved and declared advisable such amendment to Histogenics' sixth amended and restated certificate of incorporation. The Histogenics Board recommends that Histogenics' stockholders vote "FOR" Proposal No. 4 to approve such amendment to the sixth amended and restated certificate of incorporation of Histogenics effecting the increase in authorized shares of Histogenics common stock.
- The Histogenics Board recommends that Histogenics' stockholders vote "FOR" Proposal No. 5 to approve the issuance of: (a) shares of Histogenics common stock upon the exercise of the Investor Warrants to be issued in the Pre-Merger Financing, and (b) additional shares of Histogenics common stock that may be issued following the closing of the Pre-Merger Financing, in each case pursuant to the Securities Purchase Agreement and as required by and in accordance with Nasdaq Listing Rule 5635.
- The Histogenics Board has determined and believes that adjourning the Histogenics special meeting, if necessary, to solicit additional proxies if there are not sufficient votes in favor of Proposal Nos. 1 or 2 is advisable to, and in the best interests of, Histogenics and its stockholders and has approved and adopted the proposal. The Histogenics Board recommends that Histogenics' stockholders vote "FOR" Proposal No. 6 to adjourn the Histogenics special meeting, if necessary, to solicit additional proxies if there are not sufficient votes in favor of Proposal Nos. 1 or 2.

### **Record Date and Voting Power**

Only holders of record of Histogenics common stock at the close of business on the record date, July 15, 2019, are entitled to notice of, and to vote at, the Histogenics special meeting. There were approximately \_\_\_\_\_ holders of record of Histogenics common stock at the close of business on the record date. At the close of business on the record date, 94,599,601 shares of Histogenics common stock were issued and outstanding. Each share of Histogenics common stock entitles the holder thereof to one vote on each matter submitted for stockholder approval. See the section entitled "Principal Stockholders of Histogenics" in this proxy statement/prospectus/information statement for information regarding persons known to Histogenics' management to be the beneficial owners of more than 5% of the outstanding shares of Histogenics common stock.

### **Voting and Revocation of Proxies**

The proxy accompanying this proxy statement/prospectus/information statement is solicited on behalf of the Histogenics Board for use at the Histogenics special meeting.

If you are a stockholder of record of Histogenics as of the record date referred to above, you may vote in person at the Histogenics special meeting or vote by proxy using the enclosed proxy card. Whether or not you plan to attend the Histogenics special meeting, Histogenics urges you to vote by proxy to ensure your vote is counted.

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You may still attend the Histogenics special meeting and vote in person if you have already voted by proxy. As a stockholder of record you may vote in any of the following ways:

- to vote in person, attend the Histogenics special meeting and Histogenics will provide you a ballot when you arrive.
- to vote using the proxy card, simply mark, sign and date your proxy card and return it promptly in the postage-paid envelope provided. If you return your signed proxy card to Histogenics before the Histogenics special meeting, Histogenics will vote your shares as you direct on the proxy card.
- to vote by telephone or on the Internet, dial the number on the proxy card or voting instruction form or visit the website on the proxy card or voting instruction form to complete an electronic proxy card. You will be asked to provide the Histogenics number and control number from the enclosed proxy card. Your vote must be received by 11:59 p.m., Eastern time on September 11, 2019 to be counted.

If your shares of Histogenics common stock are held by your broker as your nominee, that is, in “street name,” the enclosed voting instruction card is sent by the institution that holds your shares. Please follow the instructions included on that proxy card regarding how to instruct your broker to vote your shares of Histogenics common stock. If you do not give instructions to your broker, your broker can vote your shares of Histogenics common stock with respect to “discretionary” items but not with respect to “non-discretionary” items. Discretionary items are proposals considered routine under certain rules applicable to brokers on which your broker may vote shares held in “street name” in the absence of your voting instructions. On non-discretionary items for which you do not give your broker instructions, your shares of Histogenics common stock will be treated as broker non-votes. It is anticipated that all proposals will be non-discretionary items.

All properly executed proxies that are not revoked will be voted at the Histogenics special meeting and at any adjournments or postponements of the Histogenics special meeting in accordance with the instructions contained in the proxy. If a holder of Histogenics common stock executes and returns a proxy and does not specify otherwise, the shares represented by that proxy will be voted “FOR” Proposal No. 1 to approve the Merger Agreement and the transactions contemplated thereby, including the merger, the issuance of shares of Histogenics common stock to Ocugen’s stockholders pursuant to the Merger Agreement and the change of control resulting from the merger; “FOR” Proposal No. 2 to approve an amendment to the sixth amended and restated certificate of incorporation of Histogenics effecting the Histogenics Reverse Stock Split; “FOR” Proposal No. 3 to approve an amendment to the sixth amended and restated certificate of incorporation of Histogenics to effect the Histogenics Name Change; “FOR” Proposal No. 4 to approve an amendment to the sixth amended and restated certificate of incorporation of Histogenics to increase the number of authorized shares of Histogenics common stock to a total number of 200,000,000; “FOR” Proposal No. 5 to approve the issuance of (a) shares of Histogenics common stock upon the exercise of the Investor Warrants to be issued in the Pre-Merger Financing, and (b) additional shares of Histogenics common stock that may be issued following the closing of the Pre-Merger Financing, in each case pursuant to the Securities Purchase Agreement and as required by and in accordance with Nasdaq Listing Rule 5635; and “FOR” Proposal No. 6 to approve the adjournment of the Histogenics special meeting, if necessary, to solicit additional proxies if there are not sufficient votes in favor of Proposal Nos. 1 or 2 in accordance with the recommendation of the Histogenics Board.

Histogenics’ stockholders of record, other than those Histogenics’ stockholders who have executed voting agreements, may change their vote at any time before their proxy is voted at the Histogenics special meeting in one of three ways. First, a stockholder of record of Histogenics can send a written notice to the Secretary of Histogenics stating that the stockholder would like to revoke its proxy. Second, a stockholder of record of Histogenics can submit new proxy instructions either on a new proxy card or by telephone or via the Internet. Third, a stockholder of record of Histogenics can attend the Histogenics special meeting and vote in person. Attendance alone will not revoke a proxy. If a stockholder of Histogenics of record or a stockholder who owns shares of Histogenics common stock in “street name” has instructed a broker to vote its shares of Histogenics common stock, the stockholder must follow directions received from its broker to change those instructions.



### **Required Vote**

The presence, in person or represented by proxy, at the Histogenics special meeting of the holders of a majority of the shares of Histogenics common stock outstanding and entitled to vote at the Histogenics special meeting is necessary to constitute a quorum at the meeting. Abstentions and broker non-votes will be counted towards a quorum. Approval of Proposal Nos. 1, 5 and 6 requires the affirmative vote of the holders of a majority of the shares of Histogenics common stock entitled to vote and present in person or represented by proxy at the Histogenics special meeting. Approval of Proposal Nos. 2, 3 and 4 requires the affirmative vote of holders of a majority of Histogenics common stock having voting power outstanding on the record date for the Histogenics special meeting.

Votes will be counted by the inspector of election appointed for the Histogenics special meeting, who will separately count “FOR” and “AGAINST” votes, abstentions and broker non-votes. Abstentions will be counted towards the vote total and will have the same effect as “AGAINST” votes for Proposal Nos. 1, 2, 3, 4, 5 and 6. Broker non-votes will have the same effect as “AGAINST” votes for Proposal Nos. 2, 3 and 4. For Proposal Nos. 1, 5 and 6, broker non-votes will have no effect and will not be counted towards the vote total, but will be used to determine whether a quorum is present at the Histogenics special meeting.

Each of Proposal Nos. 1 and 2 are conditioned upon each other. Therefore, the merger cannot be consummated without the approval of Proposal Nos. 1 and 2. Proposal Nos. 3, 4 and 5 are conditioned upon the consummation of the merger. If the merger is not completed or the stockholders do not approve Proposal No. 3, Histogenics will not change its name to “Ocugen, Inc.” If the merger is not completed or the stockholders do not approve Proposal No. 4, the increase in the number of authorized shares of Histogenics common stock will not be effected. If the merger is not completed or the stockholders do not approve Proposal No. 5, the Pre-Merger Financing will not be effected except that Histogenics’ stockholders’ approval of the Pre-Merger Financing is a condition to the closing of the Pre-Merger Financing. Proposal Nos. 1 and 2 are not conditioned on Proposal Nos. 3, 4 or 5 being approved.

As of July 12, 2019, the directors and executive officers of Histogenics and other stockholders who signed voting agreements beneficially owned less than one percent of the outstanding shares of Histogenics common stock entitled to vote at the Histogenics special meeting. Pursuant to the voting agreements, each such director, executive officer and other signatory stockholder has agreed to be present (in person or by proxy) at the Histogenics special meeting to vote all shares of Histogenics common stock owned by him, her or it as of the record date in favor of Proposal Nos. 1, 2 and 3. Additionally, each such stockholder has agreed, solely in his, her or its capacity as a stockholder of Histogenics, to vote against any competing acquisition proposal and any action, proposal or transaction that would reasonably be expected to result in a material breach of the voting agreement. As of July 12, 2019, Histogenics is not aware of any affiliate of Ocugen owning any shares of Histogenics common stock entitled to vote at the Histogenics special meeting.

### **Solicitation of Proxies**

In addition to solicitation by mail, the directors, officers, employees and agents of Histogenics may solicit proxies from Histogenics’ stockholders by personal interview, telephone, telegram or otherwise. Histogenics and Ocugen will share equally the costs of printing and filing this proxy statement/prospectus/information statement and proxy card. Arrangements will also be made with brokerage firms and other custodians, nominees and fiduciaries who are record holders of Histogenics common stock for the forwarding of solicitation materials to the beneficial owners of Histogenics common stock. In addition, Histogenics has engaged Innisfree M&A Incorporated, a proxy solicitation firm, to solicit proxies from Histogenics’ stockholders for a fee of \$20,000 plus costs associated with solicitation campaigns. Histogenics will also reimburse Innisfree M&A Incorporated for reasonable out-of-pocket expenses. Histogenics will reimburse these brokers, custodians, nominees and fiduciaries for the reasonable out-of-pocket expenses they incur in connection with the forwarding of solicitation materials.

**Other Matters**

As of the date of this proxy statement/prospectus/information statement, the Histogenics Board does not know of any business to be presented at the Histogenics special meeting other than as set forth in the notice accompanying this proxy statement/prospectus/information statement. If any other matters should properly come before the Histogenics special meeting, it is intended that the shares represented by proxies will be voted with respect to such matters in accordance with the judgment of the persons voting the proxies.

## THE MERGER

*This section and the section entitled “The Merger Agreement” in this proxy statement/prospectus/information statement describe the material aspects of the merger, including the Merger Agreement. While Histogenics and Ocugen believe that this description covers the material terms of the merger and the Merger Agreement, it may not contain all of the information that is important to you. You should carefully read this entire proxy statement/prospectus/information statement for a more complete understanding of the merger and the Merger Agreement, including the Original Merger Agreement attached as Annex A-1 and Merger Agreement Amendment attached as Annex A-2, and the other documents to which you are referred herein. See the section entitled “Where You Can Find More Information” in this proxy statement/prospectus/information statement.*

### **Background of the Merger**

#### ***Historical Background for Histogenics***

##### *Summary of Histogenics and NeoCart Phase 3 Clinical Trial Results in 2018*

Histogenics historically focused on the development of restorative cell therapies, including its product candidate, NeoCart, which is an innovative cell therapy that utilizes various aspects of Histogenics’ restorative cell therapy platform to treat tissue injury in the field of orthopedics, specifically cartilage damage in the knee.

In the third quarter of 2018, Histogenics announced that its Phase 3 clinical trial of NeoCart (the “NeoCart Phase 3 Trial”) did not meet the primary endpoint of a statistically significant improvement in pain and function in a dual threshold responder analysis one year after treatment as compared to microfracture. Based on the totality of the data, Histogenics initiated a dialogue with the FDA in the third quarter of 2018 to discuss the regulatory path forward for NeoCart. Histogenics’ primary objective in these discussions was to determine whether the FDA would accept a submission of a BLA for NeoCart without data from an additional clinical trial. Histogenics had a constructive dialogue with the FDA, which included requests for, and review of, additional statistical analyses, different subgroup analyses, and secondary endpoints. These additional analyses did not change the conclusion that the NeoCart Phase 3 trial failed to meet its primary and secondary endpoints.

In December 2018, Histogenics received final feedback from the FDA indicating that while the NeoCart Phase 3 Trial resulted in certain compelling data, particularly the early response in pain and function and the data in certain lesion sizes, an additional Phase 3 clinical trial would need to be completed before the FDA would accept the submission of a BLA for NeoCart. The FDA indicated receptivity to novel clinical trial methodologies and regenerative medicine advanced therapy designations in order to support additional data for a future potential submission. However, considering the time and funding required to conduct such a trial, Histogenics discontinued the development of NeoCart.

As a result of the FDA feedback, Histogenics initiated a process to evaluate strategic alternatives to maximize value for its stakeholders. Histogenics conducted the process with the assistance of Canaccord Genuity, as its financial advisor, Gunderson Dettmer Stough Villeneuve Franklin & Hachigian, LLP (“Gunderson Dettmer”), as its general corporate and securities counsel, Richards, Layton & Finger, P.A. (“RLF”), as its Delaware counsel, and Katten Muchin Rosenman LLP (“Katten”), as its litigation and insolvency counsel. During the process, Histogenics, with the assistance of its advisors, evaluated a full range of potential strategic alternatives, including but not limited to, acquisitions, business combinations, joint ventures, public and private capital raises and recapitalization, sale transaction options (including a sale of assets or intellectual property) and other possible alternatives, including a wind-down of operations and a liquidation and dissolution of Histogenics, or Chapter 11 bankruptcy protection to complete or execute a restructuring transaction or liquidation.

In January and March 2019, Histogenics implemented restructuring plans that were approved by the Histogenics Board involving reductions in headcount to reduce operating costs and conserve cash, along with other cash

conservation measures relating to Histogenics facilities. The positions eliminated as part of the restructuring plans collectively represented all but one member of Histogenics' workforce, including its Chief Executive Officer, Chief Operating Officer, Chief Medical Officer and Chief Business Officer. Histogenics engaged Mr. Adam Gridley, its former Chief Executive Officer, Mr. Stephen Kennedy, and its former Chief Operating Officer, along with a limited number of additional employees as consultants to assist with its continuing evaluation of strategic alternatives. Mr. Gridley has retained his titles of president, treasurer and secretary of Histogenics while he continues to provide consulting services to Histogenics and remains a member of the Histogenics Board.

*Detailed Background of Interactions Relating to the Merger and Histogenics' Strategic Processes*

The Histogenics Board and Histogenics senior management periodically have evaluated Histogenics' long- and short-term strategic options, including capital formation or other investment transactions, potential strategic alliances, prospects for mergers and acquisitions, strategic acquisitions and divestitures and other business combinations, as well as its continued operations as an independent company, each with a view toward enhancing stockholder value. The following is a summary of material events, meetings and discussions that are relevant to the Histogenics Board's decision to approve the Merger Agreement and recommend the Merger to Histogenics' stockholders.

In March 2018, a senior executive of a publicly traded biopharmaceutical company ("Company A") contacted Histogenics' executive management seeking an update on the NeoCart Phase 3 Trial, and its commercialization plans for NeoCart in the event it was approved by the FDA. Executives of Histogenics and Company A held several discussions, the companies entered into a confidentiality agreement on March 15, 2018, and Histogenics' executive management presented in-person to Company A management at Company A's offices in March 2018 regarding Histogenics' ongoing operations and business plan. Company A was subsequently granted access to the data room maintained by Histogenics, which contained legal and financial due diligence materials (the "Data Room").

In March 2018, Histogenics' executives met separately with senior executives of a publicly traded biopharmaceutical company ("Company B") and a private biopharmaceutical company ("Company C") at the annual meeting of the American Academy of Orthopaedic Surgeons (the "2018 AAOS Meeting") to discuss the commercialization plans, fundraising plans, and status of the NeoCart Phase 3 Trial.

In April 2018, Mr. Gridley spoke with the chief executive officer of Company A regarding Company A's interest in potential commercial collaborations, and the interest of Company A in a possible acquisition of Histogenics.

In April 2018, Company C invited a senior representative of Histogenics to present to Company C's executive management team regarding Histogenics' ongoing operations and business plan.

During April 2018 and May 2018, representatives of Company A and Histogenics held several due diligence conference calls and in-person meetings to discuss the NeoCart program and the information provided to Company A through the Data Room.

Company C and Histogenics entered into a confidentiality agreement on May 8, 2018. In May 2018, at the request of Company C, Company C executive management visited Histogenics' headquarters for an in-person management presentation during which management of Company C and Histogenics discussed potential commercial collaboration opportunities.

During June 2018, Company C was given access to the Data Room and conducted due diligence activities on Histogenics through the Data Room.

In June 2018, based on guidance from the Histogenics Board, Mr. Gridley reached out to a publicly traded biopharmaceutical company ("Company D") to inform them of the ongoing interest from other parties to determine if there would be interest in a commercial collaboration or acquisition of Histogenics by Company D.

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In June 2018, senior management of Company A indicated to Mr. Gridley that it would not be proceeding with any transaction with Histogenics at that time due to other Company A priorities.

Histogenics and Company D entered into a confidentiality agreement on July 18, 2018 and Company D provided a written request to Histogenics to provide certain business, financial, legal and other due diligence materials for review.

In August 2018, Mr. Gridley and an executive officer of a private biopharmaceutical company (“Company E”) held a preliminary call regarding a potential strategic transaction, and the companies entered into a confidentiality agreement on August 27, 2018.

On August 28, 2018, Histogenics unblinded the data from the NeoCart Phase 3 Trial. During analysis following such unblinding, it was determined that the NeoCart Phase 3 Trial had failed to meet its primary endpoint. On August 29, 30 and 31, 2018, the Histogenics Board held informational meetings at which Histogenics’ executive management discussed the data from the NeoCart Phase 3 Trial with the members of the Histogenics Board present at such meetings. During these meetings, the Histogenics Board also discussed plans to engage with the FDA, along with Histogenics’ fundraising and strategic options. Following these meetings, Histogenics’ executive management team informed the Histogenics Board that it would revise its fundraising plans to determine if there was financing available to allow Histogenics time to engage with the FDA to determine if they would accept a BLA based on the available NeoCart data set from the NeoCart Phase 3 Trial. During these meetings and in other calls with Mr. Gridley, the Histogenics Board discussed establishing a special committee comprised of independent members of the Board to evaluate Histogenics’ strategic options and instructed management to contact Canaccord Genuity, one of Histogenics’ financial advisors in earlier financing transactions, to assist the Histogenics Board in engaging in a review of Histogenics’ strategic alternatives, and to determine if the previously interested parties or other parties may be interested in acquisitions, financings, collaborations or other strategic transactions with Histogenics. Following the engagement of Canaccord Genuity, Canaccord Genuity took certain actions on behalf of Histogenics as described in the remainder of this section at the direction of the Histogenics Board, the Special Committee formed by the Histogenics Board or Histogenics’ management acting in accordance with the instructions of the Histogenics Board or the Special Committee.

The Histogenics Board held a further informational meeting on September 4, 2018 at which time the members of the Histogenics Board present at the meeting, and based on discussions with the other members of the Histogenics Board, instructed Gunderson Dettmer to prepare the documentation necessary to form a special committee to review strategic alternatives. On September 5, 2018, the members of the Histogenics Board executed an action by unanimous written consent forming such special committee, consisting of Dr. Kong (chairman) and Messrs. Baltzell, Gill and Johnson (the “Special Committee”). While the Special Committee was officially formed on September 5, 2018, it had also met on an interim, ad hoc basis for several months prior to such formal formation (though with no delegated power or authority during such interim period). Pursuant to the September 5, 2018 written consent, the Special Committee was delegated the exclusive power and authority to (1) consider, evaluate and comprehensively review Histogenics’ strategic options, including, but not limited to, potential strategic partnerships or transactions, cost reductions, reorganization, wind-down, liquidation or bankruptcy (collectively, without limitation, the “Strategic Options”); (2) take into consideration Histogenics’ risk profile and the potential impact of any Special Committee recommendation on Histogenics’ business model and strategic plan; (3) periodically report its recommendations relating to the Strategic Options to the full Histogenics Board; and (4) perform such other duties as may be requested by the Histogenics Board.

Histogenics announced the results of the NeoCart Phase 3 Trial in a press release and held a conference call with investors on September 5, 2018. Following the announcement and at the direction of the Special Committee, representatives of Canaccord Genuity and Histogenics contacted from September 10, 2018 to October 25, 2018 approximately 37 orthopedic, regenerative medicine and pharmaceutical companies worldwide to determine if they were interested in a potential strategic transaction with Histogenics.

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On September 6, 2018, the Special Committee held a conference call with Histogenics' executive management, Gunderson Dettmer and representatives of Canaccord Genuity to discuss the status of the strategic options and outreach.

Also on September 6, 2018, Mr. Gridley received an email from the chief executive officer of Company E, expressing continued interest in a strategic transaction, and requested an in-person meeting at Histogenics headquarters with Histogenics' executive management on September 12, 2018.

On September 11, 2018, a publicly traded biopharmaceutical company ("Company F"), contacted Canaccord Genuity, and expressed interest in a call with Histogenics' executive management. Histogenics and Company F entered into a confidentiality agreement on September 13, 2018. Executive management of Company F and Histogenics held a call on September 13, 2018 to discuss the data from the NeoCart Phase 3 Trial and Histogenics' plans for engaging with the FDA. Following the call, on September 13, 2018, Histogenics also granted Company F access to the Data Room and a subsequent diligence call was scheduled for September 18, 2018 between Histogenics and Company F.

On September 12, 2018, the Histogenics Board held a conference call with Histogenics' executive management and representatives of Canaccord Genuity to discuss the status of the ongoing discussions with the FDA, potential financing opportunities and the status of outreach relating to potential strategic alternatives.

Also on September 12, 2018, Histogenics' executive management and Company E met to review the data from the NeoCart Phase 3 Trial, potential FDA scenarios and Histogenics' financial status.

On September 14, 2018, representatives of Canaccord Genuity held a call with senior executives of Company C during which the Company C representatives expressed interest in a call with Histogenics' executive management. On September 17, 2018, Histogenics' executive management and Company C held a call to discuss the data from the NeoCart Phase 3 Trial and Histogenics' plans for engaging with the FDA.

On September 16, 2018, Mr. Gridley and the chief executive officer of Company E discussed initial feedback from the September 12, 2018 meeting and Company E's interest in conducting further diligence. On the same date, Company E was granted access to the Data Room and requested several data analyses from the NeoCart Phase 3 Trial clinical results and an additional due diligence call.

On September 17, 2018, the Special Committee held a conference call with Histogenics' executive management, Gunderson Dettmer and representatives of Canaccord Genuity to discuss the status of outreach relating to potential strategic alternatives.

On September 17 and 18, 2018, Mr. Gridley and the chief executive officer of Company E exchanged correspondence regarding an upcoming diligence call with the respective party's regulatory advisors.

On September 17, 2018, Mr. Gridley contacted the chief executive officer of a publicly traded biopharmaceutical company ("Company G") to determine if Company G would be interested in discussing a potential strategic transaction.

On September 19, 2018, Histogenics' executive management and Company E held a further regulatory due diligence call with Histogenics' regulatory advisors.

On September 20, 2018, Mr. Gridley and major investors in Company E held a call to discuss potential strategic transaction structures.

Histogenics' executive management and a publicly traded biopharmaceutical company ("Company H") held an initial call also on September 20, 2018 to review the data from the NeoCart Phase 3 Trial, potential FDA scenarios and Histogenics' financial status. On September 27, 2018, Histogenics and Company H entered into a confidentiality agreement and agreed to meet the following week at Company H's headquarters.

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Also, on September 20, 2018, Mr. Gridley and a senior executive of Company F held a call to discuss potential strategic transaction structures, and Mr. Gridley suggested Company F also speak to Canaccord Genuity.

On September 21, 2018, Mr. Gridley and a member of the board of directors of a publicly traded biopharmaceutical company (“Company I”) met on unrelated matters, and discussed the status of NeoCart, and whether Company I would be interested in discussing a strategic transaction.

During September 2018 and through the signing of the Merger Agreement, Mr. Gridley had ongoing conversations with a foreign publicly traded biopharmaceutical company (“Company J”) regarding their potential interest in acquiring Histogenics in a strategic transaction or purchasing the assets relating to the NeoCart program. Ultimately, Company J was unable to put forth an offer for either a strategic transaction or asset purchase.

On September 21, 2018, Histogenics’ executive management and Company G held a conference call. During the call and based on the past intermittent strategic conversations between Histogenics and Company G, Mr. Gridley inquired whether there was interest in learning more about the data from the NeoCart Phase 3 Trial and discussing a potential strategic transaction. The chief executive officer of Company G indicated they were interested and suggested the parties update their confidentiality agreement and that Mr. Gridley engage in further discussion with executive management of Company G regarding the data from the NeoCart Phase 3 Trial.

On September 24, 2018, the Special Committee held a conference call with Histogenics’ executive management, Gunderson Dettmer and representatives of Canaccord Genuity to discuss the status of outreach relating to potential strategic alternatives.

On September 26, 2018, Mr. Gridley and the chief executive officer of Company G held another call to discuss a potential strategic transaction and Company G’s ongoing due diligence.

Also on September 26, 2018, Mr. Gridley and a senior executive at Company E held another call to discuss a potential strategic transaction and Company E’s ongoing due diligence.

On September 26, 2018, Histogenics issued a press release announcing that the FDA had agreed to a Type-C Meeting to be held on October 30, 2018.

On September 27, 2018, the Histogenics Board met with Histogenics’ executive management and representatives of Canaccord Genuity and Gunderson Dettmer regarding the status of the NeoCart program, the status of FDA discussions, and the ongoing strategic process.

On September 28, 2018, Mr. Gridley met Company H executive management at their corporate headquarters to further review the NeoCart program and Histogenics’ financial models and commercialization plans.

Also on September 28, 2018, Histogenics’ executive management and Company F held another due diligence call to review Histogenics’ financial models and commercialization plans.

On October 1, 2018, the Special Committee held a conference call with Histogenics’ executive management, Gunderson Dettmer and Canaccord Genuity to discuss the status of outreach relating to a potential strategic transaction or other financing opportunities for Histogenics.

On October 2, 2018, Histogenics and Company G entered into a confidentiality agreement.

On October 3, 2018, Mr. Gridley met with a senior executive at Company G at an industry conference to review Company G’s ongoing due diligence process.

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On October 4, 2018, members of the executive management team of Histogenics and the senior executive and other representatives of Company G met to review the ongoing due diligence process and agreed to grant Company G access to the Data Room in advance of an on-site visit at Histogenics headquarters later in October 2018.

Also on October 4, 2018, Mr. Gridley and a senior executive of Company F held a call to discuss Company F's ongoing due diligence process and further details regarding potential strategic transaction structures.

On October 5, 2018, representatives of Canaccord Genuity spoke to a senior executive at Company E regarding their interest in the ongoing strategic process, during which the senior executive of Company E responded that he would provide an update to Canaccord Genuity after internal and board of directors meetings at Company E.

On October 8, 2018, the Special Committee held a conference call with Histogenics' executive management, Gunderson Dettmer and representatives of Canaccord Genuity to discuss the status of outreach relating to a potential strategic transaction or other financing opportunities for Histogenics.

On October 10, 2018, Histogenics closed an underwritten public offering of 26,155,000 shares of its common stock and warrants to purchase up to 19,616,250 shares of common stock, at a combined purchase price of \$0.65 per share of common stock and accompanying warrant. The gross proceeds from the offering were \$17.0 million, before deducting underwriting discounts and commissions and offering expenses payable by Histogenics.

Also October 10, 2018, representatives of Canaccord Genuity spoke to a senior executive at Company C regarding their interest in the ongoing strategic process, during which the senior executive at Company C indicated potential interest in a commercial collaboration or funding of Histogenics, if the FDA responded favorably to Histogenics request for the FDA to accept a submission of a BLA for NeoCart without data from an additional clinical trial.

Also on October 10, 2018, Canaccord Genuity and Histogenics prepared, and Canaccord Genuity distributed, process letters on behalf of Histogenics to Company F, Company G, Company H and Company I.

On October 11, 2018, representatives of Canaccord Genuity had a call with a senior executive at Company E, who indicated Company E would not be proceeding with discussions regarding a potential strategic transaction.

Also on October 11, 2018, Histogenics and Company I entered into a confidentiality agreement and Histogenics' executive management and Company I held an initial call to review the NeoCart Phase 3 Trial data, potential FDA scenarios and Histogenics' financial status.

Also on October 11, 2018, representatives of Histogenics and senior management at Company F held a diligence conference call to discuss reimbursement status of autologous cell therapy products.

On October 15, 2018, the Histogenics Board met with Histogenics' executive management and representatives of Gunderson Dettmer regarding general corporate matters, including potentially holding a special meeting of stockholders in order to effect a reverse stock split in order to comply with Nasdaq's continued listing requirements and regarding the status of the NeoCart program, FDA discussions, and the ongoing strategic process.

Also on October 15, 2018, representatives of Canaccord Genuity had a call with a senior executive at Company I regarding timing of the strategic process, Data Room access and certain regulatory matters. Representatives of Canaccord Genuity and the senior executive of Company I discussed setting up a meeting at Histogenics' headquarters with representatives of Histogenics and Company I to discuss a potential strategic transaction.

On October 18, 2018, Mr. Gridley had a call with a senior executive at Company F who indicated that Company F was not interested in proceeding with a strategic transaction at that time.



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On October 18 and 19, 2018, Histogenics' executive management and representatives of Company G met at Histogenics' headquarters for due diligence meetings and on-site facilities visits.

On October 22, 2018, the Special Committee held a conference call with Histogenics' executive management, Gunderson Dettmer and representatives of Canaccord Genuity to discuss the status of outreach relating to a potential strategic transaction or other financing opportunities for Histogenics.

On October 22, 2018, during an investor conference in Japan, Mr. Gridley and a representative of Canaccord Genuity contacted a number of regenerative medicine and pharmaceutical companies that had previously expressed interest in the NeoCart program, to determine if there was interest in participating in the ongoing strategic process.

On October 22 and 23, 2018, representatives of Canaccord Genuity contacted additional regenerative medicine and pharmaceutical companies from Japan.

On October 29, 2018, representatives of Canaccord Genuity had a call with a senior executive of Company G regarding Company G's continued due diligence and interest in a potential strategic transaction if the FDA determined that a BLA could be filed for NeoCart based on the data from the NeoCart Phase 3 Trial.

Also on October 29, 2018, the Special Committee held a conference call with Histogenics' executive management, Gunderson Dettmer and representatives of Canaccord Genuity to discuss the status of outreach relating to a potential strategic transaction or other financing opportunities for Histogenics.

On October 30, 2018, the Histogenics Board met with Histogenics' executive management and Gunderson Dettmer regarding the status of Histogenics' FDA Type-C discussions and planned further negotiations with the FDA.

On October 31, 2018, Mr. Gridley spoke with a senior executive of Company G regarding Company G's continued interest in pursuing a strategic transaction, contingent on the outcome of the FDA's determination of whether a BLA could be filed for NeoCart.

On November 1, 2018, Histogenics' executive management, its regulatory advisors and senior management of Company I held a call to discuss FDA and other regulatory matters.

On November 1, 2018, Histogenics issued a press release announcing that it was continuing discussions with the FDA.

On November 5, 2018, the Special Committee held a conference call with Histogenics' executive management, Gunderson Dettmer and representatives of Canaccord Genuity to discuss the status of outreach relating to a potential strategic transaction or other financing opportunities for Histogenics.

On November 5 and 6, 2018, Histogenics' executive management and senior executives and representatives of Company G met at Histogenics' headquarters for due diligence meetings and on-site facilities visits.

On November 8, 2018, Histogenics issued its third quarter 2018 financial results and held a conference call to further discuss such financial results and the continued discussions with the FDA.

On November 12, 2018, the Special Committee held a conference call with Histogenics' executive management, Gunderson Dettmer and representatives of Canaccord Genuity to discuss the status of outreach relating to a potential strategic transaction or other financing opportunities for Histogenics.

On November 19, 2018, the Histogenics Board met with executive management and representatives of Canaccord Genuity regarding the status of the NeoCart program, FDA discussions, 2019 budget planning, and

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the ongoing strategic process. During the call, the Histogenics Board discussed a wide variety of potential strategic transactions, including continuing as a standalone company, a sale of Histogenics, a potential sale of Histogenics' Nasdaq listing in a reverse merger with a private company, a sale of all or some of Histogenics' assets, a liquidation, wind down or bankruptcy.

On November 26, 2018, the Special Committee held a conference call with Histogenics' executive management, Gunderson Dettmer and representatives of Canaccord Genuity to discuss the status of outreach relating to a potential strategic transaction or other financing opportunities for Histogenics.

On November 29, 2018, Histogenics issued a press release announcing they were continuing discussions with the FDA.

On December 3, 2018, the Special Committee held a conference call with Histogenics' executive management, Gunderson Dettmer and representatives of Canaccord Genuity to discuss the status of outreach relating to a potential strategic transaction or other financing opportunities for Histogenics.

On December 10, 2018, the Special Committee held a conference call with Histogenics' executive management, Gunderson Dettmer and representatives of Canaccord Genuity to discuss the status of outreach relating to a potential strategic transaction or other financing opportunities for Histogenics. Following this date, the Special Committee met in a number of informal conference calls, but did not formally meet again as the Histogenics Board determined that it should meet as a full board to discuss matters relating to Histogenics' strategic alternatives.

On December 20, 2018, Mr. Gridley spoke with senior members of the FDA who indicated that another Phase 3 clinical trial would be required before Histogenics could file a BLA for approval of NeoCart. Later that day, the Histogenics Board met with executive management and representatives of Canaccord Genuity, Gunderson Dettmer and Katten regarding the FDA's decision, and extensively discussed Histogenics' strategic options, including alternative financing structures, a sale of Histogenics, a reverse merger with a private company, a sale of Histogenics' intellectual property, winding down and bankruptcy proceedings, among others.

On December 21, 2018, Histogenics issued a press release announcing that the FDA had indicated that an additional clinical trial would need to be completed before it would accept a submission of a BLA for NeoCart. Considering the time and funding required to conduct such a trial, Histogenics also announced that it would discontinue the development of NeoCart and did not plan to submit a BLA. In addition, Histogenics announced it had engaged Canaccord Genuity to consider a broad range of strategic options, including acquisitions, business combinations, joint ventures, public and private capital raises, recapitalization, and sale transaction options, including a sale of assets or intellectual property.

Starting on December 21, 2018, at the direction of the Histogenics Board, Canaccord Genuity contacted 16 potential strategic parties to determine interest in acquiring Histogenics, including Company A, Company B, Company C and Company D, and the associated NeoCart program, and over 40 potential reverse merger candidates, including a private biopharmaceutical company ("Company K"), a private biopharmaceutical company ("Company L") and a private biopharmaceutical company ("Company M"). As part of this contact, process letters were distributed by Canaccord Genuity on behalf of Histogenics to potential strategic parties who wished to proceed as part of the strategic process.

On December 21, 2018, representatives of Canaccord Genuity had a call with a senior executive at Company I regarding Histogenics' announcement of the FDA outcome, and suggested a further call with Histogenics' executive management.

On December 22, 2018, Histogenics' executive management and financial advisors for a private biopharmaceutical company ("Company N") held a conference call to discuss Company N's interest in a potential reverse merger transaction with Histogenics. Histogenics' executive management contacted Canaccord Genuity to coordinate a meeting with executive management of Company N.

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On December 24, 2018, representatives of Canaccord Genuity exchanged emails with a senior executive at Company G regarding Histogenics' announcement of the FDA outcome, where the senior executive from Company G indicated Company G would not be proceeding with any potential transaction.

On December 24, 2018, the chief executive officer of a private biopharmaceutical company ("Company O") emailed Mr. Gridley regarding Histogenics' announcement of the FDA outcome. Following additional correspondence, the chief executive officer of Company O and Mr. Gridley agreed to set up a call to discuss the outcome with the FDA and a potential strategic transaction.

On December 26, 2018, Mr. Gridley and the chief executive officer of Company O held a call to discuss the FDA outcome and the strategic process and agreed to arrange a further call after speaking with Canaccord Genuity.

On December 26, 2018, Mr. Gridley emailed the chief executive officer of Company D to determine interest in speaking regarding the ongoing strategic process.

On December 27, 2018, the chief executive officer of Company D emailed Mr. Gridley to schedule a time to speak during the following week.

Also on December 27, 2018, representatives of Histogenics and senior management of Company I held a due diligence call to discuss the FDA decision regarding NeoCart, potential future Phase 3 trials and plans to develop NeoCart.

On December 31, 2018, the chief executive officer of Company L emailed Mr. Gridley regarding interest in a potential strategic transaction or reverse merger.

On December 31, 2018, the chief executive officer of Company E and representatives of Canaccord Genuity spoke regarding a possible transaction. The chief executive officer of Company E indicated he would contact Mr. Gridley with further questions. There was no further contact from Company E following December 31, 2018.

Also on December 31, 2018, Mr. Gridley and the chief executive officer of Company L held a call to discuss Histogenics' ongoing strategic process.

On January 2, 2019, Mr. Gridley and the chief executive officer of Company O held a call to discuss the strategic process, a desire for the companies to enter into a confidentiality agreement, and plans to meet the following week at the annual JP Morgan Healthcare Conference (the "JP Morgan Conference").

Histogenics and Company L entered into a confidentiality agreement on January 3, 2019 and planned to meet the following week at the JP Morgan Conference.

Between January 2, 2019 and February 5, 2019, Mr. Gridley held calls with several potential investors who expressed interest in providing funding for, or acquiring Histogenics, and entered into a confidentiality agreement with at least one investor who conducted due diligence. None of these investors provided an indication of interest due to regulatory uncertainty surrounding the NeoCart program based on feedback from the FDA, and the commensurate funding required to complete development and commercialization of NeoCart.

On January 2, 2019, Mr. Gridley sent the chief executive officer of Company O a confidentiality agreement and background publicly available information regarding Histogenics and the NeoCart program. Histogenics and Company O entered into a confidentiality agreement later that day and agreed to meeting on January 8, 2019.

Histogenics and Company L entered into a confidentiality agreement on January 2, 2019.

Also on January 3, 2019, Mr. Gridley had a call with the chief executive officer of Company D regarding the ongoing strategic process and discussed the NeoCart Phase 3 Trial data, the FDA process and timelines for submitting an indication of interest.

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On January 5, 2019, representatives of Canaccord Genuity and the financial advisors of Company D held a call to discuss the ongoing strategic process, due diligence, timing and the Data Room.

On January 7, 2018, Histogenics granted representatives and financial advisors of Company D access to the Data Room.

Also on January 7, 2019, the executive chairman of Company L contacted a board member of Histogenics to express interest in a potential reverse merger transaction with Histogenics.

Also on January 7, 2019, at the JP Morgan Conference, senior executives of both Company K and Company N met separately with Histogenics' executive management to discuss their interest in a potential reverse merger transaction with Histogenics.

Also on January 7, 2019, at the JP Morgan Conference, senior executives of both Company B and a private biopharmaceutical company ("Company P") met separately with Histogenics' executive management to discuss their interest in a potential strategic acquisition of Histogenics and the NeoCart program. There was no further contact from Company B following January 7, 2019.

Also on January 7, 2019, Histogenics' executive management called a senior executive of Company C to discuss Company C's interest in a potential strategic acquisition of Histogenics and the NeoCart program. Mr. Gridley and the senior executive of Company C agreed to set up a call to discuss FDA status and funding expected to be required to continue the development of the NeoCart program.

Also on January 7, 2019, at the JP Morgan Conference, Mr. Gridley and a senior executive of Company H met to discuss Company H's interest in a potential strategic acquisition of Histogenics and the NeoCart program. However, due to the financial resources expected to be required to complete an additional Phase 3 clinical trial for NeoCart, Company H indicated they were not interested in proceeding with a strategic transaction.

On January 8, 2019, at the JP Morgan Conference, both the chief executive officer of Company O and a senior executive of a private biopharmaceutical company ("Company Q") met separately with Histogenics' executive management to discuss their respective company's interest in a potential strategic acquisition of Histogenics and the NeoCart program.

Also on January 8, 2019, Mr. Gridley and a member of Company I's board of directors met and discussed Histogenics' ongoing strategic process.

On January 9, 2019, at the JP Morgan Conference, both the chief executive officer of Company L and the chief executive officer of Company M met separately with Histogenics' executive management to discuss their respective company's interest in a potential reverse merger transaction with Histogenics.

Also on January 9, 2019, at the JP Morgan Conference, Histogenics' executive management and a senior executive of Company P met to discuss Company P's interest in a potential strategic acquisition of Histogenics and the NeoCart program.

Histogenics and Company P entered into a confidentiality agreement on January 14, 2019. Company P was granted access to the Data Room on January 15, 2019.

Also on January 10, 2019, the chief executive officer of Company M contacted Mr. Gridley requesting further information regarding Histogenics and its financial history. Mr. Gridley sent the requested publicly available information on January 10, 2019.

On January 11, 2019, the chief executive officer of Company K sent Mr. Gridley a non-binding letter of intent summarizing Company K's initial interest in a potential reverse merger transaction with Histogenics, but the

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letter did not contain sufficient details, such as a potential post-combination ownership split, which would have enabled Histogenics to effectively evaluate the potential value of the proposed transaction for Histogenics' stockholders.

Also on January 11, 2019, representatives of Canaccord Genuity spoke with the chief executive officer of Company O to discuss a potential strategic acquisition of Histogenics and the NeoCart program, including Company O's timing to submit a non-binding letter of intent.

Also on January 11, 2019, the chief executive officer of Company L sent Mr. Gridley an email expressing preliminary feedback regarding a potential reverse merger or strategic combination of Company L and Histogenics. Mr. Gridley encouraged the chief executive officer of Company L to provide more formal feedback as Company L continued its evaluation of strategic options.

On January 12, 2019, Mr. Gridley spoke to key investors of Company O to discuss a potential strategic transaction and discussed meeting the following week. Mr. Gridley also sent certain publicly available information for the key investors' representatives to review as part of their due diligence.

On January 14, 2019, Mr. Gridley and the chief executive officer of Company K exchanged emails regarding Histogenics' ongoing strategic process. Mr. Gridley and the chief executive officer of Company K agreed to schedule another call with executive management from each company to further discuss a potential transaction.

Also on January 14, 2019, representatives of Canaccord Genuity held a call with the executive management of Company I, who indicated Company I would not be proceeding with any strategic transaction discussions.

Also on January 14, 2019, the chief executive officer of Company M contacted Mr. Gridley to inquire about diligence process and potential conference calls with executive management and regulatory advisors of Histogenics.

Histogenics and Company M entered into a confidentiality agreement on January 14, 2019.

Also on January 14, 2019, the Histogenics Board held a meeting with Histogenics' executive management, Canaccord Genuity and Gunderson Dettmer to discuss the status of outreach and various negotiations relating to a potential strategic transaction or other financing opportunity for Histogenics.

Between January 14, 2019 and February 3, 2019, senior executives of Histogenics and the president of Company P exchanged emails and held conference calls to assist Company P in its ongoing due diligence.

On January 15, 2019, Mr. Gridley met with key investors of Company O to present further background on Histogenics, the NeoCart program and the potential strategic transaction process.

Also on January 15, 2019, Histogenics and key investors associated with Company O entered into a confidentiality agreement.

Also on January 15, 2019, the chief executive officer of Company O sent a non-binding letter of intent to Mr. Gridley and Canaccord Genuity. Company O's initial non-binding letter of intent proposed an all cash acquisition of Histogenics by a special purpose entity to be funded by two proposed funding sources followed by a merger into Company O. The offer was contingent on, among other things, the special purpose entity securing the necessary funds, which at such time had not been committed.

Also on January 15, 2019, representatives of Canaccord Genuity held a call with executive management of Company C to determine the status of the ongoing due diligence and strategic process.

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Also on January 15, 2019, the chief executive officer of Company L sent Mr. Gridley an email requesting availability to meet at Histogenics headquarters on January 24, 2019. The executive chairman and chief executive officer of Company L met with Mr. Gridley on January 24, 2019 to discuss Company L's continued interest in a strategic transaction.

On January 16, 2019, Histogenics' executive management and Company K held a conference call to further discuss a potential transaction, the respective businesses of the companies and potential due diligence process.

Also on January 16, 2019, representatives of Canaccord Genuity held a call with the financial advisors of Company D to determine the status of Company D's ongoing due diligence and discuss Histogenics' strategic process.

Also on January 16, 2019, Histogenics' executive management, representatives of Canaccord Genuity and senior executives of Company N held a conference call to further discuss Company N's interest in a potential reverse merger transaction with Histogenics.

On January 17, 2019, senior executives of Histogenics met with representatives of Company P at Histogenics' headquarters for a due diligence meeting.

On January 17 and 18, 2019, Histogenics' executive management and the chief executive officer of Company N exchanged emails regarding due diligence information.

Also on January 17, 2019, representatives of Canaccord Genuity and a senior executive at Company Q met and discussed Histogenics' ongoing strategic process. Company Q indicated it was interested in pursuing a purchase of Histogenics' patents and other intellectual property in the event Histogenics entered into an agreement for a reverse merger transaction.

On January 18, 2019, Histogenics and Company K entered into a confidentiality agreement and held a conference call with the executive management of each company to discuss feedback from each company's board of directors and the due diligence process.

Also on January 18, 2019, the Histogenics Board held a meeting with Histogenics' executive management, Canaccord Genuity and Gunderson Dettmer to discuss the status of outreach and various negotiations relating to a potential strategic transaction or other financing opportunity for Histogenics.

Between January 18, 2019 and January 26, 2019, Mr. Gridley and the chief executive officer of Company O discussed the non-binding letter of intent, various due diligence questions and strategic process generally. During multiple calls and email exchanges, Mr. Gridley provided additional information to the chief executive officer of Company O to facilitate further review of the NeoCart program.

Between January 18 and 29, 2019, Histogenics' executive management and a senior executive at Company Q negotiated a confidentiality agreement, which was entered into on January 29, 2019.

On January 22, 2019, the chief executive officer of Company N sent Canaccord Genuity on behalf of Histogenics a non-binding letter of intent summarizing Company N's interest and proposed conditions for a reverse merger transaction. At the direction of Mr. Gridley, representatives of Canaccord Genuity provided feedback to Company N that additional information regarding the potential consideration and value for Histogenics stockholders, along with committed fundraising would be an important consideration for the Histogenics Board.

Also on January 21, 2019, the chief executive officer of Company M contacted Mr. Gridley to inquire about diligence process and potential conference calls with executive management and regulatory advisors of Histogenics.

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Also on January 21, 2019, the Histogenics Board held a meeting with Histogenics' executive management, Canaccord Genuity and Gunderson Dettmer to discuss the status of outreach and various negotiations relating to a potential strategic transaction or other financing opportunity for Histogenics.

On January 22, 2019, Mr. Gridley and representatives of Canaccord Genuity spoke separately to the chief executive officer of Company O regarding the ongoing strategic process, Company O's non-binding letter of intent and potential opportunities to increase the consideration payable to Histogenics' stockholders.

Also on January 22, 2019, executive management of Company M, Mr. Gridley and regulatory advisors of Histogenics held a conference call to discuss the NeoCart program. Mr. Gridley and the chief executive officer of Company M also had a call to discuss potential structures of a reverse merger transaction or acquisition of Histogenics.

Effective January 23, 2019, Histogenics Board approved a restructuring plan involving reductions in headcount as part of a plan to reduce operating costs following its decision to discontinue the development of NeoCart. The positions eliminated at the time represented approximately 65% of Histogenics' workforce, including Histogenics' Chief Medical Officer and Chief Business Officer.

On January 23, 2019, Histogenics and Company K granted the other access to their respective data rooms to conduct due diligence.

On January 24, 2019, Histogenics' executive management and a senior executive of Company C exchanged emails regarding Company C's ongoing due diligence of the NeoCart program.

Also on January 24, 2019, executive management of Company M and a senior executive of Histogenics held a conference call to discuss the NeoCart manufacturing process.

On January 25, 2019, Mr. Gridley and representatives of Canaccord Genuity had separate calls with the chief executive officer of Company M regarding the ongoing due diligence process. During these calls, Mr. Gridley and Canaccord Genuity were advised that Company M had engaged independent financial advisors to assist in Company M's assessment of a potential strategic transaction with Histogenics.

On January 28, 2019, the chief executive officer of Company O provided Mr. Gridley a draft corporate presentation of Company O for review. Mr. Gridley and the chief executive officer of Company O discussed additional information that would be helpful to Histogenics Board in determining whether to pursue a transaction with Company O.

Also on January 28, 2019, the executive chairman and certain board members and investors of Company L spoke to representatives of Canaccord Genuity regarding a potential transaction. Consistent with the previous guidance from the Histogenics Board, the representatives of Canaccord Genuity advised Company L that an indication of interest should include information regarding the commitment of the funding required to consummate a transaction, timing and certainty of closing of a transaction.

Also on January 28, 2019, the Histogenics Board held a meeting with Histogenics' executive management, Canaccord Genuity and Gunderson Dettmer to discuss the status of outreach and various negotiations relating to a potential strategic transaction or other financing opportunity for Histogenics.

On January 29, 2019, Histogenics' executive management, Gunderson Dettmer, representatives of Company O and Company O's legal counsel held a call to discuss certain legal, structuring and regulatory considerations required for a potential strategic acquisition of Histogenics by Company O.

Also on January 29, 2019, the chief executive officer and board of directors of Company O presented to Histogenics Board a summary of the background on Company O, the January 15, 2019 non-binding letter of intent and the investors who were seeking to support Company O's potential acquisition of Histogenics.

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Also on January 29, 2019, the chief executive officer of Company K sent Mr. Gridley a formal letter of intent summarizing the potential terms and conditions of a reverse merger transaction, including allocating 95% of the post-combination ownership to stockholders of Company K and 5% to the stockholders of Histogenics.

Also on January 29, 2019, Histogenics' executive management informed Company Q that their strategic process was still ongoing, and were willing to discuss certain diligence topics in advance of clarity on the timing and outcome of Histogenics' strategic process.

Between January 30, 2019 and February 2, 2019, Mr. Gridley and the chief executive officer of Company O discussed potential key terms for a revised non-binding letter of intent, certainty of funding commitments from Company O's investors, timing to sign a definitive agreement for a strategic transaction and the timing to complete a strategic transaction.

On January 31, 2019, the chief executive officer of Company L sent Mr. Gridley a non-binding proposal for a reverse merger transaction, however, the proposal did not contain details regarding the proposed transaction, such as a potential post-combination ownership split, which would have enabled Histogenics to effectively evaluate the potential value of the proposed transaction for Histogenics' stockholders. On the same day, Mr. Gridley and the chief executive officer of Company L spoke to clarify certain points in the proposal, and Mr. Gridley indicated that he would follow up after discussing with the Histogenics Board.

On February 1, 2019, executive management of Company K presented a Company K overview to the Histogenics Board and Histogenics' executive management.

Also on February 1, 2019, Mr. Gridley and the chief executive officer of Company M had a call to discuss potential strategic transactions structures for a reverse merger or acquisition of Histogenics.

On February 2, 2019, the chief executive officer of Company M emailed Mr. Gridley and Canaccord Genuity a formal indication of interest regarding a reverse merger transaction between Company M and Histogenics, including allocating 85% of the post-combination ownership to stockholders of Company M and 15% to the stockholders of Histogenics and a number of closing conditions relating to Histogenics' existing liabilities.

On February 3, 2019, the chief executive officer of Company O sent Mr. Gridley a revised non-binding letter of intent reflecting the ongoing negotiations, the acquisition of Histogenics through a wholly owned subsidiary of Company O, improved consideration for Histogenics stockholders and clarity on timing for a potential strategic transaction. The revised letter of intent identified a few additional funding sources for Company O's proposed acquisition but did not include any commitment by such sources or assurances that the capital would be available.

On February 8, 2019, representatives of Canaccord Genuity spoke with the chief executive officer of Company N to reiterate Company N's need to provide additional clarity on potential ownership of a combined company and Company N's funding commitments.

On February 10, 2019, representatives of Canaccord Genuity held a call with executive management of Company N who indicated Company N would not be proceeding with a transaction.

On February 4, 2019, Mr. Gridley emailed the chief executive officer of Company O to indicate that he would review the updated non-binding letter of intent with the Histogenics Board.

Also on February 4, 2019, Mr. Gridley met with key investors and a board member of Company O to discuss the proposed strategic transaction, due diligence, Company O's ability to finance the proposed acquisition and potential timing of Histogenics' ongoing strategic process.



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Also on February 4, 2019, Mr. Gridley and the chief executive officer of Company L spoke to discuss initial feedback regarding Company L's non-binding proposal from January 31, 2019. Mr. Gridley indicated that further clarity on Company L's funding commitments and respective ownership of the combined company would be required for the Histogenics Board to properly consider the proposed reverse merger.

Also on February 4, 2019, the Histogenics Board held a conference call with Histogenics' executive management, Canaccord Genuity and Gunderson Dettmer, to discuss the status of the strategic options and outreach, including the status of the outstanding warrants from Histogenics' 2016 and 2018 financings, noting that several reverse merger candidates had included in their proposals as a condition of closing that the warrants be terminated.

On February 4 and 5, 2019, Mr. Gridley and the chief executive officer of Company M held multiple calls to discuss potential valuation, funding commitments and timing for a potential merger of the two companies.

On February 5, 2019, executive management of Histogenics, Gunderson Dettmer, executive management of Company O and Company O's legal counsel held a call to discuss certain legal and regulatory considerations for a potential strategic transaction and the drafting of a definitive agreement.

Between February 6 and 13, 2019, Mr. Gridley and the chief executive officer of Company O exchanged numerous emails and held calls to discuss the continued progress in drafting definitive agreements and ensuring Company O's funding commitments were being obtained.

On February 7, 2019, the chief executive officer of Company L sent Mr. Gridley an updated non-binding proposal regarding a merger of Histogenics and Company L, including allocating 80% of the post-combination ownership to stockholders of Company L and 20% to the stockholders of Histogenics, along with a potential earn-out structure associated with NeoCart milestones.

On February 11, 2019, the chief executive officer of Company K sent Mr. Gridley a revised letter of intent, which included allocating 90% of the post-combination ownership to stockholders of Company K and 10% to the stockholders of Histogenics. Executive management of Company K and Histogenics also held a call to discuss their respective processes and feedback from their boards of directors.

Also on February 11, 2019, Mr. Gridley and the chief executive officer of Company M held a call to discuss the outcome of a Company M board of directors meeting. During the call, the chief executive officer of Company M indicated that due to challenges of funding the combined company, Company M would not be proceeding with a strategic transaction.

Also on February 11, 2019, Mr. Gridley and the chief executive officer of Company L spoke to discuss timelines and proposed valuation of the combined company from Company L's updated February 7, 2019 non-binding proposal and indicated additional certainty on valuation and funding commitments would be required in order for the Histogenics Board to consider the non-binding proposal compared to others.

On February 12, 2019, Mr. Gridley and the chief executive officer of Company K held a call to further discuss the proposed letter of intent from Company K and Company K's ability to improve the terms of the letter of intent.

Also on February 12, 2019, the Histogenics Board held a meeting with Histogenics' executive management, Canaccord Genuity and Gunderson Dettmer to discuss the status of outreach and various negotiations relating to a potential strategic transaction or other financing opportunity for Histogenics.

On February 13, 2019, Mr. Gridley and the chief executive officer of Company K discussed the proposed post-closing valuation for a reverse merger transaction. During the discussion, the chief executive officer of Company K indicated Company K was unable to increase the proposed post-closing ownership for Histogenics' stockholders and would not be proceeding with further discussion regarding a reverse merger transaction.

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On February 14, 2019, the chief executive officer of Company L sent Mr. Gridley an email with an update on Company L's timing and potential funding commitments and agreed to speak the following week.

Between February 14 and 18, 2019, Mr. Gridley, the chief executive officer of Company O and key investors of Company O held multiple calls with prospective additional investors in Company O, and prepared due diligence materials to support a potential transaction between Histogenics and Company O.

On February 15, 2019, Mr. Gridley and executive management of Company K held a call to discuss potential alternative structures to improve the terms of Company K's letter of intent.

On February 17, 2019, Mr. Gridley sent the chief executive officer of Company K a proposed revised alternative transaction structure to improve the terms of the letter of intent for Histogenics' stockholders, which included allocating 90% of the post-combination ownership to stockholders of Company K and 10% to the stockholders of Histogenics, with additional equity to be allocated to the stockholders of Histogenics based on a formula accounting for additional cash proceeds received from potential asset sales.

On February 19, 2019, Mr. Gridley and key investors of Company O held a due diligence call with a prospective additional investor in Company O.

Also on February 19, 2019, Mr. Gridley and the chief executive officer of Company L spoke to discuss timelines for completing Company L's audited financial statements and funding commitments. Mr. Gridley suggested alternative structures to increase the potential value for Histogenics' stockholders.

Also on February 19, 2019, Histogenics' executive management and a senior executive at Company Q exchanged emails regarding the timing of Histogenics' ongoing strategic process.

On February 21, 2019, Mr. Gridley and the chief executive officer of Company O held a call to discuss the status of the potential strategic transaction, the status of Company O's funding commitments and status of drafting definitive agreements.

On February 22, 2019, Histogenics granted access to the Data Room to additional potential investors in Company O.

Also on February 22, 2019, Gunderson Dettmer sent a draft merger agreement and form of tender and support agreement to Company O and Company O's legal counsel.

Between February 22, 2019 and March 3, 2019, Histogenics' executive management, Gunderson Dettmer, executive management of Company O and Company O's legal counsel held a number of calls and exchanged comments to the draft merger agreement.

On February 25, 2019, representatives of Canaccord Genuity held a call with the chief executive officer of Company K to determine Company K's interest in proceeding with a reverse merger transaction.

Between February 26 and March 1, 2019, Mr. Gridley, the chief executive officer of Company L and financial advisors for Company L held several calls and meetings to discuss alternative transaction structures and improved value for Histogenics' stockholders. Mr. Gridley provided a counter-proposal for Company L's consideration, including allocating 80% of the post-combination ownership to stockholders of Company L and 20% to the stockholders of Histogenics, with additional equity to be allocated to the stockholders of Histogenics based on a formula accounting for additional cash proceeds received from potential asset sales.

On February 27, 2019, representatives of Canaccord Genuity held a subsequent call with the chief executive officer of Company K to determine Company K's timing for feedback from Company K's board of directors to continue to engage in a potential reverse merger transaction.

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On February 28, 2019, Mr. Gridley and a senior executive at Company Q met at an industry conference and discussed timing of Histogenics' ongoing strategic process and the due diligence process.

On March 4, 2019, Mr. Gridley and the chief executive officer of Company K held a call to discuss the status of their negotiations, and the chief executive officer of Company K indicated Company K would not be proceeding with further discussion regarding a reverse merger transaction.

Also on March 4, 2019, the Histogenics Board held a meeting to discuss with Histogenics' executive management and Gunderson Dettmer the proposed merger agreement with Company O. During the meeting, Histogenics' executive management explained that the draft merger agreement was in substantially final form, but expressed doubt that Company O would be able to consummate a transaction based on Company O's lack of financing commitments from its investors or others.

Between March 4 and 8, 2019, Histogenics' executive management, Gunderson Dettmer, Company O and Company O's legal counsel continued discussions regarding the proposed merger agreement and the final funding commitments from Company O's investors required to consummate a transaction.

Between March 4 and March 8, 2019, Mr. Gridley and representatives of Canaccord Genuity spoke with the chief executive officer, executive chairman and financial advisors for Company L regarding potential transaction structures, timing of the audit of Company L's financial statements that would be required to be filed in connection with the potential transaction and funding commitments. Histogenics and Company L agreed to hold a subsequent call on March 10, 2019.

Between March 6 and 25, 2019, Mr. Gridley and a senior executive at Company Q exchanged periodic emails regarding the due diligence process.

On March 8 and 12, 2019, a representative of Chardan Capital Marks, LLC ("Chardan") on behalf of Ocugen contacted Histogenics' executive management via email regarding potential interest of Ocugen in engaging in a reverse merger transaction.

On March 10 and 11, 2019, Mr. Gridley and the president of Company P exchanged emails and held calls to discuss Histogenics' ongoing strategic process and Company P's interest in a potential acquisition of Histogenics.

Also on March 10, 2019, the chief executive officer and executive chairman of Company L sent Mr. Gridley and Canaccord Genuity an email indicating that the proposed call would be cancelled due to important updates to Company L's strategic process. On March 11, 2019, Mr. Gridley responded via email requesting further clarity on timing from Company L.

On March 11, 2019, the Histogenics Board held a meeting with Histogenics' executive management, Canaccord Genuity and Gunderson Dettmer to discuss the status of outreach and various negotiations relating to a potential strategic transaction or other financing opportunity for Histogenics. During this meeting, Histogenics' management and the Histogenics Board determined that Company O's inability to secure funding did not give them confidence that a transaction could be consummated with Company O. Between March 11 and 30, 2019, Joshua Baltzell, the Chairman of the Histogenics Board, and Mr. Gridley held regular calls and exchanged emails with the chief executive officer, a board member and key investor from Company O regarding Company O's ability to secure funding commitments to complete the proposed transaction to acquire Histogenics.

On March 12, 2019, representatives of Canaccord Genuity held a call with the executive management of Company I who reiterated Company I's prior position that they would not be proceeding with further discussion regarding a transaction.

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Also on March 12, 2019, representatives of Canaccord Genuity held a call with the financial advisors of Company D who indicated Company D would not be proceeding with further discussion regarding a transaction.

Also on March 12, 2019, representatives of Canaccord Genuity held a call with executive management of Company C who indicated Company C would not be proceeding with further discussion regarding a transaction.

On March 13, 2019, Mr. Gridley and representatives of Chardan held a call to discuss Histogenics' ongoing strategic process and conveyed that valuation and timing to consummate a transaction were important considerations for the Histogenics Board. Mr. Gridley and representatives of Chardan agreed that Chardan and Canaccord Genuity should discuss the strategic process further.

Also on March 13, 2019, representatives of Canaccord Genuity held a call with executive management of Company C who indicated that despite its indication the prior day, Company C may be interested in proceeding with a transaction and requested a form of merger agreement and access to the Data Room, which were provided to Company C.

On March 14, 2019, Histogenics' executive management and representatives of Canaccord Genuity and Chardan held a conference call to further discuss the strategic process and agreed to enter into a confidentiality agreement and introduce the executive management team of Ocugen.

Also on March 14, 2019, the Histogenics Board, as part of its continuing strategic alternative review process, approved a further restructuring plan involving, among other cost-saving and cash conservation measures, reductions in headcount as part of a plan to reduce operating costs. The positions eliminated represented all but one of Histogenics' employees, including its Chief Executive Officer, Adam Gridley, and Chief Operating Officer, Stephen Kennedy. The Histogenics Board also discussed at the meeting on March 14, 2019 the other potential strategic alternatives that were potentially available to Histogenics at that time. Since such time, Histogenics' evaluation of strategic alternatives has been handled by Messrs. Gridley, Lieber and Kennedy in consulting capacities, along with other key former employees who Histogenics engaged as consultants upon their separation from service with Histogenics as part of the reduction in force.

Also on March 14, 2019, the chief executive officer and executive chairman of Company L sent Mr. Gridley and Canaccord Genuity an updated non-binding proposal regarding a reverse merger transaction between Histogenics and Company L, including allocating 95% of the post-combination ownership to stockholders of Company L and 5% to the stockholders of Histogenics. Mr. Gridley responded via email requesting further clarity on timing of finalizing a merger agreement, filing of the requisite regulatory documentation and potential timing to consummate a transaction.

Also on March 14, 2019, the Histogenics Board held a meeting with Histogenics' executive management, Canaccord Genuity and Gunderson Dettmer to discuss the status of outreach and various negotiations relating to a potential strategic transaction or other financing opportunity for Histogenics.

Histogenics and Ocugen entered into a confidentiality agreement on March 15, 2019. Ocugen was granted access to the Data Room on March 15, 2019.

Also on March 15, 2019, Chardan, on behalf of Ocugen, sent Canaccord Genuity a non-binding proposal which outlined the potential terms of a reverse merger transaction. Subject to various assumptions, the proposal included an anticipated pro forma post-closing equity ownership of between 88% and 92% for the former Ocugen stockholders and between 12% and 8% for Histogenics' stockholders.

Also on March 15, 2019, Mr. Gridley spoke with several members of the Histogenics Board to determine interest in engaging with Ocugen to further negotiate a potential reverse merger transaction.

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Also on March 15, 2019, representatives of Canaccord Genuity held a call with executive management of Company C to discuss Company C's ongoing due diligence and timing of submitting an indication of interest.

On March 16 and 17, 2019, based on input from the Histogenics Board, Histogenics' executive management and representatives of Canaccord Genuity reviewed and prepared potential questions and responses to Ocugen's preliminary non-binding proposal. Canaccord Genuity also spoke with Chardan to determine opportunities to improve the valuation and terms of the March 15, 2019 non-binding proposal.

Also on March 16, 2019, representatives of Canaccord Genuity provided executive management of Company C additional due diligence materials regarding the NeoCart program for Company C's review and consideration.

On March 17, 2019, representatives of Canaccord Genuity on behalf of Histogenics provided a counter-proposal to Ocugen's preliminary non-binding proposal for consideration, which provided, among other things, that Histogenics' stockholders would retain 10.5% interest in the combined entity plus additional amounts based on Histogenics' cash balance at closing.

On March 18, 2019, Chardan provided a further counter-proposal to Histogenics, which included additional clarity on timing for the consummation of a potential transaction, the terms and conditions of a transaction and increased value for Histogenics' stockholders as compared to Ocugen's prior proposal. This proposal provided, among other things, that Histogenics' stockholders would retain 10.0% interest in the combined entity plus additional amounts based on Histogenics' cash balance at closing.

Also on March 18, 2019, representatives of Canaccord Genuity and Mr. Gridley sent additional due diligence information and held a conference call with executive management of Company C.

On March 19, 2019, Histogenics' executive management, Ocugen executive management and representatives of Canaccord Genuity, Chardan, Gunderson Dettmer and Morgan Lewis held a conference call to discuss the potential transaction structure, timing and conditions of a transaction, including the requisite legal documentation required for signing and consummating a transaction.

Also on March 19, 2019, representatives of Canaccord Genuity held a call with executive management of Company C who indicated Company C would not be proceeding with further discussion regarding a transaction.

Also on March 19, 2019, Mr. Gridley and representatives of Canaccord Genuity held a call with the chief executive officer and executive chairman of Company L regarding timing of finalizing a merger agreement, filing of the requisite regulatory and financial documentation and potential consummation of a transaction. A potential lead investor who was willing to sponsor and invest in the proposed transaction joined the conference call.

Between March 19 and 21, 2019, Mr. Gridley, representatives of Gunderson Dettmer and Canaccord Genuity, and the chief executive officer, executive chairman, lead investors and legal advisors of Company L held multiple calls to clarify a potential transaction structure, timing and conditions of a transaction, including the requisite regulatory and financial documentation required for closing a transaction.

Between March 20, 2019 and March 22, 2019, Histogenics' executive management, Ocugen's executive management and representatives of Canaccord Genuity, Chardan, Gunderson Dettmer and Morgan Lewis held several calls to discuss a variety of financial and legal matters regarding a potential reverse merger transaction, including potential exclusivity of negotiations for a reverse merger transaction.

On March 21, 2019, the Histogenics Board held a meeting with Histogenics' executive management, Canaccord Genuity and Gunderson Dettmer to discuss the status of outreach and various negotiations relating to a potential strategic transaction or other financing opportunity for Histogenics.

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Between March 21 and April 1, 2019, Mr. Gridley and the president of Company P exchanged emails and held calls to discuss Histogenics' ongoing strategic process, and Company P's interest in a potential acquisition of Histogenics. On April 1, 2019, in an email to Mr. Gridley, the president of Company P indicated that Company P had still been unable to secure funding sufficient in order to engage in a transaction.

On March 23 and 24, 2019, Mr. Gridley had calls with the chief executive officer of Ocugen to discuss Histogenics' various Nasdaq compliance matters, and the chief executive officer of Ocugen expressed continued interest in proceeding with a potential reverse merger transaction.

Between March 25 and 28, 2019, Histogenics' executive management, Ocugen's executive management and representatives of Canaccord Genuity, Chardan, Gunderson Dettmer and Morgan Lewis held several calls to discuss a variety of financial and legal matters regarding a transaction, including material terms of potential draft definitive agreements, including break-up fees and disclosure schedules, and potential exclusivity of negotiations for a reverse merger transaction.

On March 25, 2019, Mr. Gridley and the chief executive officer of Company L held a call during which Mr. Gridley indicated that Company L's proposed terms of a transaction and assurances regarding its ability to timely consummate a transaction were not sufficient to enable the Histogenics Board to consider engaging in a proposed transaction with Company L. Mr. Gridley indicated that if Company L were willing to increase the potential value to Histogenics' stockholders and provide additional certainty of timing and closing, he would bring a proposal to the Histogenics Board for consideration.

Also on March 25, 2019, Mr. Gridley sent a due diligence response and materials to the senior executive at Company Q, and informed him that the strategic process was still ongoing, and would provide clarity on timing for a potential acquisition of certain intellectual property assets once a transaction had been announced.

On March 26, 2019, representatives of Canaccord Genuity also spoke with the senior executive at Company Q, who expressed interest in potentially participating in the strategic process to acquire Histogenics in total. Company Q representatives were given access to the Data Room.

On March 28, 2019, representatives of Canaccord Genuity and Ocugen exchanged calls and emails regarding Histogenics' willingness to proceed into exclusive negotiations with regard to a reverse merger transaction until April 5, 2019. Based on these calls and emails, Histogenics and Ocugen agreed to exclusively negotiate with each other with regard to a reverse merger transaction until April 5, 2019, but no formal written agreement was executed.

Also on March 28, 2019, Mr. Gridley had a call with the chief executive officer of Company L to indicate that Histogenics had entered into exclusivity regarding a potential reverse merger transaction with another party.

Between March 29 and 31, 2019, Histogenics' executive management, Ocugen's executive management and representatives of Canaccord Genuity, Chardan, Gunderson Dettmer and Morgan Lewis exchanged calls and emails regarding comments on drafts of the Original Merger Agreement and continuing due diligence activities.

Between March 29 and April 4, 2019, Histogenics' executive management and representatives of Canaccord Genuity held regular calls regarding potential asset sales with the senior executive and legal advisor for Company Q. There was no further contact from Company Q following April 4, 2019.

On April 1, 2019, the Histogenics Board held a meeting with Histogenics' executive management, Canaccord Genuity and Gunderson Dettmer to discuss the status of outreach and various negotiations relating to a potential strategic transaction or other financing opportunity for Histogenics.

Between April 1 and 4, 2019, Mr. Gridley and the chief executive officer of Company O held calls and exchanged text messages regarding Company O's continued efforts to secure funding commitments to engage in

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an acquisition of Histogenics in an all-cash tender offer. Mr. Gridley indicated that if Company O was unable to respond by April 4, 2019, Histogenics would proceed with another interested party that provided more certainty of closing a transaction and ability to consummate a strategic transaction. Company O did not respond by April 4, 2019.

On April 1, 2019, Morgan Lewis provided a draft Original Merger Agreement to Gunderson Dettmer on behalf of Ocugen.

Between April 2 and 4, 2019, Histogenics' executive management, Ocugen's executive management and representatives of Canaccord Genuity, Chardan, Gunderson Dettmer and Morgan Lewis held regular calls to discuss and negotiate a final draft Original Merger Agreement, valuation and closing conditions of a potential transaction.

On April 4, 2019, the Histogenics Board met to review the Original Merger Agreement in substantially final form and reviewed the strategic alternatives available to Histogenics. Canaccord Genuity provided the Histogenics Board with an outline of their preliminary financial analysis, based on the terms of the agreement as of April 4, 2019. At the meeting, the Histogenics Board instructed executive management to negotiate a final break-up fee package that would be acceptable to the parties.

On April 4, 2019, Mr. Gridley and Dr. Musunuri spoke to finalize certain financial terms of the Original Merger Agreement, including the final break-up fees for each of the parties.

On April 5, 2019, the Histogenics Board met with representatives of Canaccord Genuity and Gunderson Dettmer to review the most recent draft Original Merger Agreement presented by Histogenics to Ocugen. Representatives of Gunderson Dettmer reviewed for the Histogenics Board the fiduciary duties of directors and material matters to be considered when deciding to approve the sale of a Delaware corporation. Representatives of Canaccord Genuity then reviewed with the Histogenics Board Canaccord Genuity's financial analysis of the consideration provided for in the Original Merger Agreement and delivered to the Histogenics Board its oral opinion, which was confirmed by delivery of a written opinion dated April 5, 2019, to the effect that, as of such date and based upon and subject to the assumptions made, procedures followed, matters considered, and qualifications and limitations set forth in the written opinion, the exchange ratio provided for in the Original Merger Agreement was fair, from a financial point of view, to Histogenics. Representatives of Gunderson Dettmer then reviewed the material provisions of the definitive Original Merger Agreement. The Histogenics Board discussed, among other things, the deal certainty, break-up fees, termination rights provisions and closing conditions in the Original Merger Agreement. Representatives of Gunderson Dettmer then reviewed and discussed with the Histogenics Board the proposed resolutions regarding the transaction. As certain members of the Histogenics Board were not present at the meeting, the members of the Histogenics Board instructed Gunderson Dettmer, upon their recommendation, to circulate an action by unanimous written consent to approve the Original Merger Agreement and the transaction contemplated thereby. Later on April 5, 2019, the Histogenics Board executed an action by unanimous written consent which included the reasons more fully described in "The Merger—Histogenics Reasons for the Merger" that the Original Merger Agreement and the merger were advisable and in the best interests of Histogenics and its stockholders, and pursuant to which the Histogenics Board unanimously approved the Original Merger Agreement and the transactions contemplated by the Original Merger Agreement.

Later in the day on April 5, 2019, Histogenics and Ocugen executed and delivered the Original Merger Agreement, the voting agreements and the lock-up agreements.

On April 8, 2019, Histogenics and Ocugen issued a joint press release announcing the execution of the Original Merger Agreement. An investor conference call was held later that morning to explain the transaction and provide an overview of the product candidates the combined company would be developing and the expected timing of certain ongoing development efforts.

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On April 8, 2019, following the announcement of the signing of the Original Merger Agreement, certain investors, including certain of the Investors party to the Pre-Merger Financing, reached out to Canaccord Genuity proposing financings for Ocugen and/or the combined entity. Due to Canaccord Genuity's engagement as Histogenics' financial advisor, Canaccord Genuity referred such investors to Chardan to assess Ocugen's interest in pursuing such proposals.

During April 2019, Ocugen and Chardan began negotiating with certain of the Investors regarding a proposed financing of the combined company of up to \$25 million, including the issuance of warrants (the "Proposed Financing"). Representatives of Chardan and Ocugen provided status updates to representatives of Canaccord Genuity and Histogenics on a regular basis during this period.

During the remainder of April 2019 and the first week May 2019, Mr. Gridley informed members of the Histogenics Board regarding the status of proposed asset sales for Histogenics remaining assets and the terms of the Proposed Financing. During this time period, executive management of Histogenics engaged in negotiations with several potential asset purchasers, including Medavate.

During the weeks of April 22, 2019 and April 29, 2019, Histogenics and Gunderson Dettmer exchanged multiple drafts of the Asset Purchase Agreement with Medavate.

Also the remainder of April 2019 and the first week May 2019, representatives of Histogenics expressed concerns to representatives of Ocugen about moving forward with the proposed merger based on the existing terms of the Original Merger Agreement given (i) the dilution to Histogenics stockholders if the Proposed Financing were to be consummated on the proposed terms and (ii) the likelihood that Histogenics would be able to enter into an asset purchase agreement to sell Histogenics' remaining assets for greater than \$5 million (exceeding the 5% upward adjustment cap to the ownership percentage of the current Histogenics stockholders set forth in the Original Merger Agreement). Histogenics also expressed concern regarding its ability to consent to the Proposed Financing based on the existing terms of the Original Merger Agreement, noting that such consent would change the economics of the proposed transaction and potentially the need to obtain additional fairness opinion. Histogenics did not specifically propose the conditions under which it would grant consent to the Proposed Financing during these discussions, but did reiterate to Ocugen and Chardan that the Proposed Financing would significantly dilute Histogenics' stockholders in an amount greater than anticipated and Histogenics' asset sales were likely to bring more cash in at the consummation of the merger than originally contemplated. Further, Histogenics expressed concern with respect to the delay in the delivery of Ocugen's audited financial statements to Histogenics.

On May 6, 2019, a meeting of the Histogenics Board was held, with Histogenics' executive management and representatives from Gunderson Dettmer and Canaccord Genuity in attendance. The purpose of the meeting was to share with the Histogenics Board the details of the Proposed Financing and the concern that Histogenics' executive management had expressed with consenting to the Proposed Financing without an adjustment in the exchange ratio to compensate for the additional dilution to Histogenics' stockholders that could result from the Proposed Financing and the increased cash expected to be in the combined entity as the result of the asset sales. Mr. Gridley explained that if the parties were unable to reach an agreement on revised terms, the merger may not be approved by Histogenics' stockholders, and the transaction would not be able to close. The Histogenics Board discussed that it was desirable to Histogenics' stockholders to reach an agreement with Ocugen regarding revised terms so the parties can proceed with the transaction. The Histogenics Board directed Histogenics' executive management to undertake discussions with Ocugen to seek an increased percentage of the combined company for Histogenics' stockholders and to receive additional cash on a monthly basis given the costs of an additional fairness opinion and the expected delay in closing from the date originally anticipated by the Histogenics Board when approving the Original Merger Agreement.

On May 6, 2019, following the Histogenics Board meeting, discussions were undertaken between Messrs. Gridley and Musunuri regarding the conditions to Histogenics being able to potentially consent to the Proposed



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Financing as result of the potential dilution from the Proposed Financing, Histogenics' negotiated asset sale for \$6.5 million to Medavate and the expected delay in closing. On May 6 and May 7, 2019, representatives from Histogenics and Ocugen held multiple discussions regarding proposed revised terms of the Original Merger Agreement. On May 7, 2019, Messrs. Gridley and Musunuri came to a verbal agreement to revise the terms of the Original Merger Agreement such that the exchange ratio would reflect that, prior to dilution from the Proposed Financing, the Histogenics allocation would be 17% instead of 10% (with up to an additional 5%, depending on Histogenics' cash at the time of the closing of the merger) and the Ocugen allocation would be 85% instead of 90% (subject to Histogenics' cash at closing). The parties also agreed that Ocugen would pay a to-be-negotiated cash amount to Histogenics until the closing of the merger.

On May 7, 2019, Ocugen and certain of the Investors entered into a term sheet regarding the transactions contemplating the Pre-Merger Financing; Histogenics acknowledged such term sheet, but was not a party to the term sheet nor did it consent to the terms of the Pre-Merger Financing.

On May 7, 2019, Mr. Gridley provided an update to the Histogenics Board regarding general transaction and corporate matters, including the proposed revised terms of the Original Merger Agreement.

On May 8, 2019, Histogenics entered into the Asset Purchase Agreement for the Asset Sale.

On May 10, 2019, Morgan Lewis sent Gunderson Dettmer a draft of the Merger Agreement Amendment. Between May 10, 2019 and June 10, 2019, Morgan Lewis and Gunderson Dettmer exchanged drafts of the Merger Agreement Amendment.

On June 13, 2019, the Histogenics Board held a meeting, with Histogenics' executive management and representatives of each of Gunderson Dettmer and Canaccord Genuity attending. Histogenics' executive management updated the Histogenics Board on the status of the transaction timeline and the terms of the Proposed Financing. Representatives of Canaccord Genuity then reviewed with the Histogenics Board its financial analysis of the consideration to be paid by Histogenics in the merger given the revised terms of the Original Merger Agreement, and rendered an oral opinion, subsequently confirmed in writing by delivery of a written opinion, dated June 13, 2019, to the effect that, as of the date of such opinion and based upon and subject to the assumptions made, procedures followed, matters considered and qualifications and limitations on the scope of review undertaken by Canaccord Genuity as set forth in the written opinion, the exchange ratio provided for in the Merger Agreement was fair, from a financial point of view, to Histogenics, as more fully described in the section entitled "The Merger—Opinion of the Histogenics Financial Advisor." Representatives of Gunderson Dettmer then reviewed in detail the material terms of the final draft of the Merger Agreement Amendment, which had been provided to the Histogenics Board prior to the meeting. Representatives of Gunderson Dettmer then reviewed and discussed with the Histogenics Board the proposed resolutions regarding the various matters discussed at the meeting, including the Merger Agreement Amendment and the documents relating to the Proposed Financing. As certain members of the Histogenics Board were not present at the meeting, the members of the Histogenics Board instructed Gunderson Dettmer, upon their recommendation, to circulate an action by unanimous written consent to approve the Merger Agreement Amendment, the Proposed Financing and the transactions contemplated thereby. Later on June 13, 2019, the Histogenics Board executed an action by unanimous written consent which (i) determined that Merger and all related transactions set forth in and contemplated by the Merger Agreement, as amended by the Merger Agreement Amendment, continue to be fair to, advisable and in the best interests of Histogenics and its stockholders, (ii) approved and declared advisable the Merger Agreement, as amended by the Merger Agreement Amendment, (iii) determined to recommend, upon the terms and subject to the conditions set forth in the Merger Agreement, as amended by the Merger Agreement Amendment, that the stockholders of Histogenics vote to approve the merger and adopt the Merger Agreement, as amended by the Merger Agreement Amendment and (iv) approved the documents relating to the Proposed Financing, including the Securities Purchase Agreement.

Also on June 13, 2019, Histogenics and Ocugen entered into the Merger Agreement Amendment. Pursuant to the Merger Agreement Amendment, the Original Merger Agreement was amended, among other items, as follows: (i) the definition of “Exchange Ratio” was amended and restated in its entirety to be 28.7650, (ii) covenants were added restricting the issuance of any securities by both Histogenics and Ocugen until the Effective Time (as defined in the Merger Agreement) of the merger contemplated by the Merger Agreement, (iii) a condition precedent to Ocugen’s obligation to close the merger was added requiring the continued effectiveness of the Asset Purchase Agreement with Medavate and certification by Histogenics that the aggregate proceeds to be received in connection therewith shall be no less than \$6.5 million, (iv) the dates for delivery of Ocugen’s financial statements and filing of the Form S-4 were amended to June 17, 2019, and (v) the reference to “July 31, 2019” in Section 9.1(b) of the Merger Agreement, pertaining to the “End Date” by which the transactions contemplated by the Merger Agreement shall have been consummated was amended and restated to read “September 30, 2019”. Under the exchange ratio set forth in the Merger Agreement Amendment, the former Ocugen equity holders before taking into account the Pre-Merger Financing are expected to own, or hold rights to acquire, in the aggregate approximately 83.0% of the fully-diluted common stock of the combined company, and the stockholders and warrant holders of Histogenics immediately before the merger are expected to own, or hold rights to acquire, in the aggregate approximately 17.0% of the outstanding capital stock of the combined company (each prior to giving effect to the Pre-Merger Financing). Immediately after the merger, after giving effect to the Pre-Merger Financing and based on the exchange ratio of 28.7650, current holders of Ocugen’s capital stock and options and warrant to purchase shares of Ocugen common stock, are expected to own, or hold rights to acquire, in the aggregate approximately 86.24% of the Fully-Diluted Common Stock of Histogenics, and Histogenics’ current stockholders and warrant holders are expected to own, or hold rights to acquire, in the aggregate approximately 13.76% of the Fully-Diluted Common Stock of Histogenics. Additionally, pursuant to the Merger Agreement Amendment, Ocugen agreed to pay the Company (a) \$100,000 (less any earned money payments made prior to June 13, 2019 and acknowledged by the parties as such) on the date of entering into the Merger Agreement Amendment; (b) \$30,000 on June 17, 2019; (c) \$200,000 on July 15, 2019; (d) \$200,000 on August 15, 2019; (e) \$100,000 on September 16, 2019; and (f) \$100,000 on September 30, 2019; *provided* that if the Effective Time has occurred prior to the respective dates set forth in (c), (d), (e) or (f), such payment would no longer be payable on such date.

On June 13, 2019, Histogenics, Ocugen and the Investors entered into the Securities Purchase Agreement and the Registration Rights Agreement. On June 14, 2019, Histogenics subsequently announced the Merger Agreement Amendment and the Pre-Merger Financing through the filing of a Current Report on Form 8-K.

In May 2019, Ocugen entered into a bridge loan with certain of the Investors to advance \$2.1 million of the \$25.0 million aggregate purchase price under the Securities Purchase Agreement (the “Bridge Loan”). On June 28, 2019, Ocugen and the Investors entered into an agreement to amend the Bridge Loan (the “Amended Bridge Loan”) to, among other things, provide for the advancement of up to an additional \$2.5 million. Pursuant to the Amended Bridge Loan, if the merger is completed, immediately prior to the Effective Time (as defined in the Merger Agreement), Ocugen will offset \$5.29 million due under the Amended Bridge Loan from the remaining amount to be received from the Investors under the Securities Purchase Agreement and the Amended Bridge Loan will be deemed to have been repaid and cancelled. If the merger is not completed, Ocugen may be required to pay the note holders \$5.29 million.

On June 28, 2019, Histogenics and Ocugen entered into Amendment Agreements (collectively, the “Amendment”) with each Investor pursuant to which the parties agreed to amend the Securities Purchase Agreement to make certain administrative changes related to the Amended Bridge Loan. Histogenics also consented to Ocugen’s entering into the Amended Bridge Loan pursuant to the requirements of the Merger Agreement.

### ***Historical Background for Ocugen***

The Ocugen Board and management regularly review its operating and strategic plans in an effort to enhance stockholder value. These reviews involve, among other things, discussions regarding alternatives for raising the

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additional financing required to advance Ocugen's product development programs, including consideration of strategic alternatives that would allow Ocugen greater access to capital markets.

On December 13, 2018, Ocugen engaged Chardan as a financial advisor to evaluate potential financing transactions and strategic opportunities.

Ocugen's executive management had weekly calls with Chardan after signing the engagement letter. They reviewed a number of target companies and identified a few potential targets. During the months of January and February 2019, Chardan, on behalf of Ocugen, submitted several non-binding proposals. Ocugen's evaluation criteria included minimizing expansion into different disease areas, other than ophthalmology, so that capital efficiencies are maintained.

On March 8 and 12, 2019, a representative of Chardan on behalf of Ocugen contacted Histogenics' executive management via email regarding Ocugen's potential interest in engaging in a reverse merger transaction.

On March 15, 2019, Ocugen and Histogenics entered into a confidentiality agreement. Ocugen's executive management presented a corporate overview to Histogenics' executive management.

Also on March 15, 2019, Chardan, on behalf of Ocugen, sent Canaccord Genuity a non-binding proposal which outlined the potential terms of a reverse merger transaction. Subject to various assumptions, the proposal included an anticipated pro forma post-closing equity ownership of between 88% and 92% for the former Ocugen stockholders and between 12% and 8% for Histogenics' stockholders.

On March 16 and 17, 2019, Canaccord Genuity spoke with Chardan about the valuation and terms of the March 15, 2019 non-binding proposal.

On March 17, 2019, representatives of Canaccord Genuity on behalf of Histogenics provided a counter-proposal to Ocugen's preliminary non-binding proposal for consideration, which provided, among other things, that Histogenics' stockholders would retain 10.5% interest in the combined entity plus additional amounts based on Histogenics' cash balance at closing.

On March 18, 2019, Chardan, on behalf of Ocugen, provided a further counter-proposal to Histogenics, which included additional clarity on timing for the consummation of a potential transaction and the terms and conditions of a transaction. This proposal provided, among other things, that Histogenics' stockholders would retain 10.0% interest in the combined entity plus additional amounts based on Histogenics' cash balance at closing.

On March 19, 2019, Histogenics' executive management, Ocugen's executive management and representatives of Canaccord Genuity, Chardan, Gunderson Dettmer and Morgan Lewis held a conference call to discuss the potential transaction structure, timing and conditions of a transaction, including the requisite legal documentation required for signing and consummating a transaction.

Between March 20, 2019 and March 22, 2019, Histogenics' executive management, Ocugen's executive management and representatives of Canaccord Genuity, Chardan, Gunderson Dettmer and Morgan Lewis held several calls to discuss a variety of financial and legal matters regarding a potential reverse merger transaction, including potential exclusivity of negotiations for a reverse merger transaction.

On March 23 and 24, 2019, Shankar Musunuri, Ph.D., MBA, Chief Executive Officer, Chairman of the Board and Co-Founder of Ocugen had calls with Mr. Gridley to discuss Histogenics' various Nasdaq compliance matters.

Between March 25 and 28, 2019, Histogenics' executive management, Ocugen's executive management and representatives of Canaccord Genuity, Chardan, Gunderson Dettmer and Morgan Lewis held several calls to

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discuss a variety of financial and legal matters regarding a transaction, including material terms of potential draft definitive agreements, including break-up fees and disclosure schedules, and potential exclusivity of negotiations for a reverse merger transaction.

On March 28, 2019, Ocugen exchanged calls and emails with representatives of Canaccord Genuity regarding Histogenics' willingness to proceed into exclusive negotiations with regard to a reverse merger transaction until April 5, 2019. Based on these calls and emails, Ocugen and Histogenics agreed to exclusively negotiate with each other with regard to a reverse merger transaction until April 5, 2019, but no formal written agreement was executed.

Between March 29 and 31, 2019, Histogenics' executive management, Ocugen's executive management and representatives of Canaccord Genuity, Chardan, Gunderson Dettmer and Morgan Lewis exchanged calls and emails regarding comments on drafts of the Merger Agreement and continuing due diligence activities.

On April 1, 2019, Morgan Lewis provided a draft Merger Agreement to Gunderson Dettmer on behalf of Ocugen.

On April 2, 2019, the Ocugen Board held a meeting to discuss with Ocugen's executive management, Chardan and Morgan Lewis (i) the proposed reverse merger, negotiated terms of the merger and timeline to closing the proposed transaction and (ii) certain other related matters.

Between April 2 and 4, 2019, Histogenics' executive management, Ocugen's executive management and representatives of Canaccord Genuity, Chardan, Gunderson Dettmer and Morgan Lewis held regular calls to discuss and negotiate a final draft Merger Agreement, valuation and closing conditions of a potential transaction.

On April 4, 2019, Dr. Musunuri and Mr. Gridley spoke to finalize certain financial terms of the Merger Agreement, including the final break-up fees for each of the parties.

On April 4, 2019, Ocugen's advisors, including Morgan Lewis, reviewed with the Ocugen Board the terms and conditions of the Merger Agreement and discussed the fiduciary duties in the context of the consideration and approval of the merger. Following such review and discussion, the members of the Ocugen Board executed an action by unanimous written consent of the Ocugen Board (i) determining that the Merger Agreement and the merger were advisable and in the best interests of Ocugen and its stockholders, (ii) authorizing the entry by Ocugen into the Merger Agreement and (iii) approving certain other related matters.

On April 5, 2019, Ocugen and Histogenics executed and delivered the Merger Agreement, the voting agreements and the lock-up agreements.

On April 8, 2019, Ocugen and Histogenics issued a joint press release announcing the execution of the Merger Agreement.

On June 13, 2019, in connection with entering into the Securities Purchase Agreement, Ocugen and Histogenics entered into Consent and Amendment No. 1 to Agreement and Plan of Merger and Reorganization.

On June 28, 2019, Ocugen and the Investors entered into the Amended Bridge Loan. Also on June 28, 2019, Histogenics and Ocugen entered into the Amendment.

### **Histogenics Reasons for the Merger**

At a regular meeting held on April 5, 2019 and in a subsequent action by unanimous written consent, among other things, the Histogenics Board unanimously (i) determined that the Original Merger Agreement and the transactions contemplated thereby, including the merger are fair to, advisable and in the best interests of

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Histogenics and its stockholders, (ii) approved and declared advisable the Original Merger Agreement and the merger, including the issuance of shares of Histogenics common stock to the stockholders of Ocugen pursuant to the terms of the Original Merger Agreement, and (iii) determined to recommend, upon the terms and subject to the conditions set forth in the Original Merger Agreement, that the stockholders of Histogenics vote to approve the amendment of Histogenics' certificate of incorporation to effect the Histogenics Reverse Stock Split, the Original Merger Agreement and the change of control of Histogenics resulting from the merger pursuant to the Nasdaq rules.

In the course of its evaluation of the Original Merger Agreement and merger with Ocugen, the Histogenics Board held numerous meetings, consulted with Histogenics' executive management, Histogenics' outside legal counsel and Histogenics' financial advisor, and reviewed and assessed a significant amount of information, and considered a number of factors, including the following:

- the Histogenics Board's belief that Histogenics' business, operational and financial prospects, including its cash position, the substantially diminished price of its common stock following the results from the NeoCart Phase 3 Trial, the FDA decision requiring an additional clinical trial of NeoCart, and the limited time frame and expertise available to Histogenics to potentially enhance the value of its NeoCart program by conducting and completing the additional clinical studies needed to potentially file a BLA, a go it alone scenario, was highly unlikely given the lack of available financing alternatives;
- the combined organization will pursue Ocugen's business, as a clinical stage biopharmaceutical company focused on discovering, developing and commercializing a pipeline of innovative therapies that address rare and underserved eye diseases;
- the Histogenics Board's conclusion that the merger provides existing Histogenics stockholders an opportunity to participate in the potential growth of the combined company following the merger;
- the Histogenics Board's consideration that the combined company will be led by an experienced senior management team from Ocugen; and
- the Histogenics Board's consideration of the financial analysis of Canaccord Genuity and the opinion of Canaccord Genuity delivered to the Histogenics Board on April 5, 2019, to the effect that, as of the date of such opinion, and based upon and subject to the various assumptions made, procedures followed, matters considered and limitations and qualifications on the scope of the review undertaken by Canaccord Genuity, as set forth in its written opinion, the exchange ratio in the Original Merger Agreement was fair to Histogenics, from a financial point of view (such opinion was superseded by the opinion delivered by Canaccord Genuity on June 13, 2019).

The Histogenics Board also considered the recent results of operations and financial conditions of Histogenics, including:

- the perceived value of Histogenics reflected in the diminished price of its common stock following the failure of the NeoCart Phase 3 Trial;
- the loss of certain operational capabilities of Histogenics, and risks associated with continuing to operate Histogenics on a stand-alone basis, including limiting the number of employees to only those personnel essential to running a public company and relying on outside consultants and third-party contractors;
- the results of substantial efforts made over a three-month period following Histogenics' announcement of its disappointing results from its NeoCart Phase 3 Trial in September 2018 to solicit strategic alternatives for Histogenics to the merger, including the discussions that Histogenics' executive management had during this period with other strategic transaction candidates as further discussed in the section titled "The Merger—Background of the Merger";

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- the results of substantial efforts made over a three-month period following Histogenics' announcement of the FDA decision to require another clinical trial of NeoCart in December 2018 to solicit strategic alternatives for Histogenics to the merger on Histogenics' behalf, including the discussions that Histogenics' executive management and Canaccord Genuity had during this period with other strategic transaction candidates (including reverse merger transactions and asset sales) as further discussed in the section titled "The Merger—Background of the Merger";
- the current financial market conditions and historical market prices, volatility and trading information with respect to Histogenics common stock;
- the risks, costs and timing and limited amount, if any, that would be distributed to Histogenics stockholders associated with a potential liquidation of Histogenics; and
- Histogenics' inability to secure a term sheet or close a partnering or licensing transaction for NeoCart or technology since December 2017, and the likelihood that Histogenics' may be able to secure and close such a transaction before running out of operating capital.

The Histogenics Board also reviewed the terms of the Original Merger Agreement and associated transactions, including:

- the fact that the exchange ratio in the Original Merger Agreement, which was expected to give Histogenics stockholders approximately 10% (and up to 15% depending on the amount of cash available at closing) of the combined company's outstanding stock, immediately following the merger, is financially attractive in light of Histogenics' standalone value, Histogenics' recent stock price, Histogenics' strategic alternatives, and the potential value of Ocugen following the merger;
- the number and nature of the conditions to Ocugen's obligations to consummate the merger;
- the rights of, and limitation on, Histogenics under the Original Merger Agreement to consider certain unsolicited acquisition proposals under the certain circumstances, should Histogenics receive a "superior offer"; and
- the Histogenics Board's belief that the terms of the Original Merger Agreement, including the parties' representations, warranties and covenants, deal protection provisions and the conditions were reasonable for a transaction of this nature.

The Histogenics Board also considered a variety of risks and other countervailing factors related to the merger, including:

- the up to \$600,000 termination fee payable by Histogenics to Ocugen upon the occurrence of certain events and the potential effect of such termination fee in deterring other potential acquirers from proposing an alternative transaction that may be more advantageous to Histogenics stockholders;
- the up to \$300,000 termination fee payable by Ocugen to Histogenics upon the occurrence of certain events, including the failure of Ocugen to obtain the approval of the merger from Ocugen's stockholders, and the likelihood the receipt of the termination fee from Ocugen will only offset a portion of expenses incurred by Histogenics in connection with the merger;
- reimbursement of certain transaction expenses of up to \$300,000 that may be payable to Ocugen upon the occurrence of certain events, and the potential that Histogenics would not have sufficient cash resources to make such a payment;
- the substantial expenses to be incurred by Histogenics in connection with the merger;
- the possible volatility of the trading price of the Histogenics common stock resulting from the announcement of the merger;
- the risks that the merger might not be consummated in a timely manner or at all and the potential effect of the public announcement of the merger or failure to complete the merger on the reputation of Histogenics;

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- the risks to Histogenics’ business, operations and financial results in the event that the merger is not consummated;
- the strategic direction of the combined company following the closing of the merger, which will be determined by a board of directors initially designated entirely by Ocugen; and
- various other risks associated with the combined company and the merger, including those described in the sections titled “Risk Factors” beginning on page 30 and “Forward-Looking Statements” beginning on page 114.

In addition, the Histogenics Board considered the interests that certain of its directors and executive officers may have with respect to the merger that are different from or in addition to their interests as stockholders of Histogenics, generally and specifically with respect to the fact that certain officers and directors, independently and through affiliated entities, are securityholder of Histogenics, as more fully described under “The Merger—Interests of Histogenics Directors and Executive Officers in the Merger.” The Histogenics Board concluded that the risks, uncertainties, restrictions and potentially negative factors associated with the merger were outweighed by the potential benefits of the merger.

At a special meeting held on June 13, 2019 and in a subsequent action by unanimous written consent, among other things, the Histogenics Board unanimously (i) determined that the Merger Agreement, as amended by the Merger Agreement Amendment, and the transactions contemplated thereby, including the merger are fair to, advisable and in the best interests of Histogenics and its stockholders, (ii) approved and declared advisable the Merger Agreement, as amended by the Merger Agreement Amendment, and the merger, including the issuance of shares of Histogenics common stock to the stockholders of Ocugen pursuant to the terms of the Merger Agreement, as amended by the Merger Agreement Amendment, and (iii) determined to recommend, upon the terms and subject to the conditions set forth in the Merger Agreement, as amended by the Merger Agreement Amendment, that the stockholders of Histogenics vote to approve the amendment of Histogenics’ certificate of incorporation to effect the Histogenics Reverse Stock Split, the Merger Agreement, as amended by the Merger Agreement Amendment, and the change of control of Histogenics resulting from the merger pursuant to the Nasdaq rules.

In the course of its evaluation of the Merger Agreement and merger with Ocugen, the Histogenics Board held numerous meetings, consulted with Histogenics’ executive management, Histogenics’ outside legal counsel and Histogenics’ financial advisor, and reviewed and assessed a significant amount of information, and considered a number of factors, including the following:

- the Histogenics Board’s consideration that immediately following the merger, after giving effect to the Pre-Merger Financing, based on the exchange ratio of 28.7650, Histogenics’ current stockholders and warrant holders would be expected to own, or hold rights to acquire, in the aggregate approximately 13.76% of the Fully-Diluted Common Stock of Histogenics;
- the Histogenics Board’s conclusion that on the amended terms of the Merger Agreement, the merger continued to provide existing Histogenics stockholders an opportunity to participate in the potential growth of the combined company following the merger;
- the Histogenics Board’s consideration that the Merger Agreement is a more attractive alternative than terminating the Merger Agreement given that there are no other interested acquirers and that Histogenics would wind-down operations if the merger with Ocugen is not consummated; and
- the Histogenics Board’s consideration of the financial analysis of Canaccord Genuity and the opinion of Canaccord Genuity delivered to the Histogenics Board on June 13, 2019, to the effect that, as of the date of such opinion, and based upon and subject to the various assumptions made, procedures followed, matters considered and limitations and qualifications on the scope of the review undertaken by Canaccord Genuity, as set forth in its written opinion, the exchange ratio in the Merger Agreement, as amended by the Merger Agreement Amendment, was fair to Histogenics, from a financial point of

view, as more fully described in the section entitled “The Merger—Opinion of the Histogenics Financial Advisor.”

The Histogenics Board also reviewed the amended terms of the Merger Agreement and associated transactions, including:

- the fact that the exchange ratio, which is expected to give Histogenics stockholders and warrant holders approximately 13.76% of the combined company’s outstanding stock, immediately following the merger and the Pre-Merger Financing, remained financially attractive in light of Histogenics’ standalone value, Histogenics’ recent stock price, Histogenics’ strategic alternatives, and the potential value of Ocugen following the merger;
- the number and nature of the conditions to Ocugen’s obligations to consummate the merger, including the payments by Ocugen to Histogenics as follows: (a) \$100,000 (less any earnest money payments made prior to June 13, 2019 and acknowledged by the parties as such) on the date of entering into the Merger Agreement Amendment; (b) \$30,000 on June 17, 2019; (c) \$200,000 on July 15, 2019; (d) \$200,000 on August 15, 2019; (e) \$100,000 on September 16, 2019; and (f) \$100,000 on September 30, 2019; provided that if the Effective Time has occurred prior to the respective dates set forth in (c), (d), (e) or (f), such payment would no longer be payable on such date;
- the rights of, and limitation on, Histogenics under the Merger Agreement, as amended by the Merger Agreement Amendment, to consider certain unsolicited acquisition proposals under the certain circumstances, should Histogenics receive a “superior offer”; and
- the Histogenics Board’s continued belief that the terms of the Merger Agreement, as amended by the Merger Agreement Amendment, including the parties’ representations, warranties and covenants, deal protection provisions and the conditions are reasonable for a transaction of this nature.

The foregoing information and factors considered by the Histogenics Board are not intended to be exhaustive but are believed to include all of the material factors considered by the Histogenics Board. In view of the wide variety of factors considered in connection with its evaluation of the merger and the complexity of these matters, the Histogenics Board did not find it useful, and did not attempt to quantify, rank or assign relative weights to these factors. In considering the factors described above, individual members of the Histogenics Board may have given weight to different factors. The Histogenics Board conducted an overall analysis of the factors discussed above, including thorough discussions with, and questioning of, Histogenics’ executive management and the legal and financial advisors of Histogenics, and considered the factors overall to be favorable to, and to support, its determination.

The foregoing information and factors considered by the Histogenics Board are not intended to be exhaustive but are believed to include all of the material factors considered by the Histogenics Board. In view of the wide variety of factors considered in connection with its evaluation of the merger and the complexity of these matters, the Histogenics Board did not find it useful, and did not attempt to quantify, rank or assign relative weights to these factors. In considering the factors described above, individual members of the Histogenics Board may have given weight to different factors. The Histogenics Board conducted an overall analysis of the factors discussed above, including thorough discussions with, and questioning of, Histogenics’ executive management and the legal and financial advisors of Histogenics, and considered the factors overall to be favorable to, and to support, its determination.



## **Ocugen Reasons for the Merger**

In the course of reaching its decision to approve the merger, the Ocugen Board consulted with Ocugen's senior management, financial and tax advisors and legal counsel, reviewed a significant amount of information and considered a number of factors, including, among others:

- the potential increased access to sources of capital and a broader range of investors to support the clinical development of its product candidates following consummation of the transaction compared to if Ocugen continued to operate as a privately held company;
- the potential to provide its current stockholders with greater liquidity by owning stock in a public company;
- the board's belief that no alternatives to the merger were reasonably likely to create greater value for Ocugen's stockholders, after reviewing the various financing and other strategic options to enhance stockholder value that were considered by the Ocugen Board;
- the cash resources of the combined organization, which are expected to be approximately \$25 million at the closing of the merger after giving effect to the Pre-Merger Financing;
- the business, history and credibility of Histogenics and its affiliates;
- the availability of appraisal rights under the DGCL to holders of Ocugen's capital stock who comply with the required procedures under the DGCL, which allow such holders to seek appraisal of the fair value of their shares of Ocugen capital stock as determined by the Delaware Court of Chancery;
- the expectation that the merger with Histogenics would be a more time- and cost-effective means to access capital than other options considered by the Ocugen Board, including additional private financings or an initial public offering;
- the terms and conditions of the Merger Agreement, including, without limitation, the following:
  - the determination that the expected relative percentage ownership of Histogenics' stockholders and Ocugen's stockholders in the combined organization was appropriate based, in the judgment of the Ocugen Board, on the board of directors' assessment of the approximate valuations of Histogenics and Ocugen;
  - the expectation that the merger will be treated as a reorganization for U.S. federal income tax purposes;
  - the limited number and nature of the conditions of the obligation of Histogenics to consummate the merger;
  - the rights of Ocugen under the Merger Agreement to consider certain unsolicited acquisition proposals under certain circumstances should Ocugen receive a superior proposal;
  - the conclusion of the Ocugen Board that the potential termination fee of up to \$600,000 or \$700,000, payable by Histogenics or Ocugen, respectively, to the other party, and the circumstances when such fee may be payable, were reasonable; and
  - the belief that the other terms of the Merger Agreement, including the parties' representations, warranties and covenants, and the conditions to their respective obligations, were reasonable in light of the entire transaction;
- the shares of Histogenics common stock issued to Ocugen's stockholders will be registered on a Form S-4 registration statement and will become freely tradable for Ocugen's stockholders who are not affiliates of Ocugen and who are not parties to lock-up agreements;
- the voting agreements, pursuant to which certain directors, officers and stockholders of Ocugen and Histogenics, respectively, have agreed, solely in their capacity as stockholders of Ocugen and Histogenics, respectively, to vote all of their shares of Ocugen capital stock or Histogenics common stock in favor of the adoption or approval, respectively, of the Merger Agreement;

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- the ability to obtain a Nasdaq listing and the change of the combined organization's name to Ocugen, Inc. upon the closing of the merger;
- the merger may enable certain stockholders of Histogenics and Ocugen to increase the value of their current shareholding; and
- the likelihood that the merger will be consummated on a timely basis.

The Ocugen Board also considered a number of uncertainties and risks in its deliberations concerning the merger and the other transactions contemplated by the Merger Agreement, including the following:

- the possibility that the merger might not be completed and the potential adverse effect of the public announcement of the merger on the reputation of Ocugen and the ability of Ocugen to obtain financing in the future in the event the merger is not completed;
- the exchange ratio used to establish the number of shares of Histogenics common stock to be issued to Ocugen's stockholders in the merger is fixed, except for adjustments due to Histogenics' cash balances at closing, and thus the relative percentage ownership of Histogenics' stockholders and Ocugen's stockholders in the combined organization immediately following the completion of the merger is similarly fixed;
- the termination fee of up to \$700,000, payable by Ocugen to Histogenics upon the occurrence of certain events, and the potential effect of such termination fee in deterring other potential acquirers from proposing an alternative transaction that may be more advantageous to Ocugen's stockholders;
- the risk that the merger might not be consummated in a timely manner or at all;
- the expenses to be incurred in connection with the merger and related administrative challenges associated with combining the companies;
- the additional expenses and obligations to which Ocugen's business will be subject following the merger that Ocugen has not previously been subject to, and the operational changes to Ocugen's business, in each case that may result from being a public company;
- the fact that the representations and warranties in the Merger Agreement do not survive the closing of the merger and the potential risk of liabilities that may arise post-closing; and
- various other risks associated with the combined organization and the merger, including the risks described in the section entitled "Risk Factors" in this proxy statement/prospectus/information statement.

### **Opinion of the Histogenics Financial Advisor**

Canaccord Genuity is acting as financial advisor to Histogenics in connection with the merger. At a meeting of the Histogenics Board held on June 13, 2019 to evaluate the merger, Canaccord Genuity delivered to the Histogenics Board an oral opinion, which opinion was confirmed by delivery of a written opinion, dated June 13, 2019, to the effect that, as of that date and based upon and subject to certain assumptions, factors and qualifications set forth in the written opinion, the exchange ratio was fair, from a financial point of view, to Histogenics. Canaccord Genuity did not express any view on, and its opinion did not address, any other term or aspect of any other agreements or arrangements contemplated by the Merger Agreement or entered into in connection with the merger, including, without limitation, the Pre-Merger Financing or the Asset Sale. For purposes of Canaccord Genuity's opinion and related analyses, the term "exchange ratio" refers to the exchange ratio of 28.7650 set forth in the Merger Agreement but without giving effect to the Pre-Merger Financing.

**The full text of Canaccord Genuity's written opinion is attached to this proxy statement/prospectus/information statement as *Annex B* and is incorporated into this proxy statement/prospectus/information statement by reference. The description of Canaccord Genuity's opinion set forth in this proxy statement/**

prospectus/information statement is qualified in its entirety by reference to the full text of such opinion. Histogenics stockholders are encouraged to read Canaccord Genuity's opinion carefully and in its entirety for a description of the procedures followed, assumptions made, matters considered and qualifications and limitations on the review undertaken by Canaccord Genuity in connection with its opinion. Canaccord Genuity's opinion was addressed to the Histogenics Board, was only one of many factors considered by the Histogenics Board in its evaluation of the merger and only addresses the fairness, from a financial point of view and as of the date of the opinion, to Histogenics of the exchange ratio. Canaccord Genuity's opinion does not address the relative merits of the merger as compared to other business strategies or transactions that might be available to Histogenics, nor does it address the underlying business decision of Histogenics to proceed with the merger. Canaccord Genuity's opinion was directed to and for the information of the Histogenics Board only (in its capacity as such) in connection with its evaluation of the merger and does not constitute advice or a recommendation to the Histogenics Board or any other person as to how the Histogenics Board or such person should vote with respect to the merger or otherwise act on any other matter with respect to the merger. Canaccord Genuity's opinion was necessarily based on securities, economic, market and monetary conditions prevailing on, and the information made available to Canaccord Genuity as of, June 13, 2019, the date of its opinion. Subsequent developments may affect the conclusions expressed in Canaccord Genuity's opinion if such opinion were rendered as of a later date. Canaccord Genuity assumes no responsibility for updating, revising or reaffirming its opinion based on circumstances or events occurring after the date of the opinion.

In connection with Canaccord Genuity's review of the merger and developing the opinion described above, Canaccord Genuity:

- (i) reviewed certain publicly available historical business and financial information concerning Histogenics;
- (ii) reviewed certain internal historical financial statements and other historical financial and operating data concerning Histogenics and Ocugen provided to Canaccord Genuity by management of Histogenics and Ocugen, and certain projected cash balances of Histogenics prepared by management of Histogenics;
- (iii) conducted discussions with members of management of Histogenics and Ocugen regarding the past and current operations and financial condition and the prospects of Histogenics and Ocugen;
- (iv) reviewed financial and stock market data for certain companies, the securities of which are publicly traded, that Canaccord Genuity deemed to be relevant to Ocugen;
- (v) reviewed certain financial terms of certain initial public offerings executed by certain companies that Canaccord Genuity deemed to be relevant to Ocugen;
- (vi) reviewed certain financial terms of certain business combination transactions that Canaccord Genuity deemed to be relevant to Histogenics;
- (vii) reviewed the terms of the Merger Agreement provided to Canaccord Genuity by Histogenics, including the Merger Agreement Amendment in substantially final form provided on June 12, 2019, which Canaccord Genuity assumed, with the permission of the Histogenics Board, to be identical in all material respects to the amendment executed by the parties; and
- (viii) reviewed such other financial studies and analyses, performed such other investigations, and took into account such other matters as Canaccord Genuity deemed necessary, including an assessment of general securities, economic, market and monetary conditions.

In connection with its review and arriving at its opinion, Canaccord Genuity did not independently verify any of the foregoing information, relied on such information, assumed that all such information was complete and accurate in all material respects, and relied on assurances of management of Histogenics that they were not aware of any facts that would make such information misleading. With respect to the projected cash balances of

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Histogenics prepared by management of Histogenics and any related forward-looking information reviewed by Canaccord Genuity, Canaccord Genuity assumed, with the permission of the Histogenics Board, that such information has been reasonably prepared on bases reflecting the best currently available estimates and judgments of management as to the matters covered thereby, and Canaccord Genuity relied, with the permission of the Histogenics Board, on such information for purposes of its analysis and opinion. Canaccord Genuity expressed no view or opinion as to such information or the assumptions on which it was based.

Canaccord Genuity also assumed that (i) the merger will be consummated upon the terms set forth in the Merger Agreement, without any adjustment to the exchange ratio or any waiver, modification or amendment of any material term, condition or agreement therein which would be in any way meaningful to Canaccord Genuity's analysis and (ii) in the course of obtaining necessary governmental, regulatory and third-party approvals and consents for the merger, no modification, delay, limitation, restriction or conditions will be imposed which would have an adverse effect on Histogenics or Ocugen or be in any way meaningful to Canaccord Genuity's analysis. Canaccord Genuity is not a legal, accounting, regulatory or tax expert and relied on the assessments made by Histogenics and its advisors with respect to such matters.

Canaccord Genuity's opinion is limited to and addresses only the fairness, from a financial point of view, to Histogenics of the exchange ratio as of the date of the opinion. Canaccord Genuity did not express any view on, and its opinion did not address, any other term or aspect of any other agreement or arrangements contemplated by the Merger Agreement or entered into in connection with the merger, including, without limitation, the Securities Purchase Agreement and the asset purchase agreement related to the Asset Sale. Canaccord Genuity expressed no opinion as to the fairness of the merger to the holders of any class of securities, creditors or other constituencies of Histogenics or any value that the holders of Dissenting Shares (as defined in the Merger Agreement) may be entitled to receive. Canaccord Genuity's opinion does not address the relative merits of the merger as compared to other business strategies or transactions that might be available to Histogenics, nor does it address the underlying business decision of Histogenics to proceed with the merger or any view on another term or aspect of the merger, including, without limitation, the structure or form of the merger. Canaccord Genuity did not consider, and did not express an opinion as to, the fairness of the amount or nature of the compensation to any of the officers, directors or employees of Histogenics or any other party, or class of such persons. Further, Canaccord Genuity did not express any opinion as to in the future what the value of Histogenics common stock or any other securities actually will be when issued or the price or range of prices at which Histogenics common stock or any other securities may trade or otherwise be transferable at any time, including following announcement or consummation of the merger.

Canaccord Genuity was not requested to conduct, and did not conduct, nor did Canaccord Genuity rely upon, any independent valuation or appraisal of any of the assets or liabilities (contingent, derivative, off-balance sheet or otherwise) of Histogenics or Ocugen. Canaccord Genuity also did not evaluate nor express any opinion as to the solvency of any party to the Merger Agreement, or the ability of Histogenics or Ocugen to pay its obligations when they become due, or as to the impact of the merger on such matters, under any state, federal or other laws relating to bankruptcy, insolvency or similar matters.

### ***Summary of Financial Analyses***

The following is a summary of the material financial analyses performed by Canaccord Genuity in connection with rendering its opinion dated June 13, 2019 described above. The following summary, however, does not purport to be a complete description of the factors considered or financial analyses performed by Canaccord Genuity, nor does the order of analyses described represent relative importance or weight given to those analyses by Canaccord Genuity. Some of these summaries of the financial analyses include information presented in tabular format. The tables must be read together with the full text of each summary and are alone not a complete description of Canaccord Genuity's financial analyses. In performing its analyses, Canaccord Genuity made numerous assumptions with respect to industry performance, general business and economic conditions and other matters, many of which are beyond the control of Histogenics or any other parties to the Merger Agreement. Any

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estimates contained in these analyses are not necessarily indicative of actual values or predictive of future results or values, which may be significantly more or less favorable than as set forth below. Except as otherwise noted, the following quantitative information, to the extent that it is based on market data, is based on market data as it existed on or before June 12, 2019 (the date immediately prior to delivery of Canaccord Genuity's opinion) and is not necessarily indicative of current market conditions.

*Ocugen Selected Public Companies Analysis.* Canaccord Genuity reviewed certain publicly available financial information for selected development-stage ophthalmology companies that, based on its experience and professional judgment, share similar business characteristics to Ocugen. No company utilized in the selected public companies analysis is directly comparable to Ocugen and certain of these companies may have financial, business and/or operating characteristics that are materially different from those of Ocugen. However, the companies were selected, among other reasons, because they are publicly-traded companies with businesses that, for purposes of Canaccord Genuity's analysis, may be considered similar to that of Ocugen based on industry sector and the stage of development of key products.

The selected public companies are listed below:

Aldeyra Therapeutics, Inc.  
Apellis Pharmaceuticals, Inc.  
Eyenuvia, Inc.  
Kodiak Sciences Inc.

Canaccord Genuity calculated the implied enterprise value of each of the selected public companies based on information obtained from filings with the SEC, the Capital IQ database, and other public sources. For this analysis, Canaccord Genuity calculated enterprise value as fully-diluted equity value (determined using the treasury stock method and adjusted for financings), *plus* total debt (adjusted for financings and warrant liabilities, as applicable), *minus* cash and cash equivalents (adjusted for financings and milestone payments, as applicable). Based on its analysis and other considerations that Canaccord Genuity deemed relevant in its experience and professional judgment, Canaccord Genuity derived a range of implied enterprise values for Ocugen based on the first quartile and third quartile enterprise values of the selected public companies of \$86.9 million and \$585.2 million, respectively. Applying this range of implied enterprise values and adding to such range Ocugen's cash and cash equivalents of \$0.3 million and subtracting from it Ocugen's total debt of \$10.1 million (in each case as provided by Ocugen management), Canaccord Genuity derived a range of implied equity values for Ocugen of \$77.1 million to \$575.4 million.

*Ocugen Selected Initial Public Offering Precedent Analysis.* Canaccord Genuity reviewed certain publicly available financial information related to initial public offerings (IPOs) of selected development-stage ophthalmology companies that, based on Canaccord Genuity's experience and professional judgment, share similar business characteristics to Ocugen. No company utilized in the selected precedent IPO analysis is directly comparable to Ocugen and certain of these companies may have financial, business and/or operating characteristics that are materially different from those of Ocugen. However, the companies were selected, among other reasons, because they are recent issuers in IPOs with businesses that, for purposes of Canaccord Genuity's analysis, may be considered similar to that of Ocugen based on industry sector and the stage of development of key products.

The selected IPOs are listed below:

<b>IPO Pricing Date</b>	<b>Issuer</b>
10/3/18	Kodiak Sciences Inc.
1/24/18	Eyenuvia, Inc.
11/8/17	Apellis Pharmaceuticals, Inc.
7/19/17	Kala Pharmaceuticals, Inc.

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Canaccord Genuity calculated the pre-money implied enterprise value of the issuer in each of the IPOs at the time of pricing of such IPO based on information obtained from filings with the SEC, the Dealogic database, the Capital IQ database, and other public sources. For this analysis, Canaccord Genuity calculated enterprise value as fully-diluted, pre-money equity value based on the IPO offer price and the pre-offer outstanding shares of the issuer on a fully-diluted basis (determined using the treasury stock method), *plus* total debt (including warrant liabilities, as applicable), *minus* cash and cash equivalents. Based on its analysis and other considerations that Canaccord Genuity deemed relevant in its experience and professional judgment, Canaccord Genuity derived a range of implied enterprise values for Ocugen based on the first quartile and third quartile enterprise values of the issuers in the selected IPOs of \$229.7 million and \$360.1 million, respectively. Applying this range of implied enterprise values and adding to such range Ocugen's cash and cash equivalents of \$0.3 million and subtracting from it Ocugen's total debt of \$10.1 million (in each case as provided by Ocugen management), Canaccord Genuity derived a range of implied equity values for Ocugen of \$220.0 million to \$350.3 million.

*Histogenics Selected Reverse Mergers Analysis.* Canaccord Genuity reviewed publicly available financial information related to selected reverse mergers involving U.S. publicly-traded biopharmaceutical companies that Canaccord Genuity, based on its experience and professional judgment, deemed relevant to consider in relation to Histogenics and the merger. In each of the selected reverse mergers, the public company had experienced a clinical or regulatory issue and completed a reverse merger between January 1, 2017 and June 12, 2019. Although none of the selected reverse mergers is directly comparable to the merger, the public companies in the selected reverse mergers have businesses that, for purposes of Canaccord Genuity's analysis, may be considered similar to that of Histogenics based on industry sector, the stage of development of key products, and the experience of a clinical or regulatory issue.

The selected reverse mergers are listed below:

<b>Announcement</b>		
<b>Date</b>	<b>Public Company</b>	<b>Private Company</b>
3/8/19	Stellar Biotechnologies, Inc.	Edesa Biotech Inc.
3/7/19	GTx, Inc.	Oncternal Therapeutics, Inc.
1/7/19	Vital Therapies, Inc.	Immunic AG
1/4/19	AmpliPhi Biosciences Corp.	C3J Therapeutics, Inc.
11/27/18	Arsanis, Inc.	X4 Pharmaceuticals, Inc.
11/26/18	Edge Therapeutics, Inc.	PDS Biotechnology Corp.
11/19/18	Bioblast Pharma Ltd.	Enlivex Therapeutics Ltd.
7/30/18	Apricus Biosciences, Inc.	Seelos Therapeutics, Inc.
6/4/18	Versartis, Inc.	Aravive, Inc.
10/30/17	Aviragen Therapeutics, Inc.	Vaxart, Inc.
10/17/17	Neothetics, Inc.	Evoform Biosciences, Inc.
9/27/17	Alcobra Ltd.	Arcturus Therapeutics Ltd.
9/12/17	Inotek Pharmaceuticals Corp.	Rocket Pharmaceuticals, Inc.
8/8/17	Galena Biopharma, Inc.	SELLAS Life Sciences Group, Inc.
7/3/17	Opexa Therapeutics, Inc.	Acer Therapeutics Inc.
5/16/17	Mirna Therapeutics, Inc.	Synlogic, Inc.
4/18/17	Nivalis Therapeutics, Inc.	Alpine Immune Sciences, Inc.
3/17/17	Threshold Pharmaceuticals Inc.	Molecular Templates, Inc.
1/7/17	Mast Therapeutics, Inc.	Savara Inc.
1/5/17	OncoGenex Pharmaceuticals, Inc.	Achieve Life Sciences, Inc.

Canaccord Genuity calculated the implied enterprise value of each of the public companies in the selected reverse mergers based on information obtained from filings with the SEC, the Capital IQ database, and other public sources. For this analysis, Canaccord Genuity calculated enterprise value as pre-announcement, fully-diluted equity value (determined using the treasury stock method), *plus* total debt (including warrant liabilities, as applicable), *minus*

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cash and cash equivalents. Based on its analysis and other considerations that Canaccord Genuity deemed relevant in its experience and professional judgment, Canaccord Genuity derived a range of implied enterprise values for Histogenics based on the first quartile and third quartile enterprise values of the public companies in the selected reverse mergers of \$(13.8) million and \$0.9 million, respectively. Applying this range of implied enterprise values and adding to such range Histogenics' cash and cash equivalents of \$9.9 million (including the cash expected to be received by Histogenics as a result of the Asset Sale per Histogenics management) and subtracting from it Histogenics' total debt of \$0.1 million (in each case as provided by Histogenics management), Canaccord Genuity derived a range of implied equity values for Histogenics of \$(4.0) million to \$10.7 million.

*Histogenics Liquidation Analysis.* Canaccord Genuity considered a liquidation analysis, consisting of projected cash balances for Histogenics prepared by Histogenics management, in connection with the rendering of its opinion, in assessing the value, if any, that holders of shares of Histogenics common stock and Series A Preferred Stock would be expected to receive in respect of such shares in the event that Histogenics were liquidated. The liquidation proceeds were estimated by Histogenics management assuming an estimated completion date for the liquidation of August 31, 2019 and no asset sales by Histogenics prior to such date. Based on this analysis provided by Histogenics management, Canaccord Genuity noted that management estimated that there would be no cash available for distribution to holders of Histogenics common stock and Series A Preferred Stock as of August 31, 2019.

*Histogenics Trading Analysis.* Canaccord Genuity considered the market capitalization of Histogenics as of April 4, 2019, the date prior to the initial execution of the Merger Agreement. For this purpose, Canaccord Genuity calculated Histogenics' implied equity value based on its fully-diluted shares outstanding (determined using the treasury stock method) and based on publicly available information, *multiplied* by the closing price of the Histogenics common stock of \$0.11 per share on such date. Based on this analysis, Canaccord Genuity noted that the implied equity value of Histogenics as of April 4, 2019 was \$10.5 million.

*Implied Pro Forma Ownership Percentage.* Based on the analyses described above, Canaccord Genuity considered the implied equity values for Histogenics derived from the Histogenics Selected Reverse Mergers Analysis, Histogenics Liquidation Analysis and Histogenics Trading Analysis (which ranged from \$(4.0) million to \$10.7 million) with the range of implied equity values for Ocugen derived from the Ocugen Selected Public Companies Analysis (which ranged from \$77.1 million to \$575.4 million) to determine a range of implied pro forma percentage ownership for Histogenics equity holders in the combined company of 0% to 12.2%. Canaccord Genuity compared this range to the 17% pro forma ownership percentage for Histogenics equity holders implied by the exchange ratio (without giving effect to the Pre-Merger Financing) as set forth in the Merger Agreement.

Canaccord Genuity also considered the implied equity values for Histogenics derived from the Histogenics Selected Reverse Mergers Analysis, Histogenics Liquidation Analysis and Histogenics Trading Analysis (which ranged from \$(4.0) million to \$10.7 million) with the range of implied equity values for Ocugen derived from the Ocugen Selected Initial Public Offering Precedent Analysis (which ranged from \$220.0 million to \$350.3 million) to determine a range of implied pro forma percentage ownership for Histogenics equity holders in the combined company of 0% to 4.6%. Canaccord Genuity compared this range to the 17% pro forma ownership percentage for Histogenics equity holders implied by the exchange ratio (without giving effect to the Pre-Merger Financing) as set forth in the Merger Agreement.

*Implied Exchange Ratio.* Based on the analyses described above and the information provided by Histogenics and Ocugen management regarding the capitalization of Histogenics and Ocugen as of June 12, 2019, Canaccord Genuity considered the implied per share values derived from the Histogenics Selected Reverse Mergers Analysis, Histogenics Liquidation Analysis and Histogenics Trading Analysis (which ranged from \$(0.05) to \$0.11 per share) with the range of implied per share values for Ocugen derived from the Ocugen Selected Public Companies Analysis (which ranged from \$5.34 to \$36.68 per share) to determine a range of implied exchange ratios for the issuance of Histogenics common stock to Ocugen equity holders in the merger (without giving

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effect to the Pre-Merger Financing) of 333.4290 up to an indeterminable amount. Canaccord Genuity compared this range to the exchange ratio of 28.7650 set forth in the Merger Agreement.

Canaccord Genuity also considered the implied per share values derived from the Histogenics Selected Reverse Mergers Analysis, Histogenics Liquidation Analysis and Histogenics Trading Analysis (which ranged from \$(0.05) to \$0.11 per share) with the range of implied per share values for Ocugen derived from the Ocugen Selected Initial Public Offering Precedent Analysis (which ranged from \$14.33 to \$22.51 per share) to determine a range of implied exchange ratios for the issuance of Histogenics common stock to Ocugen equity holders in the merger (without giving effect to the Pre-Merger Financing) of 204.6653 up to an indeterminable amount. Canaccord Genuity compared this range to the exchange ratio of 28.7650 set forth in the Merger Agreement.

### **General**

The preparation of a fairness opinion is a complex process and is not necessarily susceptible to partial analysis or summary description. Selecting portions of the analyses or of the summary set forth above, without considering the analyses as a whole, could create an incomplete view of the processes underlying Canaccord Genuity's opinion. In arriving at its fairness determination, Canaccord Genuity considered the results of all of its analyses and did not attribute any particular weight to any factor or analysis considered by it. Rather, Canaccord Genuity made its determination as to fairness on the basis of its experience and professional judgment after considering the results of all of its analyses, taken as a whole. No company or transaction used in the above analyses as a comparison is directly comparable to Histogenics, Ocugen or the merger. The reasons for and the circumstances surrounding each of the selected companies and transactions analyzed were diverse and there are inherent differences in the business, operations, financial condition and prospects of Ocugen or Histogenics, as applicable, and the companies included in those analyses.

Canaccord Genuity prepared these analyses for purposes of providing its opinion to the Histogenics Board as to the fairness, from a financial point of view and as of the date of the opinion, to Histogenics of the exchange ratio. These analyses do not purport to be appraisals, nor do they necessarily reflect the prices at which businesses or securities actually may be sold.

The exchange ratio was determined through negotiations between Histogenics and Ocugen and was approved by the Histogenics Board. Canaccord Genuity provided advice to the Histogenics Board during these negotiations. Canaccord Genuity, however, did not recommend any specific amount of consideration to Histogenics or the Histogenics Board or that any specific amount of consideration constituted the only appropriate consideration for the merger.

As described above, Canaccord Genuity's opinion to the Histogenics Board was one of many factors taken into consideration by the Histogenics Board in making its determination to approve the Merger Agreement. The foregoing summary does not purport to be a complete description of the factors considered or financial analyses performed by Canaccord Genuity in connection with its opinion and is qualified in its entirety by reference to the full text of the written opinion of Canaccord Genuity attached to this proxy statement/prospectus/information statement as *Annex B*. The issuance of Canaccord Genuity's opinion was approved by a fairness committee of Canaccord Genuity.

Canaccord Genuity, as part of its investment banking activities, is regularly engaged in the valuation of businesses and their securities in connection with mergers and acquisitions, negotiated underwritings, secondary distributions of listed and unlisted securities, private placements and valuations for corporate and other purposes. In the ordinary course of these activities and services, Canaccord Genuity and its affiliates may acquire, hold or sell, for its and its affiliates' own accounts and the accounts of customers, equity, debt and other securities and financial instruments (including bank loans and other obligations) of Histogenics.

In the two years prior to the date of its opinion, Canaccord Genuity had not provided investment banking or other financial services of a material nature to either Histogenics or Ocugen, except as related to the merger and



otherwise described below. During such two-year period, Canaccord Genuity (i) acted as sole book-running manager for an approximately \$5.5 million registered direct equity offering of Histogenics in January 2018, (ii) acted as underwriter for an approximately \$17.0 million follow-on equity offering of Histogenics in October 2018, and (iii) was party to an Equity Distribution Agreement with Histogenics with respect to at-the-market offerings, for which services Canaccord Genuity received an aggregate amount of approximately \$1.2 million plus reimbursement of expenses. Canaccord Genuity may provide investment banking services to Histogenics, Ocugen or their respective affiliates in the future for which Canaccord Genuity may receive compensation.

The Histogenics Board selected Canaccord Genuity as its financial advisor because it is a nationally recognized investment banking firm that has substantial experience in transactions similar to the merger. Pursuant to a letter agreement, dated as of October 1, 2018 and amended as of June 13, 2019, Histogenics engaged Canaccord Genuity to act as its financial advisor in connection with various financial and strategic matters, including the merger, and the delivery of a fairness opinion as described above. Pursuant to the terms of the engagement letter, Histogenics agreed to pay Canaccord Genuity a fee of \$1.4 million for its services, of which \$30,000 was payable upon signing of the engagement letter, \$300,000 was payable upon delivery by Canaccord Genuity of its opinion dated April 5, 2019 and the public announcement of the merger, \$50,000 was payable upon delivery by Canaccord Genuity of its opinion dated June 13, 2019, and the remainder of which is contingent upon consummation of the merger. In addition, Histogenics has agreed to reimburse Canaccord Genuity for certain expenses and to indemnify Canaccord Genuity and related persons against various liabilities relating to or arising out of its engagement.

#### **Interests of Histogenics Directors and Executive Officers in the Merger**

In considering the recommendation of the Histogenics Board with respect to issuing shares of Histogenics common stock as contemplated by the Merger Agreement and the other matters to be acted upon by Histogenics' stockholders at the Histogenics special meeting, Histogenics' stockholders should be aware that certain members of the Histogenics Board and certain of Histogenics' executive officers have interests in the merger that may be different from, or in addition to, the interests of Histogenics' stockholders. These interests may present them with actual or potential conflicts of interest, and these interests, to the extent material, are described below.

Each of the Histogenics Board and the Ocugen Board was aware of these potential conflicts of interest and considered them, among other matters, in reaching their respective decisions to approve the Merger Agreement and the merger, and to recommend, as applicable, that Histogenics' stockholders approve the proposals to be presented to Histogenics' stockholders for consideration at the Histogenics special meeting as contemplated by this proxy statement/prospectus/information statement, and that Ocugen's stockholders sign and return the written consent as contemplated by this proxy statement/prospectus/information statement.

#### **Security Ownership of Certain Beneficial Owners and Management**

As of June 30, 2019, Histogenics' directors and named executive officers beneficially owned, in the aggregate, less than one percent of the shares of common stock of Histogenics, which for purposes of this subsection excludes any Histogenics shares issuable upon exercise or settlement of Histogenics stock options or warrants held by such individual. The affirmative vote of the holders of a majority of the total outstanding shares of common stock of Histogenics is required for approval of Proposal Nos. 2, 3 and 4. Approval of Proposal Nos. 1, 5 and 6 require the affirmative vote of the holders of a majority of the shares of Histogenics common stock entitled to vote and present in person or represented by proxy at the Histogenics special meeting. Abstentions will be counted towards the vote total and will have the same effect as "AGAINST" votes for Proposal Nos. 1, 2, 3, 4, 5 and 6. Broker non-votes will have the same effect as "AGAINST" votes for Proposal Nos. 2, 3 and 4. For Proposal Nos. 1, 5 and 6, broker non-votes will have no effect and will not be counted towards the vote total, but will be used to determine whether a quorum is present at the Histogenics special meeting.

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The table below sets forth information regarding the ownership of Histogenics common stock as of June 30, 2019 by Histogenics' directors and named executive officers:

<u>Directors and Named Executive Officers</u>	<u>Number of Shares Beneficially Owned</u>
Joshua Baltzell	—
David Gill(1)	14,000
David C. Hood(2)	—
Susan Washer	—
Adam Gridley(3)	7,000
Stephen Kennedy (4)	—
Jonathan Lieber(5)	5,000
Donald Haut(6)	—
All current executive officers and directors as a group (5 persons)(7)	12,000

- (1) Mr. Gill resigned from the Histogenics Board and all committees thereof effective July 18, 2019.
- (2) Mr. Hood was appointed to the Histogenics Board on July 19, 2019. Due to the pending merger, the Histogenics Board suspended the equity portion of Histogenics' amended and restated non-employee director compensation policy and Mr. Hood will not receive an equity grant thereunder.
- (3) Pursuant to a reduction in force approved by the Histogenics Board in March 2019, Mr. Gridley's employment with Histogenics terminated effective March 22, 2019.
- (4) Pursuant to a reduction in force approved by the Histogenics Board in March 2019, Mr. Kennedy's employment with Histogenics terminated effective March 22, 2019.
- (5) Mr. Lieber resigned as Histogenics' Chief Financial Officer effective December 21, 2018. Mr. Lieber was appointed as Histogenics' interim chief financial officer pursuant to a consulting agreement between Histogenics and Danforth Advisors, LLC on December 21, 2018.
- (6) Pursuant to a reduction in force approved by the Histogenics Board in January 2019, Dr. Haut's employment with Histogenics terminated effective January 23, 2019.
- (7) Excludes shares owned by Mr. Gill as he resigned from the Histogenics Board and all committees thereof effective July 18, 2019.

### ***Effect of Merger on Histogenics' Stock Options***

Under the Merger Agreement, as of immediately prior to the Effective Time, each unexpired and unexercised option to purchase common stock of Histogenics, whether vested or unvested, shall be cancelled for no consideration effective as of immediately prior to the Effective Time in accordance with Histogenics' equity incentive plans.

Based on a per share Histogenics stock price of \$ \_\_\_\_\_, none of the executive officers or directors would receive any amount, net of exercise price, if such individual exercised his or her unvested options that would have vested at the time of closing and immediately sold the common stock of Histogenics acquired upon exercise if such option to purchase common stock had not been cancelled.

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The table below sets forth information regarding the Histogenics stock options held by each of Histogenics' executive officers and directors as of June 30, 2019 (all of which will be cancelled for no consideration immediately prior to the Effective Time).

<u>Name</u>	<u>Number of Vested Company Stock Options Held</u>	<u>Number of Unvested Company Stock Options Held</u>
<b><i>Executive Officers</i></b>		
Adam Gridley	643,300	—
Jonathan Lieber	136,124	—
<b><i>Non-Employee Directors</i></b>		
Joshua Baltzell	80,000	—
David Gill(1)	80,000	—
Susan Washer	7,291	17,709

- (1) Mr. Gill resigned from the Histogenics Board and all committees thereof effective July 18, 2019. Mr. Hood was appointed to the Histogenics Board on July 19, 2019. Due to the pending merger, the Histogenics Board suspended the equity portion of Histogenics' amended and restated non-employee director compensation policy and Mr. Hood will not receive an equity grant thereunder.

### **Interests of Ocugen Directors and Executive Officers in the Merger**

In considering the recommendation of the Ocugen Board with respect to adopting the Merger Agreement, Ocugen's stockholders should be aware that members of the Ocugen Board and the executive officers of Ocugen may have interests in the merger that may be different from, or in addition to, the interests of Ocugen's stockholders. Each of the Histogenics Board and the Ocugen Board was aware of these potential conflicts of interest and considered them, among other matters, in reaching their respective decisions to approve the Merger Agreement and the merger, and to recommend, as applicable, that Histogenics' stockholders approve the proposals to be presented to Histogenics' stockholders for consideration at the Histogenics special meeting as contemplated by this proxy statement/prospectus/information statement, and that Ocugen's stockholders sign and return the written consent as contemplated by this proxy statement/prospectus/information statement.

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### **Ownership Interests**

Ocugen's directors and executive officers or entities affiliated with them currently hold shares of Ocugen's capital stock, which such shares of capital stock will be converted into shares of Histogenics common stock at the Effective Time. The table below sets forth the ownership of Ocugen's capital stock as of July 12, 2019 by Ocugen's directors and executive officers and their anticipated ownership of Ocugen common stock immediately prior to the closing of the merger.

	<b>Number of Shares of Capital Stock as of July 12, 2019 and Immediately Prior to the Closing of the Merger</b>
<b><u>Directors and Executive Officers</u></b>	
<b><u>Executive Officers</u></b>	
Shankar Musunuri, Ph.D., MBA(1)	2,868,694
Daniel Jorgensen, M.D., M.P.H., MBA	—
Rasappa Arumugham, Ph.D.	—
Vijay Tammara, Ph.D.	—
Kelly Beck, MBA, SPHR, SHRM-SCP, PMP	—
<b><u>Non-Employee Directors</u></b>	
Uday Kompella, Ph.D.(2)	2,982,983
Ramesh Kumar, Ph.D.	—
Frank Leo	215,104
Manish Potti(3)	257,457
Suha Taspolatoglu, M.D.(4)	1,549,604.5
Junge Zhang(5)	443,985

- (1) Consists of 2,868,694 shares beneficially owned by Shankar Musunuri through KVM Holdings LLC. Dr. Musunuri is a member and officer of KVM Holdings LLC and has voting and investment power over the shares held by KVM Holdings LLC.
- (2) Includes 1,000,000 shares beneficially owned by Uday Kompella, Ph.D. through Kompella LLC. Mr. Kompella has voting and investment power over the shares held by Kompella LLC.
- (3) Consists of 257,457 shares beneficially owned by Manish Potti through Scotland Parkway LLC. Mr. Potti is a managing member of Scotland Parkway LLC and has voting and investment power over the shares held by Scotland Parkway LLC.
- (4) Consists of 1,549,604.5 shares beneficially owned by Suha Taspolatogula, M.D. through Abdi Ibrahim Uluslararası İlaç Yatırımları Sanayi ve Ticaret A.Ş. Dr. Taspolatogula is the Chief Executive Officer of Abdi and has voting and investment power over the shares held by Abdi.
- (5) Consists of 443,985 shares beneficially owned by Junge Zhang through Gupiao Trust. Mr. Zhang is the beneficiary of Gupiao Trust and has voting and investment power over the shares held by Gupiao Trust.

### **Treatment of Ocugen Options and Warrants**

Under the Merger Agreement, at the Effective Time, each outstanding and unexercised option or warrant to purchase shares of Ocugen's capital stock as of immediately prior to the Effective Time, whether or not vested, shall be converted into and become an option or warrant, as applicable, to purchase shares of Histogenics common stock, in accordance with the terms and conditions of such Ocugen option or warrant, as applicable, immediately prior to the Effective Time.

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Certain of Ocugen's directors and executive officers currently hold options, subject to vesting, to purchase shares of Ocugen common stock. The table below sets forth certain information with respect to such options.

<u>Option Holder Name</u>	<u>Grant Date</u>	<u>Expiration Date</u>	<u>Exercise Price (\$)</u>	<u>Number of Shares of Common Stock Underlying Option as of March 31, 2019</u>	<u>Number of Vested Shares of Common Stock Underlying Option as of March 31, 2019</u>
<b><i>Executive Officers</i></b>					
Shankar Musunuri, Ph.D., MBA	08/26/2015	08/26/2025	0.900	180,000	180,000
Daniel Jorgensen, M.D., M.P.H., MBA	04/17/2017	04/17/2027	3.020	54,000	18,000
	12/15/2017	12/15/2027	3.624	14,000	4,667
	07/23/2018	07/23/2028	5.840	5,000	—
	12/07/2018	12/07/2028	6.480	20,000	—
Rasappa Arumugham, Ph.D.	03/22/2017	03/22/2027	3.020	48,000	32,000
	12/15/2017	12/15/2027	3.624	20,000	6,667
	07/23/2018	07/23/2028	5.840	5,000	—
	12/07/2018	12/07/2028	6.480	20,000	—
	03/22/2017	03/22/2027	3.020	48,000	32,000
Vijay Tammara, Ph.D.	09/18/2014	09/18/2024	0.220	38,000	38,000
	04/26/2016	04/26/2026	1.410	15,000	15,000
	08/17/2017	08/17/2027	3.624	15,000	5,000
	12/15/2017	12/15/2027	3.624	15,000	5,000
	07/23/2018	07/23/2028	5.840	5,000	5,000
	12/07/2018	12/07/2028	6.480	20,000	20,000
Kelly Beck, MBA, SPHR, SHRM-SCP, PMP	07/10/2017	07/10/2027	3.624	30,000	10,000
	12/15/2017	12/15/2027	3.624	25,000	8,333
	12/07/2018	12/07/2028	6.480	20,000	—
<b><i>Non-Employee Directors</i></b>					
Uday Kompella, Ph.D.	08/26/2015	08/26/2025	0.900	15,000	15,000
Ramesh Kumar, Ph.D.	—	—	—	—	—
Frank Leo	06/16/2016	06/16/2026	1.410	30,000	30,000
Manish Potti	—	—	—	—	—
Suha Taspolatoglu, M.D.	—	—	—	—	—
Junge Zhang	—	—	—	—	—

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Certain of Ocugen's directors and executive officers currently hold warrants to purchase shares of Ocugen common stock. The table below sets forth certain information with respect to such warrants.

<u>Warrant Holder Name</u>	<u>Issue Date</u>	<u>Expiration Date</u>	<u>Exercise Price (\$)</u>	<u>Number of Shares of Common Stock Underlying Warrant as of March 31, 2019</u>
<b>Executive Officers</b>				
Shankar Musunuri, Ph.D., MBA	12/08/2016	12/08/2026	2.420	845(1)
	09/14/2017	09/14/2027	3.624	15,000
Daniel Jorgensen, M.D., M.P.H., MBA	—	—	—	—
Rasappa Arumugham, Ph.D.	—	—	—	—
Vijay Tammara, Ph.D.	—	—	—	—
Kelly Beck, MBA, SPHR, SHRM-SCP, PMP	—	—	—	—
<b>Non-Employee Directors</b>				
Uday Kompella, Ph.D.	12/08/2016	12/08/2026	2.420	739
Ramesh Kumar, Ph.D.	—	—	—	—
Frank Leo	12/08/2016	12/08/2026	2.420	2,641
	05/23/2017	05/23/2027	3.624	6,898
Manish Potti	11/23/2016	11/23/2026	3.020	4,139(2)
	12/15/2016	12/15/2026	3.020	200,000(2)
Suha Taspolatoglu, M.D.	06/01/2017	06/01/2027	3.624	41,391(3)
Junge Zhang	01/10/2015	01/10/2025	1.330	300,000(4)
	09/15/2017	06/12/2017	1.330	3,449(4)

- (1) Warrants are beneficially owned by Shankar Musunuri through KVM Holdings LLC.
- (2) Warrants are beneficially owned by Manish Potti through Scotland Parkway LLC.
- (3) Warrants are beneficially owned by Suha Taspolatoglu, M.D. through Abdi Ibrahim Uluslararası İlaç Yatırımları Sanayi ve Ticaret A.Ş.
- (4) Warrants are beneficially owned by Junge Zhang through Gupiao Trust.

### **Management Prior to and Following the Merger**

As described elsewhere in this proxy statement/prospectus/information statement, including in the section captioned "Management Prior to and Following the Merger," Ocugen's directors and executive officers are expected to become the directors and executive officers of Histogenics upon the closing of the merger.

### **Indemnification and Insurance**

Under the Merger Agreement, from the Effective Time through the sixth anniversary of the date on which the Effective Time occurs, Histogenics and Ocugen, as the surviving corporation in the merger, shall indemnify and hold harmless each person who is or has served as a director, officer, fiduciary or agent of Histogenics or Ocugen against all claims, losses, liabilities, damages, judgments, fines and reasonable fees, costs and expenses, including attorneys' fees and disbursements, incurred in connection with any claim, action, suit, proceeding or investigation, whether civil, criminal, administrative or investigative, arising out of or pertaining to the fact that such person is or was a director or officer of Histogenics or Ocugen, to the fullest extent permitted under the DGCL for directors or officers of Delaware corporations. In addition, each such director and officer, or former director and officer, is entitled to advancement of expenses incurred in the defense of any such claim, action, suit, proceeding or investigation.

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Under the Merger Agreement, the provisions of Histogenics' sixth amended restated certificate of incorporation and amended and restated bylaws with respect to indemnification, advancement of expenses and exculpation of present and former directors and officers of Histogenics shall not be amended, modified or repealed for a period of six years from the Effective Time in a manner that would adversely affect the rights thereunder of individuals who, at or prior to the Effective Time, were officers or directors of Histogenics. The certificate of incorporation and bylaws of Ocugen, as the surviving corporation in the merger, shall contain provisions no less favorable with respect to indemnification, advancement of expenses and exculpation of former and present directors and officers that are presently set forth in the sixth amended and restated certificate of incorporation and amended and restated bylaws of Histogenics.

The Merger Agreement also provides that Histogenics shall maintain directors' and officers' liability insurance policies commencing at the closing time of the merger, on commercially available terms and conditions with coverage limits customary for U.S. public companies similar situated to Histogenics.

### **Limitations of Liability and Indemnification**

In addition to the indemnification obligations required by the sixth amended and restated certificate of incorporation and amended and restated bylaws of Histogenics, Histogenics has entered into indemnification agreements with each of its directors and officers. These agreements provide for the indemnification of Histogenics' directors and executive officers for all reasonable expenses and liabilities incurred in connection with any action or proceeding brought against them by reason of the fact that they are or were agents of Histogenics. Histogenics believes that these sixth amended and restated certificate of incorporation provisions, amended and restated bylaw provisions and indemnification agreements are necessary to attract and retain qualified persons as directors and officers.

### **Ocugen Stock Options and Warrants**

As of July 12, 2019, an aggregate of 1,258,451 shares of Ocugen common stock were issuable upon the exercise of outstanding stock options under the Ocugen, Inc. 2014 Stock Option Plan at a weighted-average exercise price of \$2.77 per share. At the Effective Time, each Ocugen option that is outstanding and unexercised immediately prior to the Effective Time under the Ocugen, Inc. 2014 Stock Option Plan, whether or not vested, will be converted into and become an option to purchase shares of Histogenics common stock, and Histogenics will assume the Ocugen, Inc. 2014 Stock Option Plan and each such Ocugen option in accordance with the terms of the Ocugen, Inc. 2014 Stock Option Plan and the terms of the stock option agreement by which such Ocugen option is evidenced.

As of July 12, 2019, an aggregate of 1,841,811 shares of Ocugen common stock were issuable upon the exercise of outstanding warrants at an average exercise price of \$3.04 per share. At the Effective Time, each Ocugen warrant that is outstanding and unexercised will become a warrant to purchase shares of Histogenics common stock and Histogenics will assume each Ocugen warrant in accordance with its terms.

### **Form of the Merger**

The Merger Agreement provides that at the Effective Time, Merger Sub will be merged with and into Ocugen. Upon the consummation of the merger, Ocugen will continue as the surviving corporation and will be a wholly-owned subsidiary of Histogenics.

After completion of the merger, assuming Proposal No. 3 is approved by Histogenics' stockholders at the Histogenics special meeting, Histogenics will be renamed "Ocugen, Inc." and expects to trade on Nasdaq under the symbol "OCGN."

## Merger Consideration

At the Effective Time:

- each share of Ocugen common stock outstanding immediately prior to the Effective Time (excluding shares to be canceled pursuant to the Merger Agreement, and shares held by stockholders who have exercised and perfected appraisal rights as more fully described in the section entitled “The Merger—Appraisal Rights” below) will be converted into the right to receive 28.7650 shares of Histogenics common stock, subject to adjustment for the Histogenics Reverse Stock Split (the “exchange ratio”).
- each option to purchase shares of Ocugen common stock outstanding and unexercised immediately prior to the Effective Time will be assumed by Histogenics and will become an option, subject to vesting, to purchase shares of Histogenics common stock with the number of shares of Histogenics common stock underlying such options and the exercise prices for such options adjusted to reflect the exchange ratio and the Histogenics Reverse Stock Split; and
- each warrant to purchase shares of Ocugen’s capital stock outstanding and not terminated or exercised as of immediately prior to the Effective Time will be assumed by Histogenics and will become a warrant to purchase shares of Histogenics common stock with the number of shares of Histogenics common stock underlying such warrants and the exercise prices for such warrants adjusted to reflect the exchange ratio and the Histogenics Reverse Stock Split.

Immediately following the merger, after giving effect to the Pre-Merger Financing, based on the exchange ratio of 28.7650, current holders of Ocugen’s capital stock and options and warrant to purchase shares of Ocugen common stock, are expected to own, or hold rights to acquire, in the aggregate approximately 86.24% of the Fully-Diluted Common Stock of Histogenics, and Histogenics’ current stockholders and warrant holders are expected to own, or hold rights to acquire, in the aggregate approximately 13.76% of the Fully-Diluted Common Stock of Histogenics.

The Merger Agreement does not include a price-based termination right, and there will be no adjustment to the total number of shares of Histogenics common stock that Ocugen’s stockholders will be entitled to receive for changes in the market price of Histogenics common stock. Accordingly, the market value of the shares of Histogenics common stock issued pursuant to the merger will depend on the market value of the shares of Histogenics common stock at the time the merger closes, and could vary significantly from the market value on the date of this proxy statement/prospectus/information statement.

No fractional shares of Histogenics common stock will be issuable to Ocugen’s stockholders pursuant to the merger. Instead, each stockholder of Ocugen who would otherwise be entitled to receive a fraction of a share of Histogenics common stock, after aggregating all fractional shares of Histogenics common stock issuable to such stockholder, will be entitled to receive in cash the dollar amount, rounded to the nearest whole cent, without interest, determined by multiplying such fraction by the volume weighted-average closing trading price of a share of Histogenics common stock on Nasdaq for the five consecutive trading days ending five trading days immediately prior to the date upon which the merger becomes effective.

The Merger Agreement provides that, at the Effective Time, Histogenics will deposit with an exchange agent acceptable to Histogenics and Ocugen certificates or evidence of book-entry shares representing the shares of Histogenics common stock issuable to Ocugen’s stockholders and a sufficient amount of cash to make payments in lieu of fractional shares.

The Merger Agreement provides that, promptly after the Effective Time, the exchange agent will mail to each record holder of Ocugen capital stock immediately prior to the Effective Time a letter of transmittal and instructions for surrendering and exchanging Ocugen stock certificates held by such record holder in exchange for certificates or book-entry shares of Histogenics common stock. Upon surrender of an Ocugen stock certificate for exchange to the exchange agent, together with a duly signed letter of transmittal and such other documents as



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the exchange agent or Histogenics may reasonably require, the Ocugen stock certificate surrendered will be cancelled and the holder of such Ocugen stock certificate will be entitled to receive the following:

- a certificate or certificates or book-entry shares representing the number of whole shares of Histogenics common stock that such holder has the right to receive pursuant to the provisions of the Merger Agreement, and
- cash in lieu of any fractional share of Histogenics common stock.

From and after the Effective Time, until it is surrendered, each certificate that previously evidenced shares of Ocugen common stock will be deemed to represent only the right to receive shares of Histogenics common stock, and cash in lieu of any fractional share of Histogenics common stock.

If any Ocugen stock certificate has been lost, stolen or destroyed, Histogenics may, in its discretion, and as a condition precedent to the delivery of any book-entry shares of Histogenics common stock, require the owner of such lost, stolen or destroyed certificate to provide an affidavit claiming such certificate has been lost, stolen or destroyed and that includes an obligation of such owner to indemnify Histogenics against any claim suffered by Histogenics related to the lost, stolen or destroyed Ocugen stock certificate as Histogenics may reasonably request.

Histogenics will not pay dividends or other distributions on any shares of Histogenics common stock to be issued in exchange for shares of Ocugen's capital stock represented by any unsurrendered Ocugen stock certificate until such Ocugen stock certificate is surrendered as provided in the Merger Agreement.

### **Effective Time of the Merger**

The Merger Agreement requires the parties to consummate the merger as promptly as practicable (and in any event within two business days) after all of the conditions to the consummation of the merger contained in the Merger Agreement are satisfied or waived. The merger will become effective upon the filing of a certificate of merger with the Secretary of State of the State of Delaware or at such later time as is agreed by Histogenics and Ocugen and specified in the certificate of merger. Neither Histogenics nor Ocugen can predict the exact timing of the consummation of the merger.

### **Regulatory Approvals**

In the United States, Histogenics must comply with applicable federal and state securities laws and the rules and regulations of The Nasdaq Capital Market in connection with the issuance of shares of Histogenics common stock and the filing of this proxy statement/prospectus/information statement with the SEC.

### **Tax Treatment of the Merger**

Histogenics and Ocugen desire that the merger qualify as a "reorganization" within the meaning of Section 368(a) of the Code. Histogenics and Ocugen have agreed to use their commercially reasonable efforts to cause the merger to qualify as a reorganization under Section 368(a) of the Code, and to not take any actions that would reasonably be expected to prevent the merger from so qualifying. Pursuant to the Merger Agreement, Histogenics, Merger Sub and Ocugen acknowledged and agreed that each has relied upon the advice of its own tax advisors in connection with the merger and that none of Histogenics, Merger Sub and Ocugen makes any representation or warranty as to the tax treatment of the merger. For a description of certain of the considerations regarding U.S. federal tax consequences of the merger, see the section entitled "The Merger—Material U.S. Federal Income Tax Consequences of the Merger" below.

### **Material U.S. Federal Income Tax Consequences of the Merger**

The following discussion is a summary of the material U.S. federal income tax consequences of the merger to U.S. Holders (as defined below) who exchange their Ocugen common stock for Histogenics common stock in the

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merger, but does not purport to be a complete analysis of all potential tax effects. The effects of other U.S. federal tax laws, such as estate and gift tax laws, and any applicable state, local or non-U.S. tax laws are not discussed. This discussion is based on the Code, Treasury Regulations promulgated thereunder, judicial decisions, and published rulings and administrative pronouncements of the IRS, in each case in effect as of the date hereof. These authorities may change or be subject to differing interpretations. Any such change or differing interpretation may be applied retroactively in a manner that could adversely affect a U.S. Holder. Neither Histogenics nor Ocugen has sought or intend to seek any rulings from the IRS regarding the matters discussed below. There can be no assurance the IRS or a court will not take a position regarding the tax consequences of the merger contrary to that discussed below. This discussion assumes that the merger will be consummated in accordance with the Merger Agreement and as described in this proxy statement/prospectus/information statement.

This discussion is limited to U.S. Holders that hold Ocugen common stock as a “capital asset” within the meaning of Section 1221 of the Code (generally, property held for investment). This discussion does not address all U.S. federal income tax consequences relevant to a U.S. Holder’s particular circumstances, including the impact of the alternative minimum tax or the Medicare contribution tax on net investment income. In addition, it does not address consequences relevant to U.S. Holders subject to special rules, including, without limitation:

- U.S. expatriates and former citizens or long-term residents of the United States;
- U.S. Holders whose functional currency is not the U.S. dollar;
- persons holding Ocugen common stock as part of a hedge, straddle or other risk reduction strategy or as part of a conversion transaction or other integrated investment;
- banks, insurance companies, and other financial institutions;
- real estate investment trusts or regulated investment companies;
- brokers, dealers or traders in securities;
- “controlled foreign corporations,” “passive foreign investment companies,” and corporations that accumulate earnings to avoid U.S. federal income tax;
- S corporations, partnerships or other entities or arrangements treated as partnerships for U.S. federal income tax purposes (and investors therein);
- persons for whom Ocugen common stock constitutes “qualified small business stock” within the meaning of Section 1202 of the Code;
- tax-exempt organizations or governmental organizations;
- persons subject to special tax accounting rules as a result of any item of gross income with respect to Ocugen common stock being taken into account in an “applicable financial statement” (as defined in the Code);
- persons deemed to sell Ocugen common stock under the constructive sale provisions of the Code;
- persons who hold or received Ocugen common stock pursuant to the exercise of any employee stock option or otherwise as compensation; and
- tax-qualified retirement plans.

If an entity treated as a partnership for U.S. federal income tax purposes holds Ocugen common stock, the tax treatment of a partner in the partnership will depend on the status of the partner, the activities of the partnership and certain determinations made at the partner level. Accordingly, partnerships holding Ocugen common stock and the partners in such partnerships should consult their tax advisors regarding the U.S. federal income tax consequences to them.

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THIS DISCUSSION IS FOR INFORMATION PURPOSES ONLY AND IS NOT TAX ADVICE. HOLDERS SHOULD CONSULT THEIR TAX ADVISORS WITH RESPECT TO THE APPLICATION OF THE U.S. FEDERAL INCOME TAX LAWS TO THEIR PARTICULAR SITUATIONS AS WELL AS ANY TAX CONSEQUENCES OF THE MERGER ARISING UNDER THE U.S. FEDERAL ESTATE OR GIFT TAX LAWS OR UNDER THE LAWS OF ANY STATE, LOCAL OR NON-U.S. TAXING JURISDICTION OR UNDER ANY APPLICABLE INCOME TAX TREATY.

For purposes of this discussion, a U.S. Holder is a beneficial owner of Ocugen common stock that, for U.S. federal income tax purposes, is or is treated as:

- an individual who is a citizen or resident of the United States;
- a corporation created or organized under the laws of the United States, any state thereof, or the District of Columbia;
- an estate, the income of which is subject to U.S. federal income tax regardless of its source; or
- a trust that (i) is subject to the primary supervision of a U.S. court and the control of one or more “United States persons” (within the meaning of Section 7701(a)(30) of the Code) over all of its substantial decisions or (ii) has a valid election in effect to be treated as a United States person for U.S. federal income tax purposes.

### ***U.S. Federal Income Tax Consequences of the Merger to U.S. Holders of Ocugen Common Stock***

Histogenics and Ocugen desire that the merger should qualify as a “reorganization” within the meaning of Section 368(a) of the Code.

Accordingly,:

- a U.S. Holder of shares of Ocugen common stock generally should not recognize any gain or loss upon the exchange of shares of Ocugen common stock for shares of Histogenics common stock in the merger, except with respect to cash received in lieu of fractional shares (as discussed below);
- a U.S. Holder of shares of Ocugen common stock should have a tax basis in the shares of Histogenics common stock received in the merger (including fractional shares deemed received and redeemed as described below) equal to the tax basis of the shares of Ocugen common stock surrendered in exchange therefor;
- a U.S. Holder of shares of Ocugen common stock should have a holding period for the shares of Histogenics common stock received in the merger (including fractional shares deemed received and redeemed as described below) that includes its holding period for its shares of Ocugen common stock surrendered in exchange therefor; and
- if a U.S. Holder of shares of Ocugen common stock acquired different blocks of shares of Ocugen common stock at different times or at different prices, the shares of Histogenics common stock received in the merger (including fractional shares deemed received and redeemed as described below) should be allocated pro rata to each block of shares of Ocugen common stock, and the basis and holding period of such shares of Histogenics common stock should be determined on a block-for-block approach depending on the basis and holding period of each block of shares of Ocugen common stock exchanged for such shares of Histogenics common stock.

### ***Cash in Lieu of Fractional Shares***

A U.S. Holder that receives cash in lieu of a fractional share of Histogenics common stock generally will be treated as having received such fractional share and then as having received such cash in redemption of the fractional share. Gain or loss generally will be recognized based on the difference between the amount of cash

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received in lieu of the fractional share of Histogenics common stock and the portion of the U.S. Holder's aggregate adjusted tax basis in the shares of Ocugen common stock surrendered which is allocable to the fractional share of Histogenics common stock deemed received. Such gain or loss generally will be long-term capital gain or loss if the U.S. Holder's holding period for its shares of Ocugen common stock exceeds one year at the Effective Time.

### ***Tax Consequences if the Merger Fails to Qualify as a Reorganization***

If the merger does not qualify as a "reorganization" within the meaning of Section 368(a) of the Code, a U.S. Holder of Ocugen common stock generally would recognize gain or loss for U.S. federal income tax purposes on each share of Ocugen common stock surrendered in the merger in an amount equal to the difference between the fair market value, at the time of the merger, of the Histogenics common stock received in the merger (including any cash received in lieu of a fractional share) and such U.S. Holder's tax basis in the Ocugen common stock surrendered in the merger. Gain or loss must be calculated separately for each block of Ocugen common stock exchanged by such U.S. Holder if such blocks were acquired at different times or for different prices. Any gain or loss recognized generally would be capital gain or loss, and generally would be long-term capital gain or loss if the U.S. Holder's holding period in a particular block of Ocugen common stock exceeds one year at the effective time of the merger. Long-term capital gain of non-corporate U.S. Holders (including individuals) generally is taxed at reduced U.S. federal income tax rates. The deductibility of capital losses is subject to limitations. A U.S. Holder's tax basis in shares of Histogenics common stock received in the merger would be equal to the fair market value thereof as of the effective time of the merger, and such U.S. Holder's holding period in such shares would begin on the day following the merger.

### ***Information Reporting and Backup Withholding***

If the merger qualifies as a "reorganization" under Section 368(a) of the Code, current Treasury Regulations require certain U.S. Holders who are "significant holders" of Ocugen common stock (generally, a U.S. Holder that owns at least 1% of the outstanding Ocugen common stock or has a basis in Ocugen non-stock securities of at least \$1,000,000 immediately before the merger) to comply with certain reporting requirements. Significant holders generally will be required to file a statement with their U.S. federal income tax returns for the taxable year in which the merger occurs setting forth certain information with respect to the transaction. U.S. Holders should consult their tax advisors to determine whether they are significant holders required to provide the foregoing statement. In addition, a U.S. Holder may be subject to information reporting and backup withholding when such holder receives cash in lieu of fractional shares of Histogenics common stock in the merger. Certain U.S. Holders are exempt from backup withholding, including corporations and certain tax-exempt organizations. A U.S. Holder will be subject to backup withholding if such holder is not otherwise exempt and:

- the holder fails to furnish the holder's taxpayer identification number, which for an individual is ordinarily his or her social security number;
- the holder furnishes an incorrect taxpayer identification number;
- the applicable withholding agent is notified by the IRS that the holder previously failed to properly report payments of interest or dividends; or
- the holder fails to certify under penalties of perjury that the holder has furnished a correct taxpayer identification number and that the IRS has not notified the holder that the holder is subject to backup withholding.

Backup withholding is not an additional tax. Any amounts withheld under the backup withholding rules may be allowed as a refund or a credit against a U.S. Holder's U.S. federal income tax liability, provided the required information is timely furnished to the IRS. U.S. Holders should consult their tax advisors regarding their qualification for an exemption from backup withholding and the procedures for obtaining such an exemption.

### **Nasdaq Stock Market Listing**

Histogenics common stock currently is listed on Nasdaq under the symbol “HSGX.” Histogenics has agreed to use commercially reasonable efforts to maintain its existing listing on Nasdaq, to obtain approval for listing on Nasdaq of the shares of Histogenics common stock that Ocugen’s stockholders will be entitled to receive pursuant to the merger and to obtain approval to have the combined company’s common stock listed on Nasdaq. In addition, under the Merger Agreement, each party’s obligation to complete the merger is subject to the satisfaction or waiver by each of the parties, at or prior to the merger, of various conditions, including that the existing shares of Histogenics common stock must have been continually listed on Nasdaq, and Histogenics must have caused the shares of Histogenics common stock to be issued in the merger to be approved for listing on Nasdaq as of the closing of the merger.

Prior to consummation of the merger, Histogenics intends to file an initial listing application with Nasdaq pursuant to Nasdaq “reverse merger” rules. If such application is accepted, Histogenics anticipates that the shares of Histogenics common stock will be listed on Nasdaq following the closing of the merger under the trading symbol “OCGN.”

### **Anticipated Accounting Treatment**

The merger will be recorded by Histogenics as an equity transaction in accordance with U.S. GAAP. For accounting purposes, Ocugen is considered to be acquiring Histogenics in this transaction. The transaction is expected to be accounted for as an equity transaction as Ocugen is exchanging equity for the net monetary assets of Histogenics.

### **Appraisal Rights**

#### ***Delaware Law***

If the merger is completed, Ocugen’s stockholders who do not deliver a written consent approving the merger are entitled to appraisal rights under Section 262 of the DGCL (“Section 262”), *provided* that they comply with the conditions established by Section 262. Holders of Histogenics common stock are not entitled to dissenter’s rights under Delaware law or other appraisal rights in connection with the merger.

The discussion below is not a complete summary regarding the appraisal rights of Ocugen’s stockholders under Delaware law and is qualified in its entirety by reference to the text of the relevant provisions of Delaware law, which are attached to this proxy statement/prospectus/information statement as *Annex C*. Stockholders intending to exercise appraisal rights should carefully review *Annex C* of this proxy statement/prospectus/information statement. Failure to follow precisely any of the statutory procedures set forth in *Annex C* of this proxy statement/prospectus/information statement may result in a termination or waiver of these rights. This summary does not constitute legal or other advice, nor does it constitute a recommendation that Ocugen’s stockholders exercise their appraisal rights under Delaware law.

Under Section 262, where a merger is adopted by stockholders by written consent in lieu of a meeting of stockholders pursuant to Section 228 of the DGCL, either the constituent corporation, before the effective date of the merger, or the surviving corporation, within 10 days after the effective date of the merger, must notify each stockholder of the constituent corporation entitled to appraisal rights, if any, of the approval of the merger, the effective date of the merger and that appraisal rights are available.

If the merger is completed, within 10 days after the effective date of the merger Ocugen will notify its stockholders that the merger has been approved, the effective date of the merger and that appraisal rights are available to any stockholder who has not approved the merger, if any. Holders of shares of Ocugen capital stock who desire to exercise their appraisal rights must deliver a written demand for appraisal to Ocugen within 20 days after the date of mailing of that notice, and the stockholder must not have delivered a written consent

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approving the merger. A demand for appraisal must reasonably inform Ocugen of the identity of the stockholder and that such stockholder intends thereby to demand appraisal of the shares of Ocugen capital stock held by such stockholder. Failure to deliver a written consent approving the merger will not in and of itself constitute a written demand for appraisal satisfying the requirements of Section 262. All demands for appraisal should be addressed to Ocugen, Inc., 5 Great Valley Parkway, Suite 160, Malvern, PA 19355, Attention: Kelly Beck; and should be executed by, or on behalf of, the record holder of shares of Ocugen capital stock. **ALL DEMANDS MUST BE RECEIVED BY OCUGEN WITHIN TWENTY (20) DAYS AFTER THE DATE OCUGEN MAILS A NOTICE TO ITS STOCKHOLDERS NOTIFYING THEM THAT THE MERGER HAS BEEN APPROVED, THE EFFECTIVE DATE OF THE MERGER AND THAT APPRAISAL RIGHTS ARE AVAILABLE TO ANY STOCKHOLDER WHO HAS NOT APPROVED THE MERGER, IF ANY.**

If a holder of shares of Ocugen's capital stock fails to deliver a written demand for appraisal within the time period specified above, such holder will be entitled to receive the merger consideration for such holder's shares of Ocugen capital stock as provided for in the Merger Agreement, but will have no appraisal rights with respect to his, her or its shares of Ocugen's capital stock.

To be effective, a demand for appraisal by a holder of shares of Ocugen's capital stock must be made by, or in the name of, the registered stockholder, fully and correctly, as the stockholder's name appears on the stockholder's stock certificate(s). Beneficial owners who do not also hold the shares of record may not directly make appraisal demands to Ocugen. The beneficial owner must, in these cases, have the registered owner, such as a broker, bank or other custodian, submit the required demand in respect of those shares. If shares are owned of record in a fiduciary capacity, such as by a trustee, guardian or custodian, execution of a demand for appraisal should be made by or for the fiduciary; and if the shares are owned of record by more than one person, as in a joint tenancy or tenancy in common, the demand should be executed by or for all joint owners. An authorized agent, including an authorized agent for two or more joint owners, may execute the demand for appraisal for a stockholder of record; however, the agent must identify the record owner or owners and expressly disclose the fact that, in executing the demand, he or she is acting as agent for the record owner. A record owner, such as a broker, who holds shares as a custodian for others, may exercise the record owner's right of appraisal with respect to the shares held for one or more beneficial owners, while not exercising this right for other beneficial owners. In that case, the written demand should state the number of shares as to which appraisal is sought. Where no number of shares is expressly mentioned, the demand will be presumed to cover all shares held in the name of the record owner. In addition, the stockholder must continuously hold the shares of record from the date of making the demand through the Effective Time.

If a holder of shares of Ocugen's capital stock holds shares of Ocugen's capital stock in a brokerage account or in other custodian form and such holder wishes to exercise appraisal rights, such holder should consult with such holder's bank, broker or other custodian to determine the appropriate procedures for the making of a demand for appraisal by the custodian.

At any time within 60 days after the Effective Time, any stockholder who has demanded an appraisal, but has neither commenced an appraisal proceeding or joined an appraisal proceeding as a named party, has the right to withdraw such stockholder's demand and accept the terms of the merger by delivering a written withdrawal to Ocugen. If, following a demand for appraisal, a holder of shares of Ocugen's capital stock who has demanded an appraisal has withdrawn such holder's demand for appraisal in accordance with Section 262, such holder will have the right to receive the merger consideration for such holder's shares of Ocugen capital stock.

Within 120 days after the Effective Time, any stockholder who has delivered a demand for appraisal in accordance with Section 262 will, upon written request to the surviving corporation, be entitled to receive a written statement setting forth the aggregate number of shares not voted in favor of the Merger Agreement and with respect to which demands for appraisal rights have been received and the aggregate number of holders of such shares. This written statement will be mailed to the requesting stockholder within ten days after the stockholder's written request is received by the surviving corporation or within ten days after expiration of the

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period for delivery of demands for appraisal, whichever is later. Within 120 days after the Effective Time, either the surviving corporation or any stockholder who has delivered a demand for appraisal in accordance with Section 262 may file a petition in the Delaware Court of Chancery demanding a determination of the fair value of the shares held by all such stockholders. Upon the filing of the petition by a stockholder, service of a copy of the petition must be made upon the surviving corporation. The surviving corporation has no obligation to file a petition in the Delaware Court of Chancery in the event there are dissenting stockholders, and Ocugen, which is expected to be the surviving corporation, has no present intent to file a petition in the Delaware Court of Chancery. Accordingly, the failure of a stockholder to file a petition within the period specified could nullify the stockholder's previously written demand for appraisal.

If a petition for appraisal is duly filed by a stockholder and a copy of the petition is delivered to the surviving corporation, the surviving corporation will then be obligated, within 20 days after receiving service of a copy of the petition, to provide the Delaware Court of Chancery with a duly verified list containing the names and addresses of all stockholders who have demanded an appraisal of their shares and with whom agreements as to the value of their shares have not been reached by the surviving corporation. After notice to dissenting stockholders who demanded appraisal of their shares, if any, the Delaware Court of Chancery is empowered to conduct a hearing upon the petition, and to determine those stockholders who have complied with Section 262 and who have become entitled to the appraisal rights provided thereby. The Delaware Court of Chancery may require the stockholders who have demanded appraisal for their shares to submit their stock certificates to the Register in Chancery for notation thereon of the pendency of the appraisal proceedings; and if any stockholder fails to comply with that direction, the Delaware Court of Chancery may dismiss the proceedings as to that stockholder. If immediately before the merger the shares of the class or series of stock as to which appraisal rights are available were listed on a national securities exchange, the Delaware Court of Chancery will dismiss the proceedings as to all holders of such shares who are otherwise entitled to appraisal rights unless (1) the total number of shares entitled to appraisal exceeds 1% of the outstanding shares of the class or series eligible for appraisal, (2) the value of the consideration provided in the merger for such total number of shares exceeds \$1.0 million or (3) the merger was approved pursuant to Sections 253 or 267 of the DGCL.

After determination of the stockholders entitled to appraisal of their shares, the Delaware Court of Chancery will appraise the "fair value" of the shares owned by those stockholders. This value will be exclusive of any element of value arising from the accomplishment or expectation of the merger, but may include a fair rate of interest, if any, upon the amount determined to be the fair value. At any time before the entry of judgment in the proceedings, the surviving corporation may pay to each shareowner entitled to appraisal an amount in cash, in which case interest shall accrue thereafter only upon the sum of (1) the difference, if any, between the amount paid and the fair value of the shares as determined by the Delaware Court of Chancery, and (2) interest theretofore accrued, unless paid at that time. When the value is determined, the Delaware Court of Chancery will direct the payment of the value, with interest thereon accrued during the pendency of the proceeding, if the Delaware Court of Chancery so determines, to the stockholders entitled to receive the same, upon surrender by the holders of the certificates representing those shares.

In determining fair value, and, if applicable, a fair rate of interest, the Delaware Court of Chancery is required to take into account all relevant factors. In *Weinberger v. UOP, Inc.*, the Delaware Supreme Court discussed the factors that could be considered in determining fair value in an appraisal proceeding, stating that "proof of value by any techniques or methods which are generally considered acceptable in the financial community and otherwise admissible in court" should be considered, and that "fair price obviously requires consideration of all relevant factors involving the value of a company."

Section 262 provides that fair value is to be "exclusive of any element of value arising from the accomplishment or expectation of the merger." In *Cede & Co. v. Technicolor, Inc.*, the Delaware Supreme Court stated that this exclusion is a "narrow exclusion [that] does not encompass known elements of value," but which rather applies only to the speculative elements of value arising from such accomplishment or expectation. In *Weinberger*, the Delaware Supreme Court construed Section 262 to mean that "elements of future value, including the nature of

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the enterprise, which are known or susceptible of proof as of the date of the merger and not the product of speculation, may be considered.”

Holders of shares of Ocugen’s capital stock should be aware that the fair value of such holder’s shares as determined under Section 262 could be more than, the same as, or less than the value that such holder is entitled to receive under the terms of the Merger Agreement.

Costs of the appraisal proceeding may be imposed upon the surviving corporation and the stockholders participating in the appraisal proceeding by the Delaware Court of Chancery as the Court deems equitable in the circumstances. Upon the application of a stockholder, the Delaware Court of Chancery may order all or a portion of the expenses incurred by any stockholder in connection with the appraisal proceeding, including, without limitation, reasonable attorneys’ fees and the fees and expenses of experts, to be charged pro rata against the value of all shares entitled to appraisal. In the absence of such a determination of assessment, each party bears its own expenses. Any stockholder who had demanded appraisal rights will not, after the Effective Time, be entitled to vote shares subject to that demand for any purpose or to receive payments of dividends or any other distribution with respect to those shares, other than with respect to payment as of a record date prior to the Effective Time; however, if no petition for appraisal is filed within 120 days after the Effective Time, or if the stockholder delivers a written withdrawal of his or her demand for appraisal and an acceptance of the terms of the merger within 60 days after the Effective Time, then the right of that stockholder to appraisal will cease and that stockholder will be entitled to receive the merger consideration for shares of his or her Ocugen capital stock pursuant to the Merger Agreement. Any withdrawal of a demand for appraisal made more than 60 days after the Effective Time may only be made with the written approval of the surviving corporation. No appraisal proceeding in the Delaware Court of Chancery will be dismissed as to any stockholder without the approval of the court.

Failure to follow the steps required by Section 262 for perfecting appraisal rights may result in the loss of appraisal rights. In view of the complexity of Section 262, stockholders who may wish to dissent from the merger and pursue appraisal rights should consult their legal advisors.



## THE MERGER AGREEMENT

*The following is a summary of the material terms of the Merger Agreement. Copies of the Original Merger Agreement and the Merger Agreement Amendment are attached as Annex A-1 and Annex A-2, respectively, to this proxy statement/prospectus/information statement and are incorporated by reference into this proxy statement/prospectus/information statement. The Merger Agreement has been attached to this proxy statement/prospectus/information statement to provide you with information regarding its terms. It is not intended to provide any other factual information about Histogenics, Ocugen or Merger Sub. The following description does not purport to be complete and is qualified in its entirety by reference to the Merger Agreement. You should refer to the full text of the Merger Agreement for details of the merger and the terms and conditions of the Merger Agreement.*

*The Merger Agreement contains representations and warranties that Histogenics and Merger Sub, on the one hand, and Ocugen, on the other hand, have made to one another as of specific dates. These representations and warranties have been made for the benefit of the other parties to the Merger Agreement and may be intended not as statements of fact but rather as a way of allocating the risk to one of the parties if those statements prove to be incorrect. In addition, the assertions embodied in the representations and warranties are qualified by information in confidential disclosure schedules exchanged by the parties in connection with signing the Merger Agreement. While Histogenics and Ocugen do not believe that these disclosure schedules contain information required to be publicly disclosed under the applicable securities laws, other than information that has already been so disclosed, the disclosure schedules do contain information that modifies, qualifies and creates exceptions to the representations and warranties set forth in the attached Merger Agreement. Accordingly, you should not rely on the representations and warranties as current characterizations of factual information about Histogenics or Ocugen, because they were made as of specific dates, may be intended merely as a risk allocation mechanism between Histogenics, Merger Sub and Ocugen and are modified by the disclosure schedules.*

### General

Under the Merger Agreement, at the Effective Time, Merger Sub will merge with and into Ocugen, with Ocugen surviving as a wholly-owned subsidiary of Histogenics.

### Merger Consideration

At the Effective Time, each share of Ocugen common stock outstanding immediately prior to the Effective Time (excluding shares of Ocugen's capital stock held as treasury stock or held by Ocugen, Merger Sub or any subsidiary of Ocugen, and shares held by Ocugen stockholders who have exercised and perfected appraisal rights in accordance with Delaware law) will automatically be converted into the right to receive a number of shares of Histogenics common stock equal to the exchange ratio.

The Merger Agreement does not include a price-based termination right and there will be no adjustment to the total number of shares of Histogenics common stock that Ocugen's stockholders, optionholders and warrantholders will be entitled to receive for changes in the market price of Histogenics common stock. Accordingly, the market value of the shares of Histogenics common stock issued pursuant to the merger will depend on the market value of the shares of Histogenics common stock at the time the merger closes, and could vary significantly from the market value on the date of this proxy statement/prospectus/information statement.

No fractional shares of Histogenics common stock will be issuable to Ocugen's stockholders pursuant to the Merger Agreement. Instead, each stockholder of Ocugen who would otherwise be entitled to receive a fraction of a share of Histogenics common stock, after aggregating all fractional shares of Histogenics common stock issuable to such stockholder, will be entitled to receive in cash the dollar amount, rounded to the nearest whole cent, without interest, determined by multiplying such fraction by volume weighted-average closing trading price of a share of Histogenics common stock on Nasdaq for the five consecutive trading days ending five trading days immediately prior to the date upon which the merger becomes effective.

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The Merger Agreement provides that, at the Effective Time, Histogenics will deposit with an exchange agent acceptable to Histogenics and Ocugen certificates and evidence of book-entry shares representing Histogenics common stock issuable to Ocugen's stockholders and a sufficient amount of cash to make payments in lieu of fractional shares.

The Merger Agreement provides that, promptly after the Effective Time, the exchange agent will mail to each record holder of Ocugen's capital stock immediately prior to the Effective Time a letter of transmittal and instructions for surrendering and exchanging stock certificates representing shares of Ocugen's capital stock held by such record holder in exchange for book-entry shares of Histogenics common stock. Upon surrender of a stock certificate representing shares of Ocugen's capital stock for exchange to the exchange agent, together with a duly signed letter of transmittal and such other documents as the exchange agent or Histogenics may reasonably require, the stock certificate surrendered will be cancelled and the holder of such stock certificate will be entitled to receive the following:

- a certificate or certificates or book-entry shares representing the number of whole shares of Histogenics common stock that such holder has the right to receive pursuant to the provisions of the Merger Agreement; and
- cash in lieu of any fractional share of Histogenics common stock.

At the Effective Time, all holders of certificates representing shares of Ocugen's capital stock that were outstanding immediately prior to the Effective Time will cease to have any rights as stockholders of Ocugen. In addition, no transfer of Ocugen's capital stock after the Effective Time will be registered on the stock transfer books of Ocugen.

If any stock certificate representing shares of Ocugen's capital stock has been lost, stolen or destroyed, Histogenics may, in its discretion, and as a condition to the delivery of any book-entry shares of Histogenics common stock, require the owner of such lost, stolen or destroyed certificate to deliver an affidavit claiming such certificate has been lost, stolen or destroyed and indemnify Histogenics against any claim suffered by Histogenics related to the lost, stolen or destroyed certificate or any of Histogenics common stock issued in exchange for such certificate as Histogenics may reasonably request.

From and after the Effective Time, until it is surrendered, each certificate that previously evidenced shares of Ocugen's capital stock will be deemed to represent only the right to receive book-entry shares of Histogenics common stock and cash in lieu of any fractional share of Histogenics common stock. Histogenics will not pay dividends or other distributions on any shares of Histogenics common stock to be issued in exchange for any unsurrendered stock certificate representing shares of Ocugen until the stock certificate is surrendered as provided in the Merger Agreement.

### **Treatment of Histogenics' Series A Convertible Preferred Stock, Stock Options and Warrants**

Shares of Histogenics' Series A Convertible Preferred Stock will remain outstanding according to their terms. The number of shares of Histogenics common stock underlying such preferred stock will be appropriately adjusted to reflect the Histogenics Reverse Stock Split.

Prior to the closing of the merger, the Histogenics Board will adopt appropriate resolutions and take all other actions necessary and appropriate to provide that each unexpired and unexercised option to purchase shares of Histogenics common stock will be cancelled in full for no consideration as of immediately prior to the Effective Time.

Warrants to purchase shares of Histogenics common stock will remain outstanding according to their terms. The number of shares of Histogenics common stock underlying each warrant and the exercise prices for such warrants will be appropriately adjusted to reflect the Histogenics Reverse Stock Split.

## **Treatment of Ocugen's Stock Options and Warrants**

At the Effective Time:

- each option to purchase shares of Ocugen common stock outstanding and unexercised immediately prior to the Effective Time under the Ocugen, Inc. 2014 Stock Option Plan, whether or not vested, will be converted into an option to purchase shares of Histogenics common stock. Histogenics will assume the Ocugen, Inc. 2014 Stock Option Plan, and from and after the Effective Time, each Ocugen option assumed by Histogenics may be exercised for such number of shares of Histogenics common stock as is determined by multiplying the number of shares of Ocugen common stock subject to the option by the exchange ratio and rounding that result down to the nearest whole number of shares of Histogenics common stock. The per share exercise price of the converted option will be determined by dividing the existing exercise price of the option by the exchange ratio and rounding that result up to the nearest whole cent. Any restrictions on the exercise of any Ocugen option assumed by Histogenics will continue following the conversion and the term, exercisability, vesting schedules and other provisions of assumed Ocugen options will generally remain unchanged; provided, that any Ocugen options assumed by Histogenics may be subject to adjustment to reflect changes in Histogenics' capitalization after the Effective Time and that the Histogenics Board will succeed to the authority of the Ocugen Board with respect to each assumed Ocugen option; and
- each warrant to purchase shares of Ocugen capital stock outstanding and unexercised immediately prior to the Effective Time will be assumed by Histogenics and will become a warrant to purchase that number of shares of Histogenics common stock equal to the product obtained by multiplying (i) the number of shares of Ocugen common stock' issuable upon exercise of the Ocugen warrant that were subject to such warrant immediately prior to the Effective Time by (ii) the exchange ratio, and rounding that result down to the nearest whole share. The per share exercise price for Histogenics common stock issuable upon exercise of each Ocugen warrant assumed by Histogenics shall be determined by dividing (a) the per share exercise price of the Ocugen common stock subject to such Ocugen warrant, as in effect immediately prior to the Effective Time, by (b) the exchange ratio, and rounding that result up to the nearest whole cent. Any restriction on any Ocugen warrant assumed by Histogenics shall continue in full force and effect and the terms and other provisions of such Ocugen warrant shall otherwise remain unchanged.

## **Directors and Officers of Histogenics Following the Merger**

Pursuant to the Merger Agreement, each of the directors and officers of Histogenics who will not continue as directors or officers of Histogenics or the combined organization following the consummation of the merger, shall resign effective upon the closing of the merger. In connection with the merger, the Histogenics Board will be expanded to include a total of seven directors. Pursuant to the terms of the Merger Agreement, all seven directors will be designated by Ocugen. It is anticipated that all Histogenics directors will resign as of the Effective Time. Dr. Shankar Musunuri is expected to be appointed to the board as Chairman of the board of directors, and Uday B. Kompella, Manish Potti, Junge Zhang, Frank N. Leo, Suha Taspolatoglu, and Ramesh Kumar, Ph.D. are expected to be appointed to the board as members of the board of directors. It is anticipated that Histogenics' executive officers upon the closing of the merger will be Dr. Shankar Musunuri as Chief Executive Officer, Dr. Dan Jorgensen as Chief Medical Officer, Dr. Rasappa Arumughum as Chief Scientific Officer, Dr. Vijay Tammara as Vice President, Regulatory and Quality, and Kelly Beck as Vice President, Investor Relations and Administration and Corporate Secretary.

## **Amendments to the Sixth Amended and Restated Certificate of Incorporation of Histogenics**

Stockholders of record of Histogenics common stock on the record date for the Histogenics special meeting will also be asked to approve Proposal Nos. 2 and 3, which include an amendment to the sixth amended and restated certificate of incorporation of Histogenics to effect the Histogenics Reverse Stock Split and the Histogenics

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Name Change, in each case, upon consummation of the merger, each of which requires the affirmative vote of holders of shares representing a majority of all shares of Histogenics common stock outstanding on the record date for the Histogenics special meeting.

### **Conditions to the Completion of the Merger**

Each party's obligation to complete the merger is subject to the satisfaction or waiver by each of the parties, at or prior to the merger, of various conditions, which include the following:

- the registration statement on Form S-4, of which this proxy statement/prospectus/information statement is a part, must have been declared effective by the SEC in accordance with the Securities Act and must not be subject to any stop order or proceeding, or any proceeding threatened by the SEC, seeking a stop order that has not been withdrawn;
- there must not have been issued, and remain in effect, any temporary restraining order, preliminary or permanent injunction or other order preventing the consummation of the merger or any of the other transactions contemplated by the Merger Agreement by any court of competent jurisdiction or other governmental entity of competent jurisdiction, and no law, statute, rule, regulation, ruling or decree shall be in effect which has the effect of making the consummation of the merger or any of the other transactions contemplated by the Merger Agreement illegal;
- the approval of the Merger Agreement and the transactions contemplated thereby or in connection therewith, as applicable, by holders of a (i) 66 2/3% of the outstanding shares of Ocugen common stock voting together as a single class, (ii) at least 66 2/3% of the outstanding shares of Ocugen common stock held by Series A Stockholders (as defined in the Ocugen Stockholders Agreement) and Series B Stockholders (as defined in the Ocugen Stockholders Agreement), voting together as a single class, and (iii) at least a majority of the outstanding shares of Ocugen common stock held by Series B Stockholders, voting as a separate class;
- the holders of a majority of the outstanding shares of Histogenics common stock having voting power present in person or represented by proxy at the Histogenics special meeting must have approved Proposal No. 1, the approval of the Merger Agreement and the transactions contemplated thereby, including the merger and the issuance of Histogenics common stock in the merger, and Proposal No. 2, the amendment of the restated certificate of incorporation of Histogenics to effect the Histogenics Reverse Stock Split; and
- the existing shares of Histogenics common stock must have been continually listed on Nasdaq through the closing of the merger, and Histogenics must have caused the shares of Histogenics common stock to be issued in the merger to be approved for listing on Nasdaq (subject to official notice of issuance) as of the closing of the merger.

In addition, each party's obligation to complete the merger is subject to the satisfaction or waiver by that party of the following additional conditions:

- the representations and warranties of the other party in the Merger Agreement must be true and correct on the date of the Merger Agreement and on the closing date of the merger with the same force and effect as if made on the date on which the merger is to be completed or, if such representations and warranties address matters as of a particular date, then as of that particular date, except in each case, or in the aggregate, where the failure to be so true and correct would not reasonably be expected to have a Company Material Adverse Effect or Parent Material Adverse Effect (each as defined below), as applicable (without giving effect to any references therein to any Company Material Adverse Effect or Parent Material Adverse Effect, as applicable, or other materiality qualifications);
- the other party to the Merger Agreement must have performed or complied with in all material respects all of such party's agreements and covenants required to be performed or complied with by it under the Merger Agreement at or prior to the Effective Time;

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- not more than 10% of Ocugen common stock shall be held by dissenting stockholders;
- the other party must have delivered certain certificates and other documents required under the Merger Agreement for the closing of the merger; and
- the party must have received from the other party lock-up agreements executed by certain stockholders of such party (including any stockholder of Ocugen expected to own more than 5% of the outstanding common stock of the combined organization after the merger).

In addition, the obligation of Histogenics and Merger Sub to complete the merger is further subject to the satisfaction or waiver of the following conditions:

- there shall have been no effect, change, event, circumstance, or development that (considered together with all other effects, changes, events, circumstances, or developments that have occurred prior to the applicable date of determination) has or would reasonably be expected to have a material adverse effect on the business, financial condition, assets, liabilities or results of operations of Ocugen or its subsidiaries, taken as a whole (a "Company Material Adverse Effect"); provided that effects, changes, events, circumstances or developments resulting from the following shall not be taken into account for purposes of determining whether a Company Material Adverse Effect shall have occurred:
  - any general business, economic or political conditions affecting the industry in which Ocugen or its subsidiaries operate;
  - any natural disaster or any acts of war, armed hostilities or terrorism;
  - any changes in financial, banking or securities markets;
  - any failure of Ocugen to meet internal or analysts' expectations or projections or the results of Ocugen;
  - any clinical trial programs or studies, including any adverse data, event or outcome arising out of or relating to any such programs or studies;
  - any change in, or any compliance with or action taken for the purpose of complying with any law or U.S. GAAP;
  - resulting from the announcement of the Merger Agreement or the pendency of the transactions contemplated by the Merger Agreement; or
  - resulting from the taking of any action, or the failure to take any action, by Ocugen that is required to be taken pursuant to the Merger Agreement.
- Histogenics shall have received (i) an original signed statement from Ocugen that Ocugen is not, and has not been at any time during the applicable period specified in Section 897(c)(1)(A)(ii) of the Code, a "United States real property holding corporation," as defined in Section 897(c)(2) of the Code, conforming to the requirements of Treasury Regulations Section 1.1445-2(c)(3) and 1.897-2(h), and (ii) an original signed notice to be delivered to the IRS in accordance with the provisions of Treasury Regulations Section 1.897-2(h)(2), together with written authorization for Histogenics to deliver such notice to the IRS on behalf of Ocugen following the closing of the merger, each dated as of the closing date of the merger, duly executed by an authorized officer of Ocugen, and in form and substance reasonably acceptable to Histogenics; and
- certain agreements between Ocugen and its stockholders must have been terminated.

In addition, the obligation of Ocugen to complete the merger is further subject to the satisfaction or waiver of the following conditions:

- there shall have been no effect, change, event, circumstance, or development that (considered together with all other effects, changes, circumstances, or developments that have occurred prior to the

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applicable date of determination) has or would reasonably be expected to have a material adverse effect on the business, financial condition, assets, liabilities or results of operations of Histogenics and its subsidiaries, taken as a whole (a “Parent Material Adverse Effect”); provided, that effects, changes, events, circumstances or developments resulting from the following shall not be taken into account for purposes of determining whether a Parent Material Adverse Effect shall have occurred:

- any general business, economic or political conditions affecting the industry in which Histogenics operates;
  - any natural disaster or any acts of war, armed hostilities or terrorism;
  - any changes in financial, banking or securities markets;
  - any change in the stock price or trading volume of Histogenics common stock (it being understood, however, that any effects, changes, events, circumstances or developments causing or contributing to any change in stock price or trading volume of Histogenics common stock may be taken into account in determining whether a Parent Material Adverse Effect has occurred, unless such effects, changes, events, circumstances or developments or otherwise are specifically excepted);
  - any failure of Histogenics to meet internal or analysts’ expectations or projections or the results of Histogenics;
  - any clinical trial programs or studies, including any adverse data, event or outcome arising out of or relating to any such programs or studies;
  - any change in, or any compliance with or action taken for the purpose of complying with any law or U.S. GAAP;
  - resulting from the announcement of the Merger Agreement or the pendency of the transactions contemplated by the Merger Agreement; or
  - resulting from the taking of any action, or the failure to take any action, by Histogenics that is required to be taken pursuant to the Merger Agreement.
- Ocugen must have received the resignations of each of the officers and directors of Histogenics who are not to continue as officers and directors of the combined organization after the merger; and
  - Histogenics must have caused the Histogenics Board to be constituted as required by the Merger Agreement.

### **Representations and Warranties**

The Merger Agreement contains customary representations and warranties of Histogenics and Ocugen for a transaction of this type relating to, among other things:

- corporate organization and power, and similar corporate matters;
- subsidiaries;
- authority to enter into the Merger Agreement and the related agreements;
- votes required for completion of the merger and approval of the proposals that will come before the Histogenics special meeting and that will be the subject of Ocugen’s stockholder written consent;
- except as otherwise specifically disclosed pursuant to in the Merger Agreement, the fact that the consummation of the merger would not contravene or require the consent of any third-party;
- capitalization;
- financial statements and, with respect to Histogenics, documents filed with the SEC and the accuracy of information contained in those documents;

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- material changes or events;
- absence of undisclosed liabilities;
- title to assets;
- real property and leaseholds;
- intellectual property;
- the validity of material contracts to which the parties or their subsidiaries are a party and any violation, default or breach to such contracts;
- regulatory compliance, permits and restrictions;
- legal proceedings and orders;
- tax matters;
- employee and labor matters and benefit plans;
- environmental matters;
- transactions with affiliates;
- insurance;
- any brokerage or finder's fee or other fee or commission in connection with the merger;
- anti-bribery laws; and
- with respect to Histogenics, the valid issuance in the merger of Histogenics common stock and the opinion of Canaccord Genuity.

The representations and warranties are, in many respects, qualified by materiality and knowledge, and will not survive the merger, but their accuracy forms the basis of one of the conditions to the obligations of Histogenics and Ocugen to complete the merger.

### **No Solicitation**

Each of Histogenics and Ocugen agreed that during the period commencing on the date of the Merger Agreement and ending on the earlier of the consummation of the merger or the termination of the Merger Agreement, except as described below, Histogenics and Ocugen and any of their respective subsidiaries will not, nor will either party or any of its subsidiaries authorize any of the directors, officers, employees, agents, attorneys, accountants, investment bankers, advisors or representatives retained by it or any of its subsidiaries to, directly or indirectly:

- solicit, initiate or knowingly encourage, induce or facilitate the communication, making, submission or announcement of, any "acquisition proposal" or "acquisition inquiry" or take any action that could reasonably be expected to lead to an acquisition proposal or acquisition inquiry;
- furnish any non-public information with respect to it to any person in connection with or in response to an acquisition proposal or acquisition inquiry;
- engage in discussions or negotiations with any person with respect to any acquisition proposal or acquisition inquiry;
- approve, endorse or recommend an acquisition proposal;
- execute or enter into any letter of intent or similar document or any contract contemplating or otherwise relating to any acquisition transaction (other than a confidentiality agreement permitted by the Merger Agreement); or
- publicly propose to do any of the above.

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An “acquisition inquiry” means an inquiry, indication of interest or request for information (other than an inquiry, indication of interest or request for information made or submitted by Ocugen or any of its affiliates, on the one hand, or Histogenics or any of its affiliates, on the other hand, to the other party) that would reasonably be expected to lead to an acquisition proposal.

An “acquisition proposal” means any offer or proposal, whether written or oral (other than an offer or proposal made or submitted by or on behalf of Ocugen or any of its affiliates, on the one hand, or by or on behalf of Histogenics or any of its affiliates, on the other hand, to the other party) contemplating or otherwise relating to any “acquisition transaction.”

An “acquisition transaction” means any transaction or series of related transactions involving:

- any merger, consolidation, amalgamation, share exchange, business combination, issuance or acquisition of securities, reorganization, recapitalization, tender offer, exchange offer or similar transaction: (i) in which Histogenics, Ocugen or Merger Sub is a constituent entity, (ii) in which any individual, entity, governmental entity, or “group,” as defined under applicable securities laws, directly or indirectly acquires beneficial or record ownership of securities representing more than 20% of the outstanding securities of any class of voting securities of Histogenics, Ocugen or Merger Sub or any of their respective subsidiaries or (iii) in which Histogenics, Ocugen or Merger Sub or any of their respective subsidiaries issues securities representing more than 20% of the outstanding securities of any class of voting securities of such party or any of its subsidiaries; or
- any sale, lease, exchange, transfer, license, acquisition or disposition of any business or businesses or assets that constitute or account for 20% or more of the consolidated book value or the fair market value of the assets of Histogenics, Ocugen or Merger Sub and their respective subsidiaries, as applicable, taken as a whole (excluding transactions relating to permitted divestitures of assets).

Notwithstanding the foregoing, before obtaining the applicable approvals of the stockholders of Histogenics or Ocugen required to consummate the merger, as applicable, each party may furnish non-public information regarding such party and its subsidiaries to, and may enter into discussions or negotiations with, any third-party in response to a bona fide written acquisition proposal made or received after the date of the Merger Agreement, which such party’s board of directors determines in good faith, after consultation with such party’s outside financial advisors or outside legal counsel, constitutes or is reasonably likely to result in a “superior offer,” as defined below, if:

- neither such party nor any representative of such party has materially breached the solicitation provisions of the Merger Agreement described above;
- such party’s board of directors concludes in good faith, based on the advice of outside legal counsel, that the failure to take such action is reasonably likely to be inconsistent with the fiduciary duties of such board of directors under applicable legal requirements;
- such party gives the other party at least two business days’ prior written notice of the identity of the third-party and of that party’s intention to furnish information to, or enter into discussions with, such third-party before furnishing any information or entering into discussions with such third-party;
- such party receives from the third-party an executed confidentiality agreement containing provisions at least as favorable to such party as those contained in the confidentiality agreement between Histogenics and Ocugen; and
- at least two business days prior to the furnishing of any non-public information to a third-party, such party furnishes the same non-public information to the other party to the extent not previously furnished.

A “superior offer” means an unsolicited, bona fide written acquisition proposal (with all references to 20% in the definition of acquisition transaction being treated as references to greater than 80% for these purposes) that



(a) was not obtained or made as a direct or indirect result of a breach, or violation, of the Merger Agreement, and (b) is on terms and conditions that the board of directors of the party receiving the offer determines in good faith, based on such matters that it deems relevant (including the likelihood of consummation of the transaction), as well as any written offer by the other party to the Merger Agreement to amend the terms of the Merger Agreement, and following consultation with outside legal counsel and outside financial advisors, if any, are more favorable, from a financial point of view, to that party's stockholders than the terms of the merger. An acquisition proposal will not be considered a superior offer if any financing required to consummate the transaction contemplated by such acquisition proposal is not reasonably capable of being obtained by such third-party.

The Merger Agreement also provides that each party will promptly advise the other of the status and terms of, and keep the other party reasonably informed with respect to, any acquisition proposal or any inquiry, indication of interest or request for information that would reasonably be expected to lead to an acquisition proposal or any material change or proposed material change to that acquisition proposal or inquiry, indication of interest or request for information that would reasonably be expected to lead to an acquisition proposal.

#### **Meetings of Stockholders**

Histogenics is obligated under the Merger Agreement to call, give notice of and hold the Histogenics special meeting for the purposes of considering the approval of the Merger Agreement and the transactions contemplated thereby, including the merger and the issuance of shares of Histogenics common stock to Ocugen's stockholders in the merger.

Ocugen is obligated under the Merger Agreement to obtain written consents of its stockholders sufficient to adopt the Merger Agreement thereby approving the merger and related transactions within five business days following the registration statement on Form S-4, of which this proxy statement/prospectus/information statement is a part, being declared effective by the SEC.

#### **Covenants; Conduct of Business Pending the Merger**

Histogenics has agreed that, except as permitted by the Merger Agreement (including in connection with transactions relating to permitted divestitures of assets), as required by law, or unless Ocugen shall have provided written consent, during the period commencing on the date of the Merger Agreement and continuing until the earlier to occur of the closing of the merger and the termination of the Merger Agreement, other than with respect to transactions relating to permitted divestitures of assets, Histogenics will conduct its business and operations in the ordinary course consistent with past practices and in compliance with all applicable laws, regulations and certain contracts, and to take other agreed-upon actions. Histogenics has also agreed that, subject to certain limited exceptions, without the consent of Ocugen, it will not, during the period commencing on the date of the Merger Agreement and continuing until the earlier to occur of the closing of the merger and the termination of the Merger Agreement:

- declare, accrue, set aside or pay any dividend or make any other distribution in respect of any shares of capital stock or repurchase, redeem or otherwise reacquire any shares of capital stock or other securities (except in connection with the payment of withholding taxes incurred upon the exercise, settlement or vesting of any award granted under a Histogenics employee benefit plan in accordance with the terms of such award in effect on the date of the Merger Agreement);
- sell, issue, grant, pledge or otherwise dispose of or encumber or authorize any of the foregoing with respect to: any capital stock or other security (except for Histogenics common stock issued upon the valid exercise of outstanding options, warrants to purchase shares of Histogenics common stock or Histogenics' Series A Convertible Preferred Stock); any option, warrant or right to acquire any capital stock or any other security; or any instrument convertible into or exchangeable for any capital stock or other security of Histogenics;

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- except as required to give effect to anything in contemplation of the closing of the merger, amend the certificate of incorporation, bylaws or other charter or organizational documents of Histogenics, or effect or be a party to any merger, consolidation, share exchange, business combination, recapitalization, reclassification of shares, stock split, reverse stock split or similar transaction except as related to the proposed transactions under the Merger Agreement;
- form any subsidiary or acquire any equity interest or other interest in any other entity or enter into any joint venture with any other entity;
- lend money to any person; incur or guarantee any indebtedness for borrowed money;
- guarantee any debt securities of others; or make any capital expenditure or commitment;
- other than as required by law or the terms of a Histogenics employee plan in effect as of the date of the Merger Agreement, adopt, terminate, establish or enter into any Histogenics employee plan; cause or permit any Histogenics employee plan to be amended in any material respect, other than in connection with the termination of any such employee plans; pay any bonus or make any profit sharing or similar payment to, or increase the amount of the wages, salary, commissions, fringe benefits or other compensation or remuneration payable to, any of its employees, officers or directors; increase the severance, retention or change of control benefits offered to any current or former or new employees, directors or consultants; hire or retain any new officer, employee or consultant; or terminate or give notice of termination to any officer or employee, other than termination for cause;
- recognize any labor union, labor organization, or similar entity except as otherwise required by law and after advance notice to Ocugen;
- acquire any asset or sell, lease or otherwise irrevocably dispose of any of its material assets or properties, or grant any encumbrance with respect to any assets or properties, other than transactions relating to permitted divestitures of assets;
- sell, assign, transfer, license, sublicense or otherwise dispose of any material Histogenics intellectual property (other than in transactions relating to permitted divestitures of assets or pursuant to non-exclusive licenses in the ordinary course of business);
- make, change or revoke any material tax election, fail to pay any income or other material tax as such tax becomes due and payable, file any amendment making any material change to any tax return, settle or compromise any income or other material tax liability, enter into any tax allocation, sharing, indemnification or other similar agreement or arrangement (other than customary commercial contracts entered into in the ordinary course of business the principal subject matter of which is not taxes), request or consent to any extension or waiver of any limitation period with respect to any claim or assessment for any income or other material taxes (other than pursuant to an extension of time to file any tax return granted in the ordinary course of business of not more than six months), or adopt or change any material accounting method in respect of taxes;
- enter into, materially amend or terminate certain material contracts, other than transactions relating to permitted divestitures of assets;
- other than incurrence or payment of Histogenics transaction expenses up to an aggregate of \$1,000,000, make any expenditures or incur any liabilities other than in the ordinary course of business up to, individually or in the aggregate, \$25,000 (other than in connection with transactions relating to permitted divestitures of assets);
- enter into any other transaction other than in the ordinary course of business or transactions relating to permitted divestitures of assets;
- other than as required by law or U.S. GAAP, take any action to change accounting policies or procedures;

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- initiate or settle any legal proceeding; or
- agree, resolve or commit to do any of the foregoing.

Ocugen has agreed that, except as permitted by the Merger Agreement, as required by law, or unless Histogenics shall have provided written consent, during the period commencing on the date of the Merger Agreement and continuing until the earlier to occur of the closing of the merger and the termination of the Merger Agreement, other than with respect to transactions relating to debt or equity financing by Ocugen to occur prior to the closing of the merger, Ocugen will conduct its business and operations in the ordinary course consistent with past practices and in compliance with all applicable laws, regulations and certain contracts, and to take other agreed-upon actions. Ocugen has also agreed that, subject to certain limited exceptions, without the consent of Histogenics, it will not, during the period commencing on the date of the Merger Agreement and continuing until the earlier to occur of the closing of the merger and the termination of the Merger Agreement:

- declare, accrue, set aside or pay any dividend or make any other distribution in respect of any shares of capital stock of Ocugen or repurchase, redeem or otherwise reacquire any shares of capital stock or other securities (except for shares of Ocugen common stock from terminated employees, directors or consultants of Ocugen);
- except as required to give effect to anything in contemplation of the closing of the merger, amend the certificate of incorporation, bylaws or other charter or organizational documents of Ocugen or its subsidiaries, or effect or become a party to any merger, consolidation, share exchange, business combination, recapitalization, reclassification of shares, stock split, reverse stock split or similar transaction except as related to the proposed transactions under the Merger Agreement;
- sell, issue, grant pledge or otherwise dispose of or encumber or authorize any of the foregoing with respect to: any capital stock or other security (except for Ocugen common stock issued upon the valid exercise of outstanding options, warrants to purchase shares of Ocugen common stock issued upon the valid exercise of Ocugen options or warrants); any option, warrant or right to acquire any capital stock or any other security; or any other instrument convertible into or exchangeable for any capital stock or any other security of Ocugen or its subsidiaries;
- except as required to give effect to anything in contemplation of the closing of the merger, amend the certificate of incorporation, bylaws or other charter or organizational documents of Ocugen or its subsidiaries, or effect or be a party to any merger, consolidation, share exchange, business combination, recapitalization, reclassification of shares, stock split, reverse stock split or similar transaction except as related to the proposed transactions under the Merger Agreement;
- form any subsidiary or acquire any equity interest or other interest in any other entity or enter into a joint venture with any other entity;
- lend money to any person; incur or guarantee any indebtedness for borrowed money;
- guarantee any debt securities of others; or make any capital expenditure or commitment in excess of \$500,000;
- other than as required by applicable law or the terms of any Ocugen employee benefit plan: adopt, terminate, establish or enter into any employee plan; cause or permit any employee plan to be amended in any material respect; pay any bonus or make any profit-sharing or similar payment to, or increase the amount of the wages, salary, commissions, benefits or other compensation or remuneration payable to, any of its directors, officers or employees; increase the severance or change of control benefits offered to any current or new employees, directors or consultants; or terminate or give notice of termination to any officer or any employee whose annual base salary is expected to be more than \$125,000 per year, other than any termination for cause;
- recognize any labor union, labor organization or similar entity, except as otherwise required by law and after advance notice to Histogenics;

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- enter into any transaction other than in the ordinary course of business;
- acquire any material asset or sell, lease or otherwise irrevocably dispose of any of its material assets or properties, or grant any encumbrance with respect to such assets or properties;
- sell, assign, transfer, license, sublicense or otherwise dispose of any material Ocugen intellectual property rights (other than pursuant to non-exclusive licenses in the ordinary course of business);
- make, change or revoke any material tax election, fail to pay any income or other material tax as such tax becomes due and payable, file any amendment making any material change to any tax return, settle or compromise any income or other material tax liability, enter into any tax allocation, sharing, indemnification or other similar agreement or arrangement (other than customary commercial contracts entered into in the ordinary course of business the principal subject matter of which is not taxes), request or consent to any extension or waiver of any limitation period with respect to any claim or assessment for any income or other material taxes (other than pursuant to an extension of time to file any tax return granted in the ordinary course of business of not more than six months), or adopt or change any material accounting method in respect of taxes;
- enter into, materially amend or terminate certain material contracts;
- other than incurrence or payment of any Ocugen transaction expenses, make any expenditures, incur any liabilities or discharge or satisfy any liabilities, in each case, in amounts that exceed \$500,000 in the aggregate;
- other than as required by law or U.S. GAAP, take any action to change accounting policies or procedures;
- initiate or settle any legal proceeding; or
- agree, resolve or commit to do any of the foregoing.

### **Other Agreements**

Each of Histogenics and Ocugen has agreed to use its commercially reasonable efforts to cause to be taken all actions necessary to consummate the merger and the other transactions contemplated by the Merger Agreement. In connection therewith, each party has agreed to: file or otherwise submit all applications and notices required to be filed in connection with the merger and the other transactions contemplated by the Merger Agreement;

- use reasonable best efforts to obtain each consent reasonably required to be obtained in connection with the merger and the other transactions contemplated by the Merger Agreement;
- use commercially reasonable efforts to lift any injunction prohibiting, or any other legal bar to, the merger or the other transactions contemplated by the Merger Agreement; and
- use commercially reasonable efforts to satisfy the conditions precedent to the consummation of the transactions contemplated by the Merger Agreement.

Pursuant to the Merger Agreement, Histogenics and Ocugen have further agreed that:

- Histogenics will use its commercially reasonable efforts to (i) maintain the listing of its common stock on Nasdaq until the closing of the merger and to obtain approval for listing of the combined organization on Nasdaq; (ii) to the extent required by the rules and regulations of Nasdaq, to prepare and submit to Nasdaq a notification form for the listing of the shares of Histogenics common stock to be issued in connection with the merger and to cause such shares to be approved for listing (subject to official notice of issuance); (iii) to effect the Histogenics Reverse Stock Split; and (iv) to the extent required by Nasdaq Marketplace Rule 5110, to file an initial listing application for Histogenics common stock on Nasdaq, which application will be prepared by Ocugen, and to cause such listing application to be conditionally approved prior to the Effective Time;

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- for a period of six years after the closing of the merger, Histogenics will indemnify each of the directors, officers, fiduciaries and agents of Histogenics and Ocugen to the fullest extent permitted under the DGCL and will maintain directors' and officers' liability insurance for the directors and officers of Histogenics and Ocugen; and
- Histogenics shall maintain directors' and officers' liability insurance policies commencing at the closing of the merger, on commercially reasonable terms and conditions and with coverage limits customary for U.S. public companies similarly situated to Histogenics.

### **Termination**

The Merger Agreement may be terminated at any time before the completion of the merger, whether before or after the required stockholder approvals to complete the merger have been obtained, as set forth below:

- by mutual written consent of Histogenics and Ocugen;
- by either Histogenics or Ocugen if the merger shall not have been consummated by September 30, 2019 (the "End Date"); provided, however, that this right to terminate the Merger Agreement will not be available to any party whose action or failure to act has been a principal cause of the failure of the merger to occur on or before the End Date and such action or failure to act constitutes a breach of the Merger Agreement; and provided, further, that the End Date shall be extended (a) by 60 days upon request of either party if a request for additional information has been made by any government authority, or in the event that the SEC has not declared effective the registration statement on Form S-4, of which this proxy statement/prospectus/information statement is a part, by such date, or (b) if the meeting of stockholders of Histogenics is adjourned or postponed in accordance with the Merger Agreement, (i) 10 days from the date of such adjournment or postponement if such 10 day period continues through September 30, 2019, or (ii) in the case of an additional adjournment or postponement in accordance with the Merger Agreement, an additional 10 days following such adjournment or postponement;
- by either Histogenics or Ocugen if a court of competent jurisdiction or governmental entity has issued a final and nonappealable order, decree or ruling or taken any other action that has the effect of permanently restraining, enjoining or otherwise prohibiting the merger or any of the other transactions contemplated by the Merger Agreement;
- by Histogenics if the Required Ocugen Stockholder Approval has not been obtained within the later of (i) 15 business days of the registration statement on Form S-4, of which this proxy statement/prospectus/information statement is a part, becoming effective or (ii) the date on which Histogenics stockholders have approved Proposal Nos. 1 and 2; provided that this right to terminate the Merger Agreement will not be available to Histogenics once Ocugen obtains such stockholder approval
- by either Histogenics or Ocugen if the Histogenics special meeting shall have been held and completed, including any adjournments or postponements permitted under the Merger Agreement, and Histogenics' stockholders shall have taken a final vote and shall not have approved Proposal Nos. 1 and 2; provided, that Histogenics may not terminate the Merger Agreement pursuant to this provision if the failure to obtain the approval of Histogenics' stockholders was caused by the action or failure to act of Histogenics or Merger Sub and such action or failure to act constitutes a material breach by Histogenics or Merger Sub of the Merger Agreement;
- by Ocugen, at any time prior to the approval by Histogenics' stockholders of the proposals to be considered at the Histogenics special meeting, if any of the following circumstances shall occur (each of the following, a "Histogenics triggering event"):
  - The Histogenics Board fails to recommend that the stockholders of Histogenics vote to approve Proposal Nos. 1 and 2 or withdraws or modifies its recommendation in a manner adverse to Ocugen;

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- Histogenics fails to include in this proxy statement/prospectus/information statement such recommendation;
- The Histogenics Board, or any committee thereof, publicly approves, endorses or recommends any acquisition proposal;
- Histogenics enters into any letter of intent or similar document or any contract relating to any acquisition proposal, other than a confidentiality agreement permitted pursuant to the Merger Agreement; or
- Histogenics or any director, officer or agent of Histogenics willfully and intentionally breaches the no solicitation provisions or the provisions regarding the Histogenics special meeting set forth in the Merger Agreement;
- by Histogenics, at any time prior to the adoption of the Merger Agreement by Ocugen's stockholders, if any of the following circumstances shall occur (each an "Ocugen triggering event"):
  - The Ocugen Board fails to recommend that Ocugen's stockholders vote to adopt the Merger Agreement, thereby approving the merger, or withdraws or modifies its recommendation in a manner adverse to Histogenics;
  - The Ocugen Board, or any committee thereof, publicly approves, endorses or recommends any acquisition proposal;
  - Ocugen enters into any letter of intent or similar document or any contract relating to any acquisition proposal; or
  - Ocugen or any director, officer or agent of Ocugen willfully and intentionally breaches the no solicitation provisions set forth in the Merger Agreement; or
- by Histogenics or Ocugen if the other party has breached any of its representations, warranties, covenants or agreements contained in the Merger Agreement or if any representation or warranty of the other party has become inaccurate, in either case such that the conditions to the closing of the merger would not be satisfied as of time of such breach or inaccuracy, but if such breach or inaccuracy is curable, then the Merger Agreement will not terminate pursuant to this provision as a result of a particular breach or inaccuracy until the expiration of a 15-day period after delivery of written notice of such breach.

### **Termination Fee**

#### ***Fee payable by Histogenics***

Histogenics must pay Ocugen a termination fee of an amount equal to Ocugen's expenses incurred in connection with the Merger Agreement up to \$300,000 if:

- the Merger Agreement is terminated by either Histogenics or Ocugen if the Histogenics special meeting shall have been held and completed, and Histogenics' stockholders shall have not approved Proposal Nos. 1 and 2; or
- the Merger Agreement is terminated by Histogenics after the End Date and Histogenics' stockholders have not approved Proposal Nos. 1 and 2.

Histogenics must pay Ocugen a termination fee of \$600,000 if the Merger Agreement is terminated by Ocugen if (i) prior to the Histogenics stockholder approval of Proposal Nos. 1 and 2, a Histogenics triggering event shall have occurred, (ii) at any time after the date of Merger Agreement and before the termination of the Merger Agreement, an acquisition proposal with respect to Histogenics was publicly announced, disclosed or otherwise communicated to the Histogenics Board, and (iii) within 12 months after the date of such termination, Histogenics enters into a definitive agreement for or consummates an acquisition transaction.

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Histogenics must pay Ocugen a termination fee of an amount equal to Ocugen's expenses incurred in connection with the Merger Agreement up to \$300,000 if the Merger Agreement is terminated by Ocugen because Histogenics or Merger Sub has breached any of its representations, warranties, covenants or agreements contained in the Merger Agreement or if any representation or warranty of Histogenics or Merger Sub has become inaccurate, in either case such that the conditions to the closing of the merger would not be satisfied as of the time of such breach or inaccuracy, subject to a 15-day cure period.

### ***Fee payable by Ocugen***

Ocugen must pay Histogenics a termination fee of an amount equal to Histogenics' expenses incurred in connection with the Merger Agreement up to \$300,000 if:

- the Merger Agreement is terminated by Histogenics if the Required Ocugen Stockholder Approval has not been obtained within the later of (i) 15 business days of the registration statement on Form S-4, of which this proxy statement/prospectus/information statement is a part, becoming effective or (ii) the date on which Histogenics stockholders have approved Proposal Nos. 1 and 2; or
- the Merger Agreement is terminated by Ocugen after the End Date and Ocugen has not obtained the Required Ocugen Stockholder Approval at the time of such termination.

Ocugen must pay Histogenics a termination fee of \$700,000 if the Merger Agreement is terminated by Ocugen if (i) prior to obtaining the Required Ocugen Stockholder Approval, an Ocugen triggering event shall have occurred, (ii) at any time after the date of Merger Agreement and before the termination of the Merger Agreement, an acquisition proposal with respect to Ocugen was publicly announced, disclosed or otherwise communicated to the Ocugen Board, and (iii) within 12 months after the date of such termination, Ocugen enters into a definitive agreement for or consummates an acquisition transaction.

Ocugen must pay Histogenics a termination fee of an amount equal to Histogenics' expenses incurred in connection with the Merger Agreement up to \$300,000 if the Merger Agreement is terminated by Histogenics because Ocugen has breached any of its representations, warranties, covenants or agreements contained in the Merger Agreement or if any representation or warranty of Ocugen has become inaccurate, in either case such that the conditions to the closing of the merger would not be satisfied as of the time of such breach or inaccuracy, subject to a 15-day cure period.

### **Amendment**

The Merger Agreement may be amended by the parties at any time if such amendment is in writing, is approved by the boards of directors of each party to the Merger Agreement and is signed by each party to the Merger Agreement, except that after the Merger Agreement has been adopted and approved by the stockholders of Histogenics or Ocugen, no amendment which by law requires further approval by the stockholders of Histogenics or Ocugen, as the case may be, shall be made without such further approval.

## AGREEMENTS RELATED TO THE MERGER

### Voting Agreements and Written Consent

In order to induce Histogenics to enter into the Merger Agreement, certain stockholders of Ocugen are parties to a voting agreement with Ocugen and Histogenics pursuant to which, among other things, each stockholder has agreed, solely in its capacity as a stockholder of Ocugen, to vote all of its shares of Ocugen's capital stock in favor of (1) the adoption and approval of the Merger Agreement and the transactions contemplated thereby, (2) acknowledgement that the approval given for the Merger Agreement is irrevocable and that the stockholder is aware of its appraisal rights under the DGCL, and (3) acknowledgement that the stockholder is not entitled to appraisal rights by voting in favor of the transaction and waiving appraisal rights under the DGCL. Additionally, each stockholder has agreed, solely in its capacity as a stockholder of Ocugen, to vote against any competing acquisition proposal and any action, proposal or transaction that would reasonably be expected to result in a material breach of the voting agreement. These stockholders of Ocugen have also granted an irrevocable proxy to Ocugen and its designee to vote their respective Ocugen's capital stock in accordance with the voting agreements. Ocugen's stockholders may vote their shares of Ocugen capital stock on all other matters not referred to in such proxy.

The Ocugen stockholders who are parties to these voting agreements include all directors, executive officers and certain stockholders. There can be no assurance that all of the necessary stockholder approvals will be obtained.

The stockholders of Ocugen that are party to a voting agreement with Histogenics held, as of July 12, 2019, an aggregate of 12,096,944 shares of Ocugen common stock, representing approximately 93% of the outstanding shares of Ocugen capital stock (excluding shares of Ocugen common stock issuable pursuant to the Securities Purchase Agreement).

Following the effectiveness of the registration statement of which this proxy statement/prospectus/information statement is a part and pursuant to the Merger Agreement, these stockholders will execute written consents providing for such adoption and approval.

Under these voting agreements, subject to certain exceptions, such stockholders have also agreed not to sell or transfer shares of Ocugen's capital stock and securities held by them, or any voting rights with respect thereto, until the earlier of the termination of the Merger Agreement or the completion of the merger. To the extent that any such sale or transfer is permitted pursuant to the exceptions included in the voting agreement, each person to which any shares of Ocugen's capital stock or securities are so sold or transferred must agree in writing to be bound by the terms and provisions of the voting agreement, subject to certain further exceptions.

In addition, in order to induce Ocugen to enter into the Merger Agreement, certain of Histogenics' stockholders have entered into voting agreements with Histogenics and Ocugen pursuant to which, among other things, each such stockholder has agreed, solely in his, her or its capacity as a stockholder of Histogenics, to vote all of his, her or its shares of Histogenics common stock in favor of Proposal Nos. 1, 2 and 3. Additionally, each such stockholder has agreed, solely in his, her or its capacity as a stockholder of Histogenics, to vote against any competing acquisition proposal and any action, proposal or transaction that would reasonably be expected to result in a material breach of the voting agreement. These stockholders of Histogenics have also granted Histogenics and its designee an irrevocable proxy to vote their respective shares in accordance with the voting agreements. Histogenics' stockholders may vote their shares of Histogenics common stock on all other matters not referred to in such proxy.

The Histogenics stockholders who are parties to these voting agreements are:

- Adam Gridley
- Jonathan Lieber



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- David Gill (former director)
- Kevin Rakin (former director)

As of July 12, 2019, the stockholders of Histogenics that are party to a voting agreement (including affiliated entities) owned an aggregate of 484,964 shares of Histogenics common stock representing less than one percent of the outstanding shares of Histogenics common stock.

Under these voting agreements, subject to certain exceptions, such stockholders also have agreed not to sell or transfer their shares of Histogenics common stock and securities held by them until the earlier of the termination of the Merger Agreement or the completion of the merger. To the extent that any such sale or transfer is permitted pursuant to the exceptions included in the voting agreements, each person to which any shares of Histogenics common stock or securities are so sold or transferred must agree in writing to be bound by the terms and provisions of the voting agreement, subject to certain further exceptions.

### **Lock-up Agreements**

As a condition to the closing of the merger, certain stockholders of Histogenics and certain stockholders of Ocugen have entered into lock-up agreements, pursuant to which such parties have agreed not to, except in limited circumstances, offer, pledge, sell, contract to sell, transfer or dispose of, directly or indirectly, engage in swap or similar transactions with respect to, or make any demand for or exercise any right with respect to, any shares of Histogenics common stock or any security exercisable or exchangeable for Histogenics common stock, including, as applicable, shares received in the merger and issuable upon exercise of certain warrants and options, during the period commencing at the Effective Time and continuing until the date that is 180 days from the Effective Time.

Each of the stockholders who is party to a Histogenics voting agreement, as identified above, is a party to a lock-up agreement. As of July 12, 2019, Histogenics' stockholders who have executed lock-up agreements beneficially owned in the aggregate less than one percent of the outstanding common stock of Histogenics.

Ocugen's stockholders who have executed lock-up agreements, as of July 12, 2019, beneficially owned in the aggregate approximately 93% of the outstanding shares of Ocugen's capital stock.

### **Securities Purchase Agreement**

On June 13, 2019, Ocugen and Histogenics entered into the Securities Purchase Agreement, which was subsequently amended on June 28, 2019, with the Investors pursuant to which, among other things, (i) Ocugen agreed to sell to the Investors an aggregate of 4,574,272 shares of Ocugen common stock (the "Initial Shares") and deposit an additional 4,574,272 shares of Ocugen common stock into escrow for the benefit of the Investors if 80% of the volume-weighted average trading price of a share of Histogenics common stock on Nasdaq for the first three trading days immediately following the closing date of the Pre-Merger Financing is lower than the price paid by the Investors for the Initial Shares (the "Additional Shares" and together with the Initial Shares the "Ocugen Financing Shares"), and (ii) Histogenics agreed to issue warrants representing the right to acquire an amount of Histogenics common stock up to the amount issuable in exchange for 200% of the Ocugen Financing Shares upon consummation of the merger, as further described below (the "Series A Warrants"), additional warrants to purchase shares of Histogenics common stock, as further described below (the "Series B Warrants"), and additional Series C warrants to purchase 50 million shares of Histogenics common stock (which number shall not be adjusted as a result of the Histogenics Reverse Stock Split), as further described below (the "Series C Warrants" together with the Series A Warrants and the Series B Warrants, the "Investor Warrants" and, together with the Ocugen Financing Shares, the "Purchased Securities"), and the Investors agreed to purchase the Purchased Securities, for an aggregate purchase price of approximately \$25.0 million (subject to setoff for amounts outstanding of approximately \$5.29 million under certain senior convertible secured notes previously issued or to be issued prior to the consummation of the merger to certain of the Investors by Ocugen) (the "Purchase Price").

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Upon the consummation of the merger, each Initial Share will automatically be converted into the right to receive a number of shares of Histogenics common stock equal to the exchange ratio (the “Converted Initial Shares”). Further, upon consummation of the merger, each Additional Share placed into escrow will automatically be converted into the right to receive a number of shares of Histogenics common stock equal to the exchange ratio (the “Converted Additional Shares”). The number of Converted Additional Shares issuable pursuant to the Securities Purchase Agreement will be determined by subtracting (i) the aggregate number of shares of Histogenics common stock issued in exchange for the Initial Shares (as adjusted for stock splits, stock dividends, recapitalizations, reorganizations, reclassifications, combinations, reverse stock splits and similar events) from (ii) the quotient determined by dividing (a) the aggregate Purchase Price by (b) 80% of the sum of the volume-weighted average prices of a share of Histogenics common stock on Nasdaq for the first three trading days immediately following the closing date of the Pre-Merger Financing, divided by three. Notwithstanding the foregoing, no Converted Additional Shares will be issued to Investors to the extent such issuance would result in such Investor, together with its affiliates and any other person whose beneficial ownership of Histogenics common stock would be aggregated with such Investor for purposes of Section 13(d) of the Exchange Act, beneficially owning in excess of 4.99% or 9.99% of the outstanding Histogenics common stock (including the shares of common stock issuable upon such exercise), as such percentage ownership is determined in accordance with the terms of the Securities Purchase Agreement. In the event that Histogenics fails to timely deliver any of the Converted Initial Shares or Converted Additional Shares then Histogenics shall be obligated to pay the affected Investor on each day while such failure is continuing an amount equal to 2.0% of the market value of the undelivered shares determined using any trading price of Histogenics common stock selected by the holder while the failure is continuing and if an affected Investor purchases shares of Histogenics common stock in connection with such failure (“Buy-In Shares”), then Histogenics must, at such Investor’s discretion, reimburse such Investor for the cost of such Buy-In Shares or deliver the owed shares and reimburse the Investor for the difference between the price such Investor paid for the Buy-In Shares and the market price of such shares, measured at any time of such Investor’s choosing while the delivery failure was continuing. Any Converted Additional Shares not issuable to the Investors will be returned to Histogenics as treasury shares.

Pursuant to the Securities Purchase Agreement, at any time during the period commencing from the six month anniversary of the closing date of the Pre-Merger Financing and ending at such time that all of the shares of Histogenics common stock issued or issuable in the Pre-Merger Financing, if a registration statement is not available for the resale of such shares, may be sold without restriction or limitation pursuant to Rule 144 and without the requirement to be in compliance with Rule 144(c)(1), if Histogenics (i) shall fail for any reason to satisfy the requirements of Rule 144(c)(1) under the Securities Act, including, without limitation, the failure to satisfy the current public information requirements under Rule 144(c) under the Securities Act or (ii) has ever been an issuer described in Rule 144(i)(1)(i) under the Securities Act or becomes such an issuer in the future, and Histogenics shall fail to satisfy any condition set forth in Rule 144(i)(2) under the Securities Act (each, a “Public Information Failure”), then Histogenics shall pay to each holder of Purchased Securities an amount in cash equal to 2.0% of such holder’s pro rata portion of the Purchase Price on the day of such Public Information Failure and on every thirtieth day thereafter until the earlier of (i) the date such Public Information Failure is cured and (ii) such time that such Public Information Failure no longer prevents a holder of Purchased Securities from selling such Purchased Securities pursuant to Rule 144 under the Securities Act without any restrictions or limitations.

The Securities Purchase Agreement contains customary representations and warranties of Ocugen, Histogenics and the Investors. Each Investor’s obligation to purchase the Purchased Securities pursuant to the Securities Purchase Agreement is subject to the satisfaction or waiver of certain conditions, including:

- Ocugen and Histogenics executing and delivering each other document required to be delivered under the Securities Purchase Agreement, including a registration rights agreement providing certain registration rights to the Investors (the “Registration Rights Agreement”), one or more escrow agreements with respect to the Additional Shares (each, an “Escrow Agreement”) and lock-up agreements executed by certain holders of Ocugen common stock;

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- the representations and warranties made by Ocugen and Histogenics being true and correct as of the date when made and as of the closing date of the Pre-Merger Financing;
- receiving closing legal opinions;
- receiving an acknowledged copy of the irrevocable transfer agent instructions delivered to Histogenics' transfer agent;
- Histogenics obtaining any and all stockholder approvals required by Nasdaq with respect to the issuances of the Converted Additional Shares and the Investor Warrants and the shares of Histogenics common stock upon exercise thereof without giving effect to any limitation on exercise contained therein;
- receiving a certificate evidencing the formation and good standing of Ocugen and Histogenics;
- the satisfaction or waiver of each of the conditions precedent to the closing of the merger contained in the Merger Agreement; and
- Histogenics having effected the Histogenics Reverse Stock Split with respect to the Histogenics common stock such that the volume-weighted average price of a share of Histogenics common stock as of the trading day immediately preceding the closing of the Pre-Merger financing shall be no less than \$10.00 per share on an adjusted basis giving effect to the Histogenics Reverse Stock Split.

Ocugen's obligation to sell the Ocugen Financing Shares and Histogenics' obligation to issue the Series A Warrants, the Series B Warrants and the Series C Warrants to each Investor pursuant to the Securities Purchase Agreement is subject to the satisfaction or waiver of certain conditions, including:

- such Investor executing and delivering each other document required to be delivered under the Securities Purchase Agreement, including the Registration Rights Agreement and such Investor's Escrow Agreement; and
- such Investor delivering to Ocugen its pro rata portion of the Purchase Price;
- the representations and warranties made by such Investor being true and correct as of the date when made and as of the closing date of the Pre-Merger Financing;
- such Investor having performed, satisfied and complied in all material respects with the covenants, agreements and conditions required by the Securities Purchase Agreement to be performed, satisfied or complied with by such Investor at or prior to the closing of the Pre-Merger Financing; and
- the satisfaction or waiver of each of the conditions precedent to the closing of the merger contained in the Merger Agreement.

The representations and warranties contained in the Securities Purchase Agreement will survive the closing of the Pre-Merger Financing.

The Securities Purchase Agreement restricts Histogenics from filing a registration statement or any amendment or supplement thereto, causing any registration statement to be declared effective by the SEC, or granting any registration rights, in each case subject to certain limited exceptions, until the date that is 30 days after the earlier of (i) such time as all of the shares of Histogenics common stock issued or issuable in the Pre-Merger Financing may be sold without restriction or limitation pursuant to Rule 144 and without the requirement to be in compliance with Rule 144(c)(1), (ii) the one year anniversary of the closing date of the Pre-Merger Financing, and (iii) the date that the first registration statement registering for resale shares of Histogenics common stock issued or issuable in the Pre-Merger Financing has been declared effective by the SEC; provided, that clause (iii) shall only apply if there are no shares held by the Investors left unregistered due to a limitation on the maximum number of shares of Histogenics common stock permitted to be registered by the staff of the SEC pursuant to Rule 415 under the Securities Act (the earliest of (i), (ii) and (iii), the "Trigger Date").

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Pursuant to the Securities Purchase Agreement, until the Trigger Date, subject to certain exceptions, neither Ocugen nor Histogenics may (i) offer, sell, grant any option to purchase, or otherwise dispose of any of its or its subsidiaries' debt, equity or equity equivalent securities, including any debt, preferred stock or other instrument or security that is convertible into or exchangeable or exercisable for Ocugen common stock, Histogenics common stock or equivalent securities, including any rights, warrants or options to subscribe for or purchase Ocugen common stock or Histogenics common stock or convertible into or exchangeable or exercisable for Ocugen common stock or Histogenics common stock at a price which varies or may vary with the market price of the Ocugen common stock or Histogenics common stock, including by way of one or more reset(s) to any fixed price (any such offer, sale, grant, disposition or announcement being referred to as a "Subsequent Placement"), (ii) enter into, or effect a transaction under, any agreement, including, but not limited to, an equity line of credit or "at-the-market" offering, whereby Ocugen or Histogenics may issue securities at a future determined price, or (iii) be party to any solicitations, negotiations or discussions with regard to the foregoing.

Additionally, so long as any Investor Warrants remain outstanding, Ocugen, Histogenics and each of their subsidiaries shall be prohibited from effecting or entering into an agreement to effect any Subsequent Placement involving a transaction in which Ocugen, Histogenics or any of their subsidiaries (i) issues or sells any stock or securities convertible into or exercisable or exchangeable for Ocugen common stock or Histogenics common stock ("Convertible Securities") either (a) at a conversion, exercise or exchange rate or other price that is based upon and/or varies with the trading prices of or quotations for the shares of Ocugen common stock or Histogenics common stock at any time after the initial issuance of such Convertible Securities, or (b) with a conversion, exercise or exchange price that is subject to being reset at some future date after the initial issuance of such Convertible Securities or upon the occurrence of specified or contingent events directly or indirectly related to the business of Ocugen or Histogenics or the market for Ocugen common stock or Histogenics common stock, other than pursuant to a customary "weighted average" anti-dilution provision or (ii) enters into any agreement (including, without limitation, an equity line of credit or an "at-the-market" offering) whereby Ocugen, Histogenics or any of their subsidiaries may sell securities at a future determined price (other than standard and customary "preemptive" or "participation" rights).

The Securities Purchase Agreement may be amended only by an instrument in writing signed by Ocugen, Histogenics and the holders of at least a majority of the aggregate amount of Purchased Securities issued and issuable pursuant to the Securities Purchase Agreement, the Series A Warrants, the Series B Warrants and the Series C Warrants. No provision of the Securities Purchase Agreement may be waived other than by an instrument in writing signed by the party against whom enforcement is sought.

Upon written notice by the non-breaching party, the Securities Purchase Agreement may be terminated and the sale and purchase of the Purchased Securities abandoned if the closing of the Pre-Merger Financing has not occurred on or before September 30, 2019 due to any party's failure to satisfy the conditions to closing.

### **Series A Warrants**

The Series A Warrants will have an initial exercise price equal to 125% of the lesser of the aggregate Purchase Price divided by the sum of (i) the number of Converted Initial Shares and (ii) the number of Converted Additional Shares without giving effect to any limitation on delivery pursuant to Section 1(c)(iv) of the Securities Purchase Agreement, will be immediately exercisable and will have a term of 60 months from the date of issuance. The Series A Warrants will be exercisable for an amount of Histogenics common stock up to the amount issuable upon consummation of the merger in exchange for 200% of the Ocugen Financing Shares purchased by the holder.

The Series A Warrants will provide that, following the issuance of the Series A Warrants, if Histogenics issues or sells, enters into a definitive, binding agreement pursuant to which Histogenics is required to issue or sell or is deemed, pursuant to the Provisions of the Series A Warrants, to have issued or sold, any shares of Histogenics common stock for a price per share lower than the exercise price then in effect (a "Dilutive Issuance"), subject to

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certain limited exceptions, then (i) the exercise price of the Series A Warrants shall be reduced to such lower price per share and (ii) the number of shares issuable upon exercise of the Series A Warrants shall be increased to the number of shares of Histogenics common stock determined by multiplying (a) the exercise price in effect immediately prior to such Dilutive Issuance by (b) the number of shares of Histogenics issuable upon exercise of the Series A Warrants immediately prior to such Dilutive Issuance (without giving effect to any limitation on exercise contained therein), and dividing the product thereof by the exercise price resulting from such Dilutive Issuance. If Histogenics issues or sells, or is deemed to have issued or sold any shares of Histogenics common stock for a price per share lower than the exercise price then in effect after the first three years following the issuance of the Series A Warrants, subject to certain limited exceptions, then the exercise price of the Series A Warrants shall be reduced to an amount equal to the product of (i) the exercise price then in effect and (ii) the quotient determined by dividing (a) the sum of (x) the product derived by multiplying the exercise price then in effect and the number of shares of Histogenics common stock outstanding immediately prior to the new issuance plus (y) the consideration received by Histogenics for the new issuance, by (b) the product derived by multiplying (x) the exercise price then in effect by (y) the number of shares of Histogenics common stock outstanding immediately after the new issuance. In addition, the exercise price and the number of shares of Histogenics common stock issuable upon exercise of the Series A Warrants will also be subject to adjustment in connection with stock splits, dividends or distributions or other similar transactions.

Pursuant to the Series A Warrants, Histogenics will agree not to enter into, allow or be party to certain fundamental transactions, generally including any merger with or into another entity, sale of all or substantially all of Histogenics' assets, tender offer or exchange offer, or reclassification of Histogenics common stock (a "Fundamental Transaction") until the 45th trading day immediately following the earlier to occur of (i) the first date on which the holders can sell all the shares issuable upon exercise of the Series A Warrants and the Series B Warrants without restriction or limitation pursuant to Rule 144 under the Securities Act and without the requirement to be in compliance with Rule 144(c)(1) and (ii) the one year anniversary of the closing date of the Pre-Merger Financing (the "Reservation Date"). Thereafter, Histogenics will agree not to enter into or be party to a Fundamental Transaction unless the successor entity in such transaction assumes in writing all of the obligations of Histogenics under the Series A Warrants and the other Financing documents, upon which the Series A Warrants shall become exercisable for shares of Histogenics common stock, shares of the common stock of the successor entity or the consideration that would have been issuable to the holders had they exercised the Series A Warrants prior to such Fundamental Transaction, at the holders' election. Additionally, if the Successor Entity is a publicly traded corporation, the holders may elect to receive an equivalent security of the Successor Entity, in exchange for the Series A Warrants. Any security issuable or potentially issuable to the holder pursuant to the terms of the Series A Warrants on the consummation of a Fundamental Transaction must be registered and freely tradable by the holder without any restriction or limitation or the requirement to be subject to any holding period pursuant to any applicable securities laws.

Additionally, at the request of a holder delivered before the 90th day after the consummation of a Fundamental Transaction, Histogenics or the successor entity must purchase such holder's warrant for the value calculated using the Black-Scholes option pricing model as of the day immediately following the public announcement of the applicable Fundamental Transaction, or, if the Fundamental Transaction is not publicly announced, the date the Fundamental Transaction is consummated.

The Series A Warrants will also contain a "cashless exercise" feature that allows the holders to exercise the Series A Warrants without making a cash payment in the event that there is no effective registration statement registering the shares issuable upon exercise of the Series A Warrants. The Series A Warrants will be subject to a blocker provision which restricts the exercise of the Series A Warrants if, as a result of such exercise, the holder, together with its affiliates and any other person whose beneficial ownership of common Stock would be aggregated with the holder's for purposes of Section 13(d) of the Exchange Act would beneficially own in excess of 4.99% or 9.99% of the outstanding common stock of Histogenics (including the shares of common stock issuable upon such exercise), as such percentage ownership is determined in accordance with the terms of the Series A Warrants.

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If Histogenics fails to issue to a holder of Series A Warrants the number of shares of Histogenics common stock to which such holder is entitled upon such holder's exercise of the Series A Warrants, then Histogenics shall be obligated to pay the holder on each day while such failure is continuing an amount equal to 2.0% of the market value of the undelivered shares determined using a trading price of Histogenics common stock selected by the holder while the failure is continuing and if the holder purchases shares of Histogenics common stock in connection with such failure ("Series A Buy-In Shares"), then Histogenics must, at the holder's discretion, reimburse the holder for the cost of such Series A Buy-In Shares or deliver the owed shares and reimburse the holder for the difference between the price such holder paid for the Series A Buy-In Shares and the market price of such shares, measured at any time of the holder's choosing while the delivery failure was continuing.

Further, the Series A Warrants will provide that, in the event that Histogenics does not have sufficient authorized shares to deliver in satisfaction of an exercise of a Series A Warrant, then unless the holder elects to void such attempted exercise, the holder may require Histogenics to pay an amount equal to the product of (i) the number of shares that Histogenics is unable to deliver and (ii) the highest volume-weighted average price of a share of Histogenics common stock as quoted on Nasdaq during the period beginning on the date of such attempted exercise and ending on the date that Histogenics makes the applicable payment.

### **Series B Warrants**

The Series B Warrants will have an exercise price per share of \$0.01, will be immediately exercisable and will expire on the day following the later to occur of (i) the Reservation Date, and (ii) the date on which the Series B Warrants have been exercised in full (without giving effect to any limitation on exercise contained therein) and no shares remain issuable thereunder. The Series B Warrants will be initially exercisable for an amount of Histogenics common stock equal to the number (if positive) obtained by subtracting (i) the sum of (a) the number of Converted Initial Shares and (b) the number of Converted Additional Shares delivered or deliverable to the holder pursuant to the Securities Purchase Agreement, from (ii) the quotient determined by dividing (a) the pro rata portion of the Purchase Price paid by such holder by (b) 80% of the sum of the volume-weighted average prices of a share of Histogenics common stock on Nasdaq for the first three trading days immediately following the closing date of the Pre-Merger Financing, divided by three.

Additionally, every ninth trading day up to and including the 45<sup>th</sup> trading day (each, a "Reset Date") following (i) each date on which a registration statement registering any registrable securities for resale by a holder of Purchased Securities is declared effective and/or is available for use, (ii) if there is no effective registration statement that is available for use registering all of the shares issuable upon exercise of the Series A Warrants and the Series B Warrants, the earlier to occur of (a) the first date on which the holders can sell all the shares issuable upon exercise of the Series A Warrants and the Series B Warrants without restriction or limitation pursuant to Rule 144 under the Securities Act of 1933, as amended (the "Securities Act"), and (b) the six month anniversary of the closing date of the Pre-Merger Financing (such earlier date, the "Six Month Reset Date") and (iii) in the event of a Public Information Failure at any time following the Six Month Reset Date, then the earlier to occur of (a) the date the Public Information Failure is cured and no longer prevents the holder from selling all of the shares issuable upon exercise of the Series A Warrants and the Series B Warrants pursuant to Rule 144 without restriction or limitation, (b) the first date on which the holders can sell all the shares issuable upon exercise of the Series A Warrants and the Series B Warrants without restriction or limitation pursuant to Rule 144 under the Securities Act and without the requirement to be in compliance with Rule 144(c)(1), and (c) the one year anniversary of the closing date of the Pre-Merger Financing (such 45 trading day period, the "Reset Period" and each such 45<sup>th</sup> trading day after (i), (ii), or (iii), the "End Reset Date"), the number of shares issuable upon exercise of the Series B Warrants shall be increased to the number (if positive) obtained by subtracting (i) the sum of (a) the number of Converted Initial Shares and (b) the number of Converted Additional Shares delivered or deliverable to the holder pursuant to the Securities Purchase Agreement, from (ii) the quotient determined by dividing (a) the pro rata portion of the Purchase Price paid by such holder, by (b) the greater of (y) 80% of the arithmetic average of the two lowest dollar volume-weighted average prices of a share of Histogenics common stock on Nasdaq during the applicable Reset Period immediately preceding the applicable

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Reset Date to date and (z) \$1.00 (which amount shall not be adjusted for reverse stock splits or other similar events).

Pursuant to the Series B Warrants, Histogenics will also agree not to enter into, allow or be party to a Fundamental Transaction until the Reservation Date. Thereafter, Histogenics will agree not to enter into or be party to a Fundamental Transaction unless the successor entity in such transaction assumes in writing all of the obligations of Histogenics under the Series B Warrants and the other Financing documents, upon which the Series B Warrants shall become exercisable for shares of Histogenics common stock, shares of the common stock of the successor entity or the consideration that would have been issuable to the holders had they exercised the Series B Warrants prior to such Fundamental Transaction, at the holders' election. Additionally, if the Successor Entity is a publicly traded corporation, the holders may elect to receive an equivalent security of the Successor Entity, in exchange for the Series B Warrants. Any security issuable or potentially issuable to the holder pursuant to the terms of the Series B Warrants on the consummation of a Fundamental Transaction must be registered and freely tradable by the holder without any restriction or limitation or the requirement to be subject to any holding period pursuant to any applicable securities laws.

The Series B Warrants will also contain a "cashless exercise" feature that allows the holders to exercise the Series B Warrants without making a cash payment. The Series B Warrants will be subject to a blocker provision which restricts the exercise of the Series B Warrants if, as a result of such exercise, the holder, together with its affiliates and any other person whose beneficial ownership of Histogenics common stock would be aggregated with the holder's for purposes of Section 13(d) of the Exchange Act would beneficially own in excess of 4.99% or 9.99% of the outstanding common stock of Histogenics (including the shares of common stock issuable upon such exercise), as such percentage ownership is determined in accordance with the terms of the Series B Warrants.

If Histogenics fails to issue to a holder of Series B Warrants the number of shares of Histogenics common stock to which such holder is entitled upon such holder's exercise of the Series B Warrants, then Histogenics shall be obligated to pay the holder on each day while such failure is continuing an amount equal to 2.0% of the market value of the undelivered shares determined using any trading price of Histogenics common stock selected by the holder while the failure is continuing and if the holder purchases shares of Histogenics common stock in connection with such failure ("Series B Buy-In Shares"), then Histogenics must, at the holder's discretion, reimburse the holder for the cost of such Series B Buy-In Shares or deliver the owed shares and reimburse the holder for the difference between the price such holder paid for the Series B Buy-In Shares and the market price of such shares, measured at any time of the holder's choosing while the delivery failure was continuing.

Further, in the event that Histogenics does not have sufficient authorized shares to deliver in satisfaction of an exercise of a Series B Warrant, then unless the holder elects to void such attempted exercise, the holder may require Histogenics to pay an amount equal to the product of (i) the number of shares that Histogenics is unable to deliver and (ii) the highest volume-weighted average price of a share of Histogenics common stock as quoted on Nasdaq during the period beginning on the date of such attempted exercise and ending on the date that Histogenics makes the applicable payment.

### **Series C Warrants**

The Series C Warrants will be exercisable for up to 50 million shares of Histogenics common stock and will have an exercise price equal to 125% of the aggregate Purchase Price divided by the sum of (i) the number of Converted Initial Shares and (ii) the number of Converted Additional Shares without giving effect to any limitation on delivery pursuant to Section 1(c)(iv) of the Securities Purchase Agreement, will be immediately exercisable and will expire upon the 45th trading day immediately following the earlier to occur of (i) the date the holder can sell all shares issuable upon exercise of the Series C Warrants pursuant to Rule 144 without restriction or limitation and without the requirement to be in compliance with Rule 144(c)(1) and (ii) the date that is 12 months from the date of issuance, provided that if such date falls on a day other than a business day or on

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which trading does not take place on Nasdaq (a “Holiday”), the next day that is not a Holiday (the “Series C Expiration Date”).

If the volume-weighted average trading price of a share of Histogenics common stock on Nasdaq is less than or equal to \$1.20 per share (as adjusted for stock splits, stock dividends, recapitalizations, reorganizations, reclassifications, combinations, reverse stock splits and similar events) on any five trading days following the date of issuance and prior to the Series C Expiration Date, the holder may, in lieu of making any cash payment in connection with the exercise of the Series C Warrants, elect to receive a number of shares of Histogenics common stock equal to the number of Series C Warrants. The number of shares issuable upon exercise and the exercise price of the Series C Warrants shall not be adjusted by the Histogenics Reverse Stock Split.

Pursuant to the Series C Warrants, Histogenics will also agree not to enter into, allow or be party to a Fundamental Transaction until the Reservation Date. Thereafter, Histogenics agreed not to enter into or be party to a Fundamental Transaction unless the successor entity in such transaction assumes in writing all of the obligations of Histogenics under the Series C Warrants and the other Financing documents, upon which the Series C Warrants shall become exercisable for shares of Histogenics common stock, shares of the common stock of the successor entity or the consideration that would have been issuable to the holders had they exercised the Series C Warrants prior to such Fundamental Transaction, at the holders’ election. Additionally, if the Successor Entity is a publicly traded corporation, the holders may elect to receive an equivalent security of the Successor Entity, in exchange for the Series C Warrants. Any security issuable or potentially issuable to the holder pursuant to the terms of the Series C Warrants on the consummation of a Fundamental Transaction must be registered and freely tradable by the holder without any restriction or limitation or the requirement to be subject to any holding period pursuant to any applicable securities laws.

The Series C Warrants will also contain a “cashless exercise” feature that allows the holders to exercise the Series C Warrants without making a cash payment. The Series C Warrants will be subject to a blocker provision which restricts the exercise of the Series C Warrants if, as a result of such exercise, the holder, together with its affiliates and any other person whose beneficial ownership of Histogenics common stock would be aggregated with the holder’s for purposes of Section 13(d) of the Exchange Act would beneficially own in excess of 4.99% or 9.99% of the outstanding common stock of Histogenics (including the shares of common stock issuable upon such exercise), as such percentage ownership is determined in accordance with the terms of the Series C Warrants.

If Histogenics fails to issue to a holder of Series C Warrants the number of shares of Histogenics common stock to which such holder is entitled upon such holder’s exercise of the Series C Warrants, then Histogenics shall be obligated to pay the holder on each day while such failure is continuing an amount equal to 2.0% of the market value of the undelivered shares determined using any trading price of Histogenics common stock selected by the holder while the failure is continuing and if the holder purchases shares of Histogenics common stock in connection with such failure (“Series C Buy-In Shares”), then Histogenics must, at the holder’s discretion, reimburse the holder for the cost of such Series C Buy-In Shares or deliver the owed shares and reimburse the holder for the difference between the price such holder paid for the Series C Buy-In Shares and the market price of such shares, measured at any time of the holder’s choosing while the delivery failure was continuing.

Further, in the event that Histogenics does not have sufficient authorized shares to deliver in satisfaction of an exercise of a Series C Warrant, then unless the holder elects to void such attempted exercise, the holder may require Histogenics to pay an amount equal to the product of (i) the number of shares that Histogenics is unable to deliver and (ii) the highest volume-weighted average price of a share of Histogenics common stock as quoted on Nasdaq during the period beginning on the date of such attempted exercise and ending on the date that Histogenics makes the applicable payment.

### **Registration Rights Agreement**

In connection with the Pre-Merger Financing, Histogenics entered into the Registration Rights Agreement with the Investors. Pursuant to the Registration Rights Agreement, Histogenics is required to file an initial resale



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registration statement with respect to shares of Histogenics capital stock (the “Registrable Securities”), held by or issuable to the Investors, within 10 days of the closing of the Pre-Merger Financing. Additionally, Histogenics is required to file additional resale registration statements with respect to the Registrable Securities within 30 days of each End Reset Date, to the extent that such Registrable Securities are not already registered for resale on a prior registration statement. Histogenics will be required to use commercially reasonable efforts to maintain the effectiveness of these registration statements until the Registrable Securities covered by these registration statements have been disposed of or are no longer Registrable Securities.

If Histogenics fails to file and obtain and maintain effectiveness of the resale registration statements required under the Registration Rights Agreement or fails, subject to limited grace periods, to maintain the effectiveness of the resale registration statements, then Histogenics shall be obligated to pay to each affected holder of Registrable Securities an amount equal to 2.0% of the aggregate Purchase Price of such Investor’s Registrable Securities whether or not included in such registration statement on each of the day of such failure and on every thirtieth day thereafter (pro-rated for periods of less than 30 days) until the date such failure is cured.

These registration rights granted under the Registration Rights Agreement are subject to certain conditions and limitations, including Histogenics’ right to delay or withdraw a registration statement under certain circumstances. The registration rights granted in the Registration Rights Agreement are subject to customary indemnification and contribution provisions.

### **Financing Lock-Up Agreements**

In connection with the Pre-Merger Financing, Histogenics and Ocugen will enter into lock-up agreements with each officer, director or other person that will be subject to Section 16 of the Exchange Act, with respect to Histogenics immediately following the consummation of the merger, and each holder of greater than 3% of Ocugen common stock (excluding shares of Ocugen common stock issuable pursuant to the Securities Purchase Agreement) immediately prior to the consummation of the merger (the “Financing Lock-Up Parties”), pursuant to which each of the Financing Lock-Up Parties will agree that until the date that is 30 calendar days after the Trigger Date, subject to certain customary exceptions, such Financing Lock-Up Party will not and will cause its affiliates not to (i) offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, make any short sale or otherwise transfer or dispose of or lend, directly or indirectly, any shares of Histogenics common stock or any securities convertible into, exercisable or exchangeable for or that represent the right to receive Histogenics common stock, (ii) enter into any swap or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of any of the Financing Lock-Up Party’s shares of Histogenics common stock or such other securities, in cash or otherwise, (iii) make any demand for or exercise any right or cause to be filed a registration statement, including any amendments thereto, with respect to the registration of any shares of Histogenics common stock or such other securities, in cash or otherwise, (iv) grant any proxies or powers of attorney with respect to any shares of Histogenics common stock or such other securities, deposit any shares of Histogenics common stock or such other securities into a voting trust or enter into a voting agreement or similar arrangement or commitment with respect to any shares of Histogenics common stock or such other securities, or (v) publicly disclose the intention to do any of the foregoing.

## MATTERS BEING SUBMITTED TO A VOTE OF HISTOGENICS' STOCKHOLDERS

### **Proposal No. 1: Approval of the Merger Agreement, the Merger, the Issuance of Common Stock in the Merger and the Change of Control Resulting from the Merger**

At the Histogenics special meeting, Histogenics' stockholders will be asked to approve the Merger Agreement and the transactions contemplated thereby, including the merger, the issuance of Histogenics common stock to Ocugen's stockholders pursuant to the Merger Agreement and the change of control resulting from the merger. Immediately following the merger, and after giving effect to the Pre-Merger Financing, it is expected that current holders of Ocugen's capital stock and options and warrant to purchase shares of Ocugen common stock, are expected to own, or hold rights to acquire, in the aggregate approximately 86.24% of the Fully-Diluted Common Stock of Histogenics, and Histogenics' current stockholders and warrant holders are expected to own, or hold rights to acquire, in the aggregate approximately 13.76% of the Fully-Diluted Common Stock of Histogenics. Histogenics will assume outstanding and unexercised warrants and options to purchase shares of Ocugen capital stock, and such securities will be converted into warrants and options, as applicable, to purchase shares of Histogenics common stock.

The terms of, reasons for and other aspects of the Merger Agreement, the merger, the issuance of Histogenics common stock pursuant to the Merger Agreement and the change of control resulting from the merger are described in detail in the other sections in this proxy statement/prospectus/information statement.

#### ***Required Vote***

The affirmative vote of the holders of a majority of the shares of Histogenics common stock entitled to vote and present in person or represented by proxy at the Histogenics special meeting is required for approval of Proposal No. 1. Abstentions will have the same effect as votes "AGAINST" this Proposal.

**THE HISTOGENICS BOARD RECOMMENDS THAT HISTOGENICS' STOCKHOLDERS VOTE "FOR" PROPOSAL NO. 1 TO APPROVE THE MERGER AGREEMENT AND THE TRANSACTIONS CONTEMPLATED THEREBY, INCLUDING THE MERGER, THE ISSUANCE OF HISTOGENICS COMMON STOCK PURSUANT TO THE MERGER AGREEMENT AND THE CHANGE OF CONTROL RESULTING FROM THE MERGER. EACH OF PROPOSAL NOS. 1 AND 2 ARE CONDITIONED UPON EACH OTHER AND THE APPROVAL OF EACH SUCH PROPOSAL IS REQUIRED TO CONSUMMATE THE MERGER.**

### **Proposal No. 2: Approval of an Amendment to the Sixth Amended and Restated Certificate of Incorporation of Histogenics Effecting the Histogenics Reverse Stock Split**

#### ***General***

At the Histogenics special meeting, Histogenics' stockholders will be asked to approve an amendment to the sixth amended and restated certificate of incorporation of Histogenics effecting the Histogenics Reverse Stock Split. Upon the effectiveness of the amendment to the sixth amended and restated certificate of incorporation of Histogenics effecting the Histogenics Reverse Stock Split, or the split effective time, the issued shares of Histogenics common stock immediately prior to the split effective time will be reclassified into a smaller number of shares within a range, as determined by the Histogenics Board, such that a stockholder of Histogenics will own one new share of Histogenics common stock for every 53 to 67 (or any number in between) shares of issued common stock held by that stockholder immediately prior to the split effective time.

If Proposal No. 2 is approved, the Histogenics Reverse Stock Split would become effective in connection with the closing of the merger. The Histogenics Board may effect only one reverse stock split in connection with this Proposal No. 2. The Histogenics Board's decision will be based on a number of factors, including market conditions, existing and expected trading prices for Histogenics common stock and the listing requirements of Nasdaq.

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The form of the amendment to the sixth amended and restated certificate of incorporation of Histogenics to effect the Histogenics Reverse Stock Split, as more fully described below, will effect the Histogenics Reverse Stock Split but will not change the number of authorized shares of common stock or preferred stock, or the par value of Histogenics common stock or preferred stock.

### ***Purpose***

The Histogenics Board approved the proposal approving the amendment to the sixth amended and restated certificate of incorporation of Histogenics effecting the Histogenics Reverse Stock Split for the following reasons:

- the Histogenics Board believes effecting the Histogenics Reverse Stock Split may be an effective means of avoiding a delisting of Histogenics common stock from Nasdaq in the future;
- the Histogenics Board believes that the Histogenics Reverse Stock Split will result in a number of authorized but unissued shares of Histogenics common stock sufficient for the issuance of shares of Histogenics common stock to Ocugen's stockholders pursuant to the Merger Agreement; and
- the Histogenics Board believes a higher stock price may help generate investor interest in Histogenics and help Histogenics attract and retain employees.

If the Histogenics Reverse Stock Split successfully increases the per share price of Histogenics common stock, the Histogenics Board believes this increase may increase trading volume in Histogenics common stock and facilitate future financings by Histogenics.

### ***Nasdaq Requirements for Listing on Nasdaq***

Histogenics common stock is quoted on Nasdaq under the symbol "HSGX." Histogenics intends to file an initial listing application with Nasdaq to seek listing on Nasdaq upon the closing of the merger.

According to Nasdaq rules, an issuer must, in a case such as this, apply for initial inclusion following a transaction whereby the issuer combines with a non-Nasdaq entity, resulting in a change of control of the issuer and potentially allowing the non-Nasdaq entity to obtain a Nasdaq listing. Accordingly, the listing standards of Nasdaq will require Histogenics to have, among other things, a \$4.00 per share minimum bid price upon the closing of the merger. Therefore, the Histogenics Reverse Stock Split may be necessary in order to consummate the merger.

One of the effects of the Histogenics Reverse Stock Split will be to effectively increase the proportion of authorized shares which are unissued relative to those which are issued. This could result in Histogenics' management being able to issue more shares without further stockholder approval. For example, before the Histogenics Reverse Stock Split, Histogenics' authorized but unallocated shares immediately prior to the closing of the merger would be approximately 591,599 compared to shares issued and outstanding of approximately 94,599,601. If Histogenics effects the Histogenics Reverse Stock Split using a 1:60 ratio (the midpoint of the range of the Histogenics Reverse Stock Split), its authorized but unissued shares immediately prior to the closing of the merger would be approximately 9,860 compared to shares issued of approximately 1,580,665. Histogenics currently has no plans to issue shares, other than in connection with the merger and as required by the Pre-Merger Financing, and to satisfy obligations under the Histogenics warrants and employee stock options from time to time as these warrants and options are exercised. The Histogenics Reverse Stock Split will not affect the number of authorized shares of Histogenics common stock which will continue to be authorized pursuant to the certificate of incorporation of Histogenics.

### ***Potential Increased Investor Interest***

On August , 2019, Histogenics common stock closed at \$ per share. An investment in Histogenics common stock may not appeal to brokerage firms that are reluctant to recommend lower priced securities to their clients.

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Investors may also be dissuaded from purchasing lower priced stocks because the brokerage commissions, as a percentage of the total transaction, tend to be higher for such stocks. Moreover, the analysts at many brokerage firms do not monitor the trading activity or otherwise provide coverage of lower priced stocks. Also, the Histogenics Board believes that most investment funds are reluctant to invest in lower priced stocks.

There are risks associated with the Histogenics Reverse Stock Split, including that the Histogenics Reverse Stock Split may not result in an increase in the per share price of Histogenics common stock.

Histogenics cannot predict whether the Histogenics Reverse Stock Split will increase the market price for Histogenics common stock. The history of similar stock split combinations for companies in like circumstances is varied. There is no assurance that:

- the market price per share of Histogenics common stock after the Histogenics Reverse Stock Split will rise in proportion to the reduction in the number of shares of Histogenics common stock outstanding before the Histogenics Reverse Stock Split;
- the Histogenics Reverse Stock Split will result in a per share price that will attract brokers and investors who do not trade in lower priced stocks;
- the Histogenics Reverse Stock Split will result in a per share price that will increase the ability of Histogenics to attract and retain employees; or
- the market price per share will either exceed or remain in excess of the \$1.00 minimum bid price as required by Nasdaq for continued listing, or that Histogenics will otherwise meet the requirements of Nasdaq for inclusion for trading on Nasdaq, including the \$4.00 minimum bid price upon the closing of the merger.

The market price of Histogenics common stock will also be based on performance of Histogenics and other factors, some of which are unrelated to the number of shares outstanding. If the Histogenics Reverse Stock Split is effected and the market price of Histogenics common stock declines, the percentage decline as an absolute number and as a percentage of the overall market capitalization of Histogenics may be greater than would occur in the absence of a reverse stock split. Furthermore, the liquidity of Histogenics common stock could be adversely affected by the reduced number of shares that would be outstanding after the Histogenics Reverse Stock Split.

### ***Principal Effects of the Histogenics Reverse Stock Split***

The amendment to the sixth amended and restated certificate of incorporation of Histogenics effecting the Histogenics Reverse Stock Split is set forth in *Annex D* to this proxy statement/prospectus/information statement.

The Histogenics Reverse Stock Split will be effected simultaneously for all outstanding shares of Histogenics common stock. The Histogenics Reverse Stock Split will affect all of Histogenics' stockholders uniformly and will not affect any stockholder's percentage ownership interest in Histogenics, except to the extent that the Histogenics Reverse Stock Split results in any of Histogenics' stockholders owning a fractional share. Shares of Histogenics common stock issued pursuant to the Histogenics Reverse Stock Split will remain fully paid and nonassessable. The Histogenics Reverse Stock Split does not affect the total proportionate ownership of Histogenics following the merger. The Histogenics Reverse Stock Split will not affect Histogenics continuing to be subject to the periodic reporting requirements of the Exchange Act.

### ***Procedure for Effecting the Histogenics Reverse Stock Split and Exchange of Stock Certificates***

If Histogenics' stockholders approve the amendment to the sixth amended and restated certificate of incorporation of Histogenics effecting the Histogenics Reverse Stock Split, and if the Histogenics Board still believes that a reverse stock split is in the best interests of Histogenics and its stockholders, Histogenics will file

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the amendment to the sixth amended and restated certificate of incorporation with the Secretary of State of the State of Delaware at such time as the Histogenics Board has determined to be the appropriate split effective time. The Histogenics Board may delay effecting the Histogenics Reverse Stock Split without resoliciting stockholder approval. Beginning at the split effective time, each certificate representing pre-split shares will be deemed for all corporate purposes to evidence ownership of post-split shares.

As soon as practicable after the split effective time, Histogenics' stockholders will be notified that the Histogenics Reverse Stock Split has been effected. Histogenics expects that the Histogenics transfer agent will act as exchange agent for purposes of implementing the exchange of stock certificates. Holders of pre-split shares will be asked to surrender to the exchange agent certificates representing pre-split shares held in certificated form in exchange for certificates representing post-split shares in accordance with the procedures to be set forth in a letter of transmittal to be sent by Histogenics. In the event that the Histogenics Name Change under Proposal No. 3 is approved by Histogenics' stockholders, the certificates reflecting the post-split shares will also reflect the Histogenics Name Change. No new certificates will be issued to a stockholder until such stockholder has surrendered such stockholder's outstanding certificate(s) together with the properly completed and executed letter of transmittal to the exchange agent. Any pre-split shares submitted for transfer, whether pursuant to a sale or other disposition, or otherwise, will automatically be exchanged for post-split shares. **Stockholders should not destroy any stock certificate(s) and should not submit any certificate(s) unless and until requested to do so.**

### ***Fractional Shares***

No fractional shares will be issued in connection with the Histogenics Reverse Stock Split. Stockholders of record who otherwise would be entitled to receive fractional shares because they hold a number of pre-split shares not evenly divisible by the number of pre-split shares for which each post-split share is to be reclassified, will be entitled, upon surrender to the exchange agent of certificates representing such shares, to a cash payment in lieu thereof at a price equal to the fraction to which the stockholder would otherwise be entitled multiplied by the closing price of the common stock on Nasdaq on the date immediately preceding the split effective time. The ownership of a fractional interest will not give the holder thereof any voting, dividend, or other rights except to receive payment therefor as described herein.

By approving the amendment to the sixth amended and restated certificate of incorporation of Histogenics effecting the Histogenics Reverse Stock Split, stockholders will be approving the combination of 53 to 67 shares of Histogenics common stock, as determined by the Histogenics Board, into one share of Histogenics common stock.

Stockholders should be aware that, under the escheat laws of the various jurisdictions where stockholders reside, where Histogenics is domiciled, and where the funds will be deposited, sums due for fractional interests that are not timely claimed after the effective date of the split may be required to be paid to the designated agent for each such jurisdiction, unless correspondence has been received by Histogenics or the exchange agent concerning ownership of such funds within the time permitted in such jurisdiction. Thereafter, stockholders otherwise entitled to receive such funds will have to seek to obtain them directly from the state to which they were paid.

### ***Potential Anti-Takeover Effect***

Although the increased proportion of unissued authorized shares to issued shares could, under certain circumstances, have an anti-takeover effect, for example, by permitting issuances that would dilute the stock ownership of a person seeking to effect a change in the composition of the Histogenics Board or contemplating a tender offer or other transaction for the combination of Histogenics with another company, the Histogenics Reverse Stock Split proposal is not being proposed in response to any effort of which Histogenics is aware to accumulate shares of Histogenics common stock or obtain control of Histogenics, other than in connection with the merger, nor is it part of a plan by management to recommend a series of similar amendments to the

Histogenics Board and stockholders. Other than the proposals being submitted to Histogenics' stockholders for their consideration at the Histogenics special meeting, the Histogenics Board does not currently contemplate recommending the adoption of any other actions that could be construed to affect the ability of third parties to take over or change control of Histogenics. For more information, please see the section entitled "Risk Factors—Risks Related to the Common Stock of Histogenics", and "Description of Histogenics' Capital Stock—Anti-Takeover Effects of Provisions of Histogenics Charter Documents" and "—Anti-Takeover Effects of Delaware Law."

***Material U.S. Federal Income Tax Consequences of the Histogenics Reverse Stock Split***

The following discussion is a summary of the material U.S. federal income tax consequences of the Histogenics Reverse Stock Split to Histogenics U.S. Holders, but does not purport to be a complete analysis of all potential tax consequences that may be relevant to Histogenics U.S. Holders. The effects of other U.S. federal tax laws, such as estate and gift tax laws, and any applicable state, local or non-U.S. tax laws are not discussed. This discussion is based on the Code, Treasury Regulations promulgated thereunder, judicial decisions, and published rulings and administrative pronouncements of the IRS, in each case in effect as of the date hereof. These authorities may change or be subject to differing interpretations. Any such change or differing interpretation may be applied retroactively in a manner that could adversely affect a Histogenics U.S. Holder. Histogenics has not sought and does not intend to seek any rulings from the IRS regarding the matters discussed below. There can be no assurance the IRS or a court will not take a position contrary to that discussed below regarding the tax consequences of the Histogenics Reverse Stock Split.

This discussion is limited to Histogenics U.S. Holders that hold Histogenics common stock as a "capital asset" within the meaning of Section 1221 of the Code (generally, property held for investment). This discussion does not address all U.S. federal income tax consequences that may be relevant to a Histogenics U.S. Holder's particular circumstances, including the impact of the alternative minimum tax or the Medicare contribution tax on net investment income. In addition, it does not address consequences relevant to Histogenics U.S. Holders subject to special rules, including, without limitation:

- U.S. expatriates and former citizens or long-term residents of the United States;
- Histogenics U.S. Holders whose functional currency is not the U.S. dollar;
- persons holding Histogenics common stock as part of a hedge, straddle or other risk reduction strategy or as part of a conversion transaction or other integrated investment;
- banks, insurance companies, and other financial institutions;
- real estate investment trusts or regulated investment companies;
- brokers, dealers or traders in securities;
- persons for whom Histogenics common stock constitutes "qualified small business stock" within the meaning of Section 1202 of the Code;
- "controlled foreign corporations," "passive foreign investment companies," and corporations that accumulate earnings to avoid U.S. federal income tax;
- S corporations, partnerships or other entities or arrangements treated as partnerships for U.S. federal income tax purposes (and investors therein);
- tax-exempt organizations or governmental organizations;
- persons subject to special tax accounting rules as a result of any item of gross income with respect to Histogenics common stock being taken into account in an "applicable financial statement" (as defined in the Code);
- persons deemed to sell Histogenics common stock under the constructive sale provisions of the Code;

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- persons who hold or received Histogenics common stock pursuant to the exercise of any employee stock option or otherwise as compensation; and
- tax-qualified retirement plans.

If an entity treated as a partnership for U.S. federal income tax purposes holds Histogenics common stock, the tax treatment of a partner in the partnership will depend on the status of the partner, the activities of the partnership and certain determinations made at the partner level. Accordingly, partnerships holding Histogenics common stock and the partners in such partnerships should consult their tax advisors regarding the U.S. federal income tax consequences to them.

**THIS DISCUSSION IS FOR INFORMATION PURPOSES ONLY AND IS NOT TAX ADVICE. HOLDERS SHOULD CONSULT THEIR TAX ADVISORS WITH RESPECT TO THE APPLICATION OF THE U.S. FEDERAL INCOME TAX LAWS TO THEIR PARTICULAR SITUATIONS AS WELL AS ANY TAX CONSEQUENCES OF THE HISTOGENICS REVERSE STOCK SPLIT ARISING UNDER THE U.S. FEDERAL ESTATE OR GIFT TAX LAWS OR UNDER THE LAWS OF ANY STATE, LOCAL OR NON-U.S. TAXING JURISDICTION OR UNDER ANY APPLICABLE INCOME TAX TREATY.**

### *Histogenics Reverse Stock Split*

The Histogenics Reverse Stock Split should constitute a “recapitalization” for U.S. federal income tax purposes. As a result, a Histogenics U.S. Holder generally should not recognize gain or loss upon the Histogenics Reverse Stock Split, except with respect to cash received in lieu of a fractional share of Histogenics common stock, as discussed below. A Histogenics U.S. Holder’s aggregate tax basis in the shares of Histogenics common stock received pursuant to the Histogenics Reverse Stock Split should equal the aggregate tax basis of the shares of Histogenics common stock surrendered (excluding any portion of such basis that is allocated to any fractional share of Histogenics common stock), and such Histogenics U.S. Holder’s holding period in the shares of Histogenics common stock received should include the holding period in the shares of Histogenics common stock surrendered. Treasury Regulations provide detailed rules for allocating the tax basis and holding period of the shares of Histogenics common stock surrendered to the shares of Histogenics common stock received pursuant to the Histogenics Reverse Stock Split. Holders of shares of Histogenics common stock acquired on different dates and at different prices should consult their tax advisors regarding the allocation of the tax basis and holding period of such shares.

A Histogenics U.S. Holder that receives cash in lieu of a fractional share of Histogenics common stock pursuant to the Histogenics Reverse Stock Split should recognize capital gain or loss in an amount equal to the difference between the amount of cash received and the Histogenics U.S. Holder’s tax basis in the shares of Histogenics common stock surrendered that is allocated to such fractional share of its common stock. Such capital gain or loss should be long-term capital gain or loss if the Histogenics U.S. Holder’s holding period for Histogenics common stock surrendered exceeded one year at the effective time of the Histogenics Reverse Stock Split.

### *Information Reporting and Backup Withholding*

A Histogenics U.S. Holder may be subject to information reporting and backup withholding when such holder receives cash in lieu of fractional shares of Histogenics common stock in the Histogenics Reverse Stock Split. Certain Histogenics U.S. Holders are exempt from backup withholding, including corporations and certain tax-exempt organizations. A Histogenics U.S. Holder will be subject to backup withholding if such holder is not otherwise exempt and:

- the holder fails to furnish the holder’s taxpayer identification number, which for an individual is ordinarily his or her social security number;
- the holder furnishes an incorrect taxpayer identification number;

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- the applicable withholding agent is notified by the IRS that the holder previously failed to properly report payments of interest or dividends; or
- the holder fails to certify under penalties of perjury that the holder has furnished a correct taxpayer identification number and that the IRS has not notified the holder that the holder is subject to backup withholding.

Backup withholding is not an additional tax. Any amounts withheld under the backup withholding rules may be allowed as a refund or a credit against a Histogenics U.S. Holder's U.S. federal income tax liability, provided the required information is timely furnished to the IRS. Histogenics U.S. Holders should consult their tax advisors regarding their qualification for an exemption from backup withholding and the procedures for obtaining such an exemption.

### ***Vote Required; Recommendation of the Histogenics Board***

The affirmative vote of holders of a majority of the shares of Histogenics common stock having voting power outstanding on the record date for the Histogenics special meeting is required to approve the amendment to the sixth amended and restated certificate of incorporation of Histogenics effecting the Histogenics Reverse Stock Split. Abstentions and broker non-votes will have the same effect as votes "AGAINST" this Proposal.

**THE HISTOGENICS BOARD RECOMMENDS THAT HISTOGENICS' STOCKHOLDERS VOTE "FOR" PROPOSAL NO. 2 TO APPROVE THE AMENDMENT TO THE SIXTH AMENDED AND RESTATED CERTIFICATE OF INCORPORATION OF HISTOGENICS EFFECTING THE HISTOGENICS REVERSE STOCK SPLIT. EACH OF PROPOSAL NOS. 1 AND 2 ARE CONDITIONED UPON EACH OTHER AND THE APPROVAL OF EACH SUCH PROPOSAL IS REQUIRED TO CONSUMMATE THE MERGER.**

### **Proposal No. 3: Approval of Histogenics Name Change**

At the Histogenics special meeting, Histogenics' stockholders will be asked to approve the amendment to the sixth amended and restated certificate of incorporation of Histogenics to effect the Histogenics Name Change. The primary reason for the corporate name change is that management believes this will allow for brand recognition of Ocugen's products and programs following the consummation of the merger. Histogenics' management believes that the current name will no longer accurately reflect the business of Histogenics and the mission of Histogenics subsequent to the consummation of the merger.

The affirmative vote of holders of a majority of the shares of Histogenics common stock having voting power outstanding on the record date for the Histogenics special meeting is required to approve the amendment to the sixth amended and restated certificate of incorporation to effect the Histogenics Name Change. Abstentions and broker non-votes will have the same effect as votes "AGAINST" this Proposal.

**THE HISTOGENICS BOARD RECOMMENDS THAT HISTOGENICS' STOCKHOLDERS VOTE "FOR" PROPOSAL NO. 3 TO APPROVE THE HISTOGENICS NAME CHANGE. PROPOSAL NO. 3 IS CONDITIONED UPON THE APPROVAL OF EACH OF PROPOSAL NOS. 1 AND 2.**

### **Proposal No. 4: Approval of An Amendment to Histogenics' Sixth Amended and Restated Certificate of Incorporation to Increase the Number of Authorized Shares of Histogenics Common Stock To a Total Number of 200,000,000 Shares**

At the Histogenics special meeting, Histogenics will ask its stockholders to approve the amendment to its sixth amended and restated certificate of incorporation to increase the number of authorized shares of Histogenics common stock. On June 13, 2019 the Histogenics Board approved a proposal to amend Histogenics' sixth



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amended and restated certificate of incorporation to increase the number of authorized shares of Histogenics common stock from 100,000,000 shares to 200,000,000 (the “Share Increase”). On the record date, there were 94,599,601 shares of Histogenics common stock issued and outstanding, and 4,508,800 shares of Histogenics common stock reserved for issuance. Accordingly, approximately 591,599 shares of the total number of Histogenics common stock currently authorized remain available for issuance or may be reserved for issuance.

### **Form of the Histogenics Share Increase Amendment**

The proposed amendment (the “Histogenics Share Increase Amendment”) would amend Paragraph A of Article IV of Histogenics’ sixth amended and restated certificate of incorporation to read in its entirety as follows:

“A. The total number of shares of all classes of stock which the Corporation shall have authority to issue is two hundred ten million (210,000,000), consisting of two hundred million (200,000,000) shares of Common Stock, par value \$0.01 per share (the “Common Stock”), and ten million (10,000,000) shares of Preferred Stock, par value \$0.01 per share (the “Preferred Stock”).”

### **Background and Reasons for the Share Increase**

Histogenics is party to the Securities Purchase Agreement, pursuant to which Histogenics has agreed to use commercially reasonable efforts to seek to increase the number of authorized shares of Histogenics common stock to 200,000,000 shares.

Histogenics’ sixth amended and restated certificate of incorporation, as amended, currently authorize the issuance of up to 100,000,000 shares of Histogenics common stock and 10,000,000 shares of preferred stock. As of the close of business on the record date, there were 94,599,601 shares of Histogenics common stock issued and outstanding, and 4,508,800 shares of Histogenics common stock reserved for issuance. Accordingly, approximately 591,599 shares of the total number of Histogenics common stock currently authorized remain available for issuance or may be reserved for issuance.

If the Histogenics Share Increase Amendment is approved by stockholders, upon its effectiveness Histogenics will have a total of 200,000,000 authorized shares of Histogenics common stock, with 94,599,601 shares of Histogenics common stock issued and outstanding (as of the record date), and 4,508,800 shares reserved for issuance, leaving a balance of 100,591,599 shares of Histogenics common stock authorized and unissued and not reserved for any specific purpose.

### **Purpose of the Amendment**

The Histogenics Board believes it is in the best interest of Histogenics to increase the number of authorized shares of Histogenics common stock in order to give Histogenics greater flexibility in considering and planning for future general corporate needs, including, but not limited to, grants under equity compensation plans, stock splits, financings, potential strategic transactions, as well as other general corporate transactions. The Histogenics Board believes that additional authorized shares of Histogenics common stock will enable Histogenics to take timely advantage of market conditions and favorable financing and acquisition opportunities that become available to Histogenics by allowing the issuance of such shares without the expense and delay of another stockholder meeting.

Histogenics is party to the Securities Purchase Agreement pursuant to which Histogenics has agreed to use commercially reasonable efforts to seek to increase the number of authorized shares of Histogenics common stock to 200,000,000 shares.

Other than described herein, Histogenics has no current plan, commitment, arrangement, understanding or agreement to issue additional shares of Histogenics common stock from the additional 100,000,000 shares to be

authorized pursuant to the Share Increase. The authorized but unissued shares will only be issued at the direction of the Histogenics Board, and upon separate stockholder approval if and as required by applicable law or regulation. Additionally, at this time, the increase in authorized shares of Histogenics common stock is not related to any plans or intentions to enter into a merger (including the merger), consolidation, acquisition or similar business transaction other than pursuant to the requirement in the Securities Purchase Agreement to use commercially reasonable efforts to seek the increase.

#### **Rights of Additional Authorized Shares**

Any newly authorized shares of Histogenics common stock will be identical to the shares of Histogenics common stock now authorized and outstanding. The Histogenics Share Increase Amendment will not alter the voting powers or relative rights of the Histogenics common stock. In accordance with Histogenics' sixth amended and restated certificate of incorporation and the DGCL, any of Histogenics' authorized but unissued shares of preferred stock are "blank check" preferred stock which shall have such voting rights, dividend rights, liquidation preferences, conversion rights and perceptible rights as may be designated by the Histogenics Board pursuant to a certificate of designation.

#### **Potential Adverse Effects of the Amendment**

Adoption of the Histogenics Share Increase Amendment will have no immediate dilutive effect on the proportionate voting power or other rights of Histogenics' existing stockholders. To the extent any outstanding warrants, options or other convertible securities of Histogenics are exercised, or Histogenics issues additional shares of common stock in the future, Histogenics' stockholders will experience dilution. The Histogenics Board has no current plan to issue shares from the additional authorized shares provided by the Histogenics Share Increase Amendment. However, any future issuance of additional authorized shares of Histogenics common stock may, among other things, dilute the earnings per share of Histogenics common stock and the equity and voting rights of those holding Histogenics common stock at the time the additional shares are issued. Additionally, this potential dilutive effect may cause a reduction in the market price of Histogenics common stock.

#### **Potential Anti-Takeover Effects**

The Share Increase could adversely affect the ability of third parties to take Histogenics over or change the control of Histogenics by, for example, permitting issuances that would dilute the stock ownership of a person seeking to effect a change in the composition of the Histogenics Board or contemplating a tender offer or other transaction for the combination of Histogenics with another company that the Histogenics Board determines is not in Histogenics' best interests or in the best interests of Histogenics' stockholders. The ability of the Histogenics Board to cause Histogenics to issue substantial amounts of Histogenics common stock or preferred stock without the need for stockholder approval, except as may be required by law or regulation, upon such terms and conditions as Histogenics Board may determine from time to time in the exercise of its business judgment may, among other things, result in practical impediments with respect to changes in Histogenics' control or have the effect of diluting the stock ownership of holders of Histogenics common stock seeking to obtain control of Histogenics. The issuance of Histogenics common stock or preferred stock, while providing desirable flexibility in connection with potential financings and other corporate transactions, may have the effect of discouraging, delaying or preventing a change in Histogenics' control. The Histogenics Board, however, does not intend or view the Histogenics Share Increase Amendment to effect the Share Increase as an anti-takeover measure, nor does it contemplate its use in this manner at any time in the foreseeable future.

#### **Appraisal or Dissenters' Rights**

Pursuant to the DGCL, stockholders are not entitled to appraisal rights or dissenter's rights with respect to the Histogenics Share Increase Amendment or the Share Increase.

### **Effectiveness of Amendment**

If the Histogenics Share Increase Amendment is approved by the stockholders at the Histogenics special meeting, it will become effective upon the filing of a certificate of amendment with the Delaware Secretary of State or such later effective date and time as specified in the certificate of amendment in accordance with Delaware law.

### **Required Vote**

Assuming that a quorum is present at the special meeting, this proposal will be approved only if a majority of the total outstanding shares of Histogenics common stock vote “FOR” this Proposal No. 4. Abstentions from voting on the proposal and broker non-votes will not be counted as votes cast and accordingly will have the same effect as a vote “AGAINST” this Proposal No. 4.

**THE HISTOGENICS BOARD RECOMMENDS THAT HISTOGENICS’ STOCKHOLDERS VOTE “FOR” PROPOSAL NO. 4 TO AMEND HISTOGENICS’ SIXTH AMENDED AND RESTATED CERTIFICATE OF INCORPORATION TO INCREASE THE NUMBER OF AUTHORIZED SHARES OF HISTOGENICS COMMON STOCK.**

### **Proposal No. 5: Approval of the Issuance of Histogenics Common Stock Upon Exercise of the Investor Warrants and Additional Histogenics Common Stock Following Closing of Pre-Merger Financing**

At the Histogenics special meeting, Histogenics’ stockholders will be asked to the issuance of Histogenics common stock to the Investors upon exercise of the Investor Warrants. The terms of, reasons for and other aspects of the Securities Purchase Agreement, the Pre-Merger Financing, the issuance of Histogenics common stock upon exercise of the Investor Warrants and the potential additional shares of Histogenics common stock that may be issued following the closing of the Pre-Merger Financing are described in detail in the sections of this proxy statement/prospectus/information statement entitled “Agreements Related to the Merger-Securities Purchase Agreement,” “Agreements Related to the Merger-Series A Warrants,” “Agreements Related to the Merger-Series B Warrants,” “Agreements Related to the Merger-Series C Warrants” and “Agreements Related to the Merger-Registration Rights Agreement.”

Shares of Histogenics common stock are currently listed on the Nasdaq Capital Market and Histogenics is subject to the listing rules of Nasdaq. Nasdaq Listing Rule 5635(d) requires Histogenics to obtain stockholder approval prior to the issuance of Histogenics common stock in connection with certain non-public offerings involving the sale, issuance or potential issuance by Histogenics of Histogenics common stock (and/or securities convertible into or exercisable for Histogenics common stock) equal to 20% or more of the Histogenics common stock outstanding before the entry into the agreement governing the issuance of such securities. Shares of Histogenics common stock issuable upon the exercise or conversion of warrants, options, debt instruments, preferred stock or other equity securities issued or granted in such non-public offerings will be considered shares issued in such a transaction in determining whether the 20% limit has been reached, except in certain circumstances such as issuing warrants that are not exercisable for a minimum of six months and have an exercise price that exceeds market value. Accordingly, because the exercise prices of the Investor Warrants are or may be less than the market value of the Histogenics common stock, and the Investor Warrants in any event include price-based anti-dilution provisions that could further reduce the exercise price of the Investor Warrants, Histogenics may not issue in the Pre-Merger Financing more than a number of shares equal to 19.99% of the Histogenics common stock outstanding as of the entry into the Securities Purchase Agreement unless Histogenics’ stockholders first approve such issuance. As the number of shares of Histogenics common stock issuable upon exercise of the Investor Warrants is subject to adjustment in accordance with the terms of the Investor Warrants (see the sections of this proxy statement/prospectus/information statement entitled “Agreements Related to the Merger-Series A Warrants,” “Agreements Related to the Merger-Series B Warrants” and “Agreements Related to the Merger-Series C Warrants” for further detail), and the number of Converted Additional Shares is also subject to adjustment in accordance with the Securities Purchase Agreement, the aggregate number of shares of Histogenics

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common stock that may be issued in the Pre-Merger Financing may exceed 19.99% of the Histogenics common stock outstanding as of the entry into the Securities Purchase Agreement, and therefore Nasdaq Listing Rule 5635(d) requires that Histogenics obtain the consent of its stockholders.

As of the record date, Histogenics had 94,599,601 shares of common stock issued and outstanding. Assuming (i) the merger is effected, (ii) an exchange ratio of 28.7650 shares of pre-reverse stock split Histogenics common stock for each outstanding share of Ocugen common stock as of immediately prior to the merger, (iii) a total of 17,598,410 shares of Ocugen common stock issued and outstanding as of immediately prior to the merger, (iv) the issuance of the maximum number of Converted Additional Shares and (v) ignoring restrictions in the Securities Purchase Agreement preventing exercises of Investor Warrants if the exercising Investor would beneficially own in excess of 4.99% or 9.99% of the outstanding common stock of Histogenics (including the shares of common stock issuable upon such exercise), following the issuance of the maximum number of shares issuable upon exercise of the Investor Warrants, the Investors would hold an aggregate of approximately 89.7% of Histogenics' total outstanding common stock following such issuance.

Assuming a quorum is present at the Histogenics special meeting, approval of the issuance of (a) shares of Histogenics common stock upon the exercise of the Investor Warrants to be issued in the Pre-Merger Financing, and (b) additional shares of Histogenics common stock that may be issued following the closing of the Pre-Merger Financing, in each case pursuant to the Securities Purchase Agreement and as required by and in accordance with Nasdaq Listing Rule 5635, requires the affirmative vote of a majority of the total votes cast on this matter, in accordance with Nasdaq Listing Rule 5635(e)(4).

Upon the approval of this Proposal No. 5, Histogenics' stockholders will have agreed to the closing of the transactions contemplated by the Securities Purchase Agreement, including the issuance of (a) shares of Histogenics common stock upon the exercise of the Investor Warrants to be issued in the Pre-Merger Financing, and (b) additional shares of Histogenics common stock that may be issued following the closing of the Pre-Merger Financing, in each case pursuant to the Securities Purchase Agreement, which shares of Histogenics common stock may be in excess of 20% of Histogenics' issued and outstanding common stock as of the entry into the Securities Purchase Agreement. The issuance of shares of Histogenics common stock upon exercise of the Investor Warrants and any additional shares of Histogenics common stock to be issued in accordance with the Pre-Merger Financing would dilute, and thereby reduce, each existing stockholder's proportionate ownership in Histogenics common stock.

The Pre-Merger Financing is being effected to provide the combined organization with capital to continue its operations following the closing of the merger. If this Proposal No. 5 is not approved by stockholders, Histogenics will not be able to close the Pre-Merger Financing, and there can be no assurance that Ocugen or Histogenics will be able to raise capital on alternative terms, or at all.

### **Required Vote and Recommendation of the Histogenics Board**

The affirmative vote of a majority of the votes cast (meaning the number of shares voted "FOR" the proposal must exceed the number of share voted "AGAINST" the proposal) in person or represented by proxy at the Histogenics special meeting is required for approval of Proposal No. 5. Abstentions from voting on the proposal and broker non-votes will not be counted as votes cast and accordingly will have no effect upon the outcome of the proposal.

**THE HISTOGENICS BOARD RECOMMENDS THAT HISTOGENICS' STOCKHOLDERS VOTE "FOR" PROPOSAL NO. 5 TO APPROVE THE ISSUANCE OF (A) SHARES OF HISTOGENICS COMMON STOCK UPON THE EXERCISE OF THE INVESTOR WARRANTS TO BE ISSUED IN THE PRE-MERGER FINANCING, AND (B) ADDITIONAL SHARES OF HISTOGENICS COMMON STOCK THAT MAY BE ISSUED FOLLOWING THE CLOSING OF THE PRE-MERGER FINANCING.**

**Proposal No. 6: Approval of Possible Adjournment of the Histogenics Special Meeting**

If Histogenics fails to receive a sufficient number of votes to approve Proposal Nos. 1 or 2, Histogenics may propose to adjourn the Histogenics special meeting, for a period of not more than 30 days, for the purpose of soliciting additional proxies to approve Proposal Nos. 1 or 2. Histogenics currently does not intend to propose adjournment at the Histogenics special meeting if there are sufficient votes to approve Proposal Nos. 1 or 2. The affirmative vote of a majority of the votes cast (meaning the number of shares voted "FOR" the proposal must exceed the number of share voted "AGAINST" the proposal) present in person or represented by proxy at the Histogenics special meeting is required to approve the adjournment of the Histogenics special meeting for the purpose of soliciting additional proxies to approve Proposal Nos. 1 or 2. Abstentions from voting on the proposal and broker non-votes will not be counted as votes cast and accordingly will have no effect upon the outcome of the proposal.

**THE HISTOGENICS BOARD RECOMMENDS THAT HISTOGENICS' STOCKHOLDERS VOTE "FOR" PROPOSAL NO. 6 TO ADJOURN THE SPECIAL MEETING, IF NECESSARY, TO SOLICIT ADDITIONAL PROXIES IF THERE ARE NOT SUFFICIENT VOTES IN FAVOR OF PROPOSAL NOS. 1 OR 2. EACH OF PROPOSAL NOS. 1 AND 2 IS CONDITIONED UPON THE OTHER AND THE APPROVAL OF EACH SUCH PROPOSAL IS REQUIRED TO CONSUMMATE THE MERGER.**

## HISTOGENICS BUSINESS

### Overview

Histogenics historically focused on the development of restorative cell therapies (“RCTs”). Histogenics uses the term RCT to refer to a new class of products that are designed to offer patients rapid-onset pain relief and restored function through the repair of damaged or worn tissue. Histogenics’ product, NeoCart®, is an innovative cell therapy that utilizes various aspects of its RCT platform to treat tissue injury in the field of orthopedics, specifically cartilage damage in the knee.

### Recent Developments

In the third quarter of 2018, Histogenics announced that its Phase 3 clinical trial of NeoCart did not meet the primary endpoint of a statistically significant improvement in pain and function in a dual threshold responder analysis one year after treatment as compared to microfracture. In the modified Intent to Treat (“mITT”) population (which excludes those patients who were randomized but not treated with NeoCart), 74.2% of the NeoCart patients exhibited clinically meaningful improvements in pain and function compared to 62.0% of microfracture patients at one year ( $p=0.071$ ). However, in this mITT population, patients treated with NeoCart achieved a statistically significant improvement in pain and function ( $p=0.018$ ) six months after treatment as compared to patients treated with microfracture. In addition, NeoCart achieved a statistically significant improvement in pain and function at one year in certain patient populations including patients with lesion sizes greater than 2.2 cm<sup>2</sup> and those with a Body Mass Index, or BMI, of greater than 28. Both NeoCart and microfracture were well tolerated and exhibited strong safety profiles.

Based on the totality of the data, Histogenics initiated a dialogue with the United States Food and Drug Administration (the “FDA”) in the third quarter of 2018 to discuss the regulatory path forward for NeoCart. Histogenics’ primary objective in these discussions was to determine whether the FDA would accept a submission of a Biologics License Application (“BLA”) for NeoCart without data from an additional clinical trial. Histogenics had a constructive dialogue with the FDA, which included requests for and review of additional statistical analyses, different subgroup analyses, and secondary endpoints. These additional analyses, while compelling, did not change the conclusion that the NeoCart Phase 3 trial failed to meet its primary and secondary endpoints.

In December 2018, Histogenics received final feedback from the FDA indicating that while the NeoCart Phase 3 clinical trial resulted in certain compelling data, particularly the early response in pain and function and the data in certain lesion sizes, an additional Phase 3 clinical trial would need to be completed before the FDA would accept the submission of a BLA for NeoCart. The FDA indicated receptivity to novel clinical trial methodologies and regenerative medicine advanced therapy designations in order to support additional data for a future potential submission. However, considering the time and funding required to conduct such a trial, Histogenics discontinued the development of NeoCart and is not planning to submit a BLA.

### Current Strategy

As a result of the FDA feedback, Histogenics initiated a process to evaluate strategic alternatives to maximize value for all of its stakeholders. To assist with this process, the Histogenics Board engaged a financial advisory firm, Canaccord Genuity, to help explore its available strategic alternatives, including possible mergers and business combinations, a sale of part or all of its assets, and collaboration and licensing arrangements as further discussed in the section titled “The Merger—Background of the Merger.” On April 8, 2019, Histogenics and Ocugen announced the signing of the Original Merger Agreement, which was amended on June 13, 2019. Although Histogenics has entered into the Merger Agreement and intends to consummate the merger, there is no assurance that it will be able to successfully consummate the merger on a timely basis, or at all. If, for any

reason, the merger is not completed, Histogenics will reconsider its strategic alternatives and could pursue one or more of the following courses of action:

- *Pursue potential collaborative, partnering or other strategic arrangements for Histogenics' NeoCart assets, including a sale or other divestiture of its NeoCart assets.* Histogenics has discontinued further development of its NeoCart program and does not currently have any plans to resume development of its NeoCart program. Histogenics continues its efforts to seek potential collaborative, partnering or other strategic arrangements for its NeoCart assets, including a sale or other divestiture of its NeoCart assets. As these assets constitute substantially all of Histogenics' assets, stockholder approval will be required in order to consummate any sale of such assets.
- *Pursue another strategic transaction like the Merger.* The Histogenics Board may elect to pursue an alternative strategy, one of which may be a strategic transaction similar to the Merger.
- *Dissolve and liquidate Histogenics' assets.* If, for any reason, the Merger is not consummated and Histogenics is unable to identify and complete an alternative strategic transaction like the merger or potential collaborative, partnering or other strategic arrangements for its NeoCart assets, or to continue to operate Histogenics' business due to its inability to raise additional funding for the development of its NeoCart program or otherwise, Histogenics may be required to dissolve and liquidate its assets. In such case, Histogenics would be required to pay all of its debts and contractual obligations, and to set aside certain reserves for potential future claims, and there can be no assurances as to the amount or timing of available cash left to distribute to its stockholders after paying its debts and other obligations and setting aside funds for reserves.
- *Continue development of Histogenics' NeoCart program.* If, for any reason, the merger is not consummated, Histogenics may determine to move forward with its NeoCart program. However, Histogenics does not have sufficient capital resources and Histogenics will require significant additional financial resources in order to initiate and complete a further Phase 3 clinical trial for NeoCart. Based on its recent strategic process, Histogenics does not believe that it would be able to consummate a financing on reasonable terms sufficient to obtain such additional financial resources.

In January and March 2019, the Histogenics Board implemented restructuring plans involving reductions in headcount to reduce operating costs and conserve cash, along with other cash conservation measures relating to its facilities. The positions eliminated as part of the restructuring plans together represented all but one member of its workforce, including its Chief Executive Officer, Chief Operating Officer, Chief Medical Officer and Chief Business Officer. Histogenics has engaged Mr. Adam Gridley, its former Chief Executive Officer, Mr. Stephen Kennedy, its former Chief Operating Officer, and certain former key employees as consultants to assist with its ongoing operation and in order to consummate the merger. Mr. Gridley has retained his statutory titles of president, treasurer and secretary of Histogenics while he continues to provide consulting services to Histogenics, and remains a director of Histogenics.

On May 8, 2019, Histogenics entered into the Asset Purchase Agreement regarding the Asset Sale. The closing of the Asset Sale is subject to and conditioned upon the consummation of the merger.

### **NeoCart Phase 3 Clinical Trial**

The NeoCart Phase 3 clinical trial is believed to be the largest and first prospectively designed, randomized clinical trial in North America evaluating the safety and efficacy of a restorative cell therapy to treat knee cartilage damage. It is also believed to be the only trial with a dual threshold responder analysis endpoint.

As part of the prospective data analysis, Histogenics collected a variety of patient reported outcome endpoints, including all measures of the Knee Injury and Osteoarthritis Outcomes Score ("KOOS") and the International Knee Documentation Committee ("IKDC") score, which are validated, patient-centered assessments of pain and function that are commonly used in current clinical trials of cartilage therapies. On almost all of these measures, two of

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which are being utilized as primary endpoints in ongoing clinical trials by third parties in the U.S. for other therapies, NeoCart demonstrated statistically significant improvements versus microfracture at one and two years.

The Phase 3 clinical trial is the first study prospectively enrolled consistent with current FDA guidance, which provides for the use of microfracture as a comparator treatment in trials to repair knee cartilage damage. The published FDA guidance also specifically calls for a study population that, given the clinical limitations and variable results of microfracture, Histogenics believes provides more favorable results than what is typically seen in microfracture in both the literature and a real-world setting.

The primary endpoint for the Phase 3 clinical trial was a dual-threshold responder analysis measuring the improvement in KOOS pain and IKDC function scores for each patient treated with NeoCart compared to those treated with microfracture one year after the time of treatment. Dual-threshold responders were defined as patients who, relative to their baseline measurements, had at least a 12-point improvement in the KOOS pain sub-score assessment and a 20-point improvement in the IKDC subjective assessment. The trial also evaluated additional pain, quality of life, and function outcomes using all five measures of KOOS subscales, including Sports and Recreation. The change from baseline and the relative change between the NeoCart and microfracture arms was also measured at one year which contrasts with clinical trials of other products, either on the market or in development, that measured these changes at two years.

Demographics for both study arms were similar and represent a patient population that was intended to ensure that microfracture would respond favorably, including patients with an average age of approximately 39 years old and a Body Mass Index of approximately 27. Furthermore, the mean lesion size was 2.1 cm in the NeoCart arm and 1.8 cm in the microfracture arm. There were no other significant differences between the treatment arms.

The results with respect to the primary endpoint (dual threshold responder analysis one year after treatment) are summarized below:

	NeoCart		Microfracture		Difference	
	Positive Responders	Responder Rate	Positive Responders	Responder Rate		
<b>ITT</b>	121/170	71.2%	49/79	62.0%	9.2	p=0.1877
<b>mITT</b>	121/163	74.2%	49/79	62.0%	12.2	P=0.0714
<b>As Treated</b>	120/162	74.1%	50/80	62.5%	11.6	p=0.0735
<b>Per Protocol</b>	118/155	76.1%	43/65	66.2%	10.0	p=0.1362

Key additional findings from the clinical trial include:

NeoCart demonstrated statistically significant improvements in pain and function at both one and two years after treatment as measured by changes in the KOOS and IKDC scores.

### KOOS pain score (mITT Population) Change from Baseline (NeoCart Baseline = 54.0; Microfracture Baseline = 52.4)

Visit	NeoCart		Microfracture		P-Value
	N	Mean	N	Mean	
<b>3-months</b>	160	24.1	75	22.4	0.0487*
<b>6-months</b>	157	28.6	75	27.0	0.0819
<b>1-year</b>	158	31.4	72	28.7	0.0239*
<b>2-years</b>	87	32.2	34	28.9	0.0080*
<b>3-years</b>	39	34.3	16	30.7	0.1071

\* Statistically significant



**IKDC subjective knee exam score (mITT Population)  
Change from Baseline  
(NeoCart Baseline = 40.3; Microfracture Baseline = 40.0)**

Visit	NeoCart		Microfracture		P-Value
	N	Mean	N	Mean	
3-months	159	13.7	76	14.5	0.9686
6-months	156	24.4	74	22.4	0.1572
1-year	158	33.1	71	28.3	0.0126*
2-years	87	35.3	34	30.2	0.0366*
3-years	38	39.9	16	32.6	0.2691

\* Statistically significant

NeoCart is based on Histogenics' RCT platform, which Histogenics believes has the potential to be used for a broad range of additional therapeutic indications and combines expertise in the following areas:

- Cell therapy and processing: the handling of tissue biopsies and the extraction, isolation and expansion of the cells;
- Biomaterials and Scaffold: three-dimensional biomaterials and structures that enable the proper delivery, distribution and organization of cells in their natural environment to support tissue formation;
- Tissue engineering: the use of a combination of cells, engineering and biomaterials to improve or restore biological functions; and
- Bioadhesives: natural, biocompatible materials that act as adhesives for biological tissue and allow for natural cell and tissue infiltration and integration with native cells.

**Intellectual Property**

Patent and trade secret protection is critical to Histogenics' business. Histogenics protects its cell processing technology, materials science and products for tissue repair through a variety of methods, including seeking, maintaining and defending patents and other intellectual property intended to cover its products and compositions, their methods of use and processes for their manufacture, its platform technologies, its trade secrets and any other inventions that are commercially important to the development of its business. Histogenics actively seeks patent protection in the United States and select foreign countries.

As of March 31, 2019, Histogenics' intellectual property portfolio was composed of 34 issued patents and 11 patent applications in the United States that Histogenics owns, and 15 issued patents and one patent application in the United States that Histogenics licenses from academic institutions and business entities. Histogenics also has approximately 100 counterpart patent and patent applications owned or licensed in certain foreign jurisdictions. Histogenics' portfolio of owned and in-licensed patents and patent applications covers aspects of: its implants, including NeoCart and its protein implants; its tissue engineering processor; its adhesives; its growth factors, methods of delivery of therapeutic agents and promoters for increased expression of protein; its method for treatment of ligament and tendon injuries; surgical tools for placing its implants; and its bone composites. The patents that cover the listed technologies have statutory expiration dates between 2019 and 2031.

Histogenics has entered into license agreements with various academic institutions and business entities to obtain the rights to use certain patents and patent applications for the development and commercialization of Histogenics' technology and products. Histogenics also relies on know-how and continuing technological innovation to develop and maintain its proprietary position.

Histogenics licenses from Purpose Co., Ltd. (f/k/a Takagi Sangyo Co. Ltd. and f/k/a Takagi Industrial Co., Ltd.) (Purpose) an exclusive right to 39 issued patents and 6 pending patent applications worldwide relating to an

exogenous tissue processor. Through this agreement, Histogenics has a sublicense to three issued U.S. patents and eight issued foreign patents owned by The Brigham and Women's Hospital, Inc. ("BWH") and Purpose that relate to methods of cultivating a cell or tissue of a living body to be cultivated inside a culture chamber and apparatuses for cultivating a cell or tissue. Histogenics also has an exclusive license to two issued U.S. patents and one pending U.S. patent application for restoration of articular cartilage matrix from the Board of Trustees of The Leland Stanford Junior University. The patents that have issued or may yet issue that have been licensed to Histogenics under these agreements will have statutory expiration dates between 2020 and 2031.

Histogenics has an exclusive license to a portfolio consisting of two families of issued patents and pending patent applications owned by Angiotech Pharmaceuticals (US), Inc. and Angiodevice International GmbH. This exclusivity is for the use of CT3, Histogenics' proprietary adhesive, for use in combination with intellectual property for the repair of articular cartilage, ligament, meniscus or tendon damage. The patents relate to methods of preparing biocompatible gels, biocompatible gel-forming compositions, methods of treating tissues by administering biocompatible gel-forming compositions, composition for forming a matrix useful as a high strength medical sealant, biocompatible polymer device for use in treating tissues, systems for forming a high strength medical sealant, methods for providing a high strength medical sealant on a surface, methods for applying a sealing layer to a native tissue surface, methods for effecting surgical adhesion, and methods for providing a sealant coating on the surface of a synthetic implant. Any patents within this portfolio that have issued or may yet issue will have statutory expiration dates between 2019 and 2022.

Histogenics has an exclusive license to one patent family relating to growth factors and high level expression of heterologous proteins owned by Yeda Research and Development Co., Ltd. Any patents within this portfolio that have issued or may yet issue will have statutory expiration dates between 2021 and 2023.

Histogenics continually assesses and refines its intellectual property strategy in order to fortify its position in its target markets. Histogenics cannot ensure that patents will be granted with respect to any of its pending owned or in-licensed patent applications or with respect to any patent applications Histogenics may own or license in the future, nor can Histogenics be sure that any of its existing owned or in-licensed patents or any patents Histogenics may own or license in the future will be useful in protecting its technology. Please see "Risk Factors—Risks Related to Histogenics' Intellectual Property" for additional information on the risks associated with Histogenics' intellectual property strategy and portfolio.

#### **Material Technology License Agreements**

##### ***MEDINET Co., Ltd.***

In December 2017, Histogenics entered into a License and Commercialization Agreement (the "MEDINET Agreement") with MEDINET Co., Ltd. ("MEDINET") with regards to the commercialization of NeoCart in Japan. Pursuant to the terms of the MEDINET Agreement, Histogenics is eligible to receive up to an aggregate of approximately \$86.9 million in milestone payments plus royalties, consisting of (i) a non-refundable upfront payment of \$10.0 million which Histogenics received in January 2018, (ii) potential regulatory and development milestone payments of up to an aggregate of \$10.5 million, (iii) overall sales-dependent milestones of up to an aggregate of \$66.4 million and (iv) tiered royalties on net sales of NeoCart in Japan. In return for such consideration, Histogenics granted to MEDINET exclusive commercialization rights to NeoCart in Japan for the replacement or repair of damaged, worn or defective cartilage in humans and non-human animals.

The MEDINET Agreement will remain in effect until the later of (i) expiration of the last-to-expire valid and enforceable patent covering NeoCart in Japan and (ii) ten years from the first commercial sale of NeoCart in Japan. MEDINET has an option to extend the term for five years upon written notice to Histogenics prior to the end of the initial term. MEDINET has the right to terminate the MEDINET Agreement for any or no reason at any time, and Histogenics may terminate the MEDINET Agreement in the event MEDINET or one of its affiliates or sublicensees challenges a patent covering NeoCart in Japan. Additionally, either party may terminate

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the MEDINET Agreement for an uncured material breach by the other party or upon certain insolvency or bankruptcy proceedings involving the other party. Histogenics and MEDINET have agreed to indemnify each other for third-party claims arising out of either Histogenics' or its affiliates' willful misconduct or negligence, breaches of representations, warranties, covenants, obligations or agreements contained in the MEDINET Agreement, or MEDINET's exploitation of NeoCart in its respective territory, subject to specified exclusions.

Histogenics and MEDINET have agreed to enter into supply, quality and pharmacovigilance agreements (the MEDINET Supply Agreements), pursuant to which MEDINET will purchase its requirements of NeoCart and the related biopsy kit from Histogenics. Pursuant to the terms of the MEDINET Agreement, the MEDINET Supply Agreements will contain provisions addressing several topics, including those set forth in the MEDINET Agreement.

### ***Purpose Co., Ltd.***

In May 2016, Histogenics amended its license agreement (the Amendment) with Purpose whereby Histogenics acquired the development and commercialization rights to NeoCart in Japan. Under the Amendment, Histogenics assumed sole responsibility for the development and commercialization of all or any portion its products in Japan. In addition, the amended agreement provides Histogenics with an exclusive, perpetual (with respect to patent rights, for the full term of each patent licensed) and sublicensable license, under Purpose's patent rights and technology relating to their tissue processor, in Japan, to make, use, sell, import and otherwise exploit products or services covered by claims of such Purpose patents or Purpose's technology, in connection with articular cartilage, ligaments, tendons and meniscus. The Amendment also terminates the license that Purpose held under the original license agreement to develop and commercialize Histogenics' patents and technology in Japan.

Pursuant to the Amendment, Histogenics is obligated to pay Purpose payments of up to \$10 million in the event certain milestones are satisfied as well as a royalty payment in the low single digits on the net sales in Japan for Histogenics products that rely on a Purpose patent or incorporate or necessarily rely upon any Purpose technology. Such royalty payment shall be reduced if the applicable Histogenics products do not rely on an outstanding Purpose patent.

The other terms of the agreement with Purpose remain in effect including Histogenics' ability outside of Japan to (1) make, use and sell products or services covered by claims of Purpose's patents and (2) use and create derivative works of Purpose's technology for the design, development, manufacture, testing, support and commercialization of any product or service that incorporates or builds upon Purpose's technology, in each case, only in connection with articular cartilage, ligaments, tendons and meniscus. Purpose retained the right to sell its single unit exogenous tissue processor machines to research institutes for general but noncommercial use anywhere in the world.

As part of Histogenics' agreement with Purpose, they continue to manufacture and sell single unit exogenous tissue processor machines to Histogenics. In addition, Purpose exclusively sublicensed to Histogenics its rights and obligations under the BWH-Purpose license, as amended from time to time. Under the Purpose-BWH license agreement, BWH granted Purpose an exclusive, royalty-bearing, worldwide, sublicensable license, under its rights in licensed patents and patent applications co-owned by BWH and Purpose, to make, use and sell (1) apparatuses for cultivating a cell or tissue, (2) tissue or cell products made using such apparatuses, (3) tissue or cell products made using processes for cultivating a cell or tissue as disclosed in the licensed patents and patent applications and (4) any apparatus that cultivates cells or tissues using such processes, in each case, whose manufacture, use, or sale is covered by the claims of the licensed patents and patent applications, only for therapeutic use. BWH may terminate this agreement if Purpose, itself or through its sublicensees, does not achieve commercial distribution and sale of the licensed products in the United States by December 31, 2019. In return for extending the termination period through December 31, 2019 pursuant to an amendment effective November 2015, Histogenics agreed to pay BWH \$50,000 in November 2015 and three annual payments of \$30,000 on the anniversary of the effective date of such amendment for the three years thereafter.

Pursuant to Histogenics' sublicense from Purpose, Histogenics is obligated to pay royalties and milestone payments and sublicense payments due on the BWH-Purpose license agreement. Histogenics has paid minimum royalty amounts of \$200,000 and sublicense payments of \$285,000 through December 31, 2018. Purpose agreed to pay BWH a royalty rate in the low single digits of Histogenics' net sales of licensed products, subject to a minimum of \$20,000 annually, until the license agreement terminates or until royalty payments no longer have to be made. Purpose is obligated to make one additional sublicense payment of \$25,000 and milestone payments to BWH of (1) \$75,000 upon the first patient treated in Phase 3 clinical trials for each licensed product or licensed process and (2) \$75,000 upon final FDA approval for each licensed product or licensed process.

The agreement remains in effect for the life of the licensed patents, expected to be until October 19, 2028. Purpose may terminate the agreement by providing written notice to BWH at least 60 days in advance. BWH has the right to terminate the agreement if Purpose fails to make minimum royalty payments or other payments or otherwise breaches the agreement and such breach is not cured within 30 days of BWH providing notice to Purpose. Upon termination of the BWH-Purpose license agreement, Histogenics' sublicense will convert to a nonexclusive license to Purpose's interest in the licensed products or processes. Upon written notice to Purpose of Histogenics' intent to stop using the technology sublicensed to Histogenics in the BWH-Purpose license, Purpose will reassume all responsibility under the BWH-Purpose license.

#### ***Angiotech Pharmaceuticals (US), Inc. and Angiodevice International GmbH***

In May 2005, Histogenics entered into a worldwide license agreement with Angiotech Pharmaceuticals (US), Inc. and Angiodevice International GmbH (collectively, Angiotech) for the right, under Angiotech's licensed patents and patent applications and technical information, to make, use and sell any product that includes both Histogenics' intellectual property and CT3 for the repair of articular cartilage, ligament, meniscus or tendon damage, including related osteochondral defects. The license excludes any product in which one nonliving ingredient is included in CT3 for the primary purpose of producing a physiological, metabolic or biological effect in mammals. The license grant was made exclusive under the fifth amendment to the license agreement that came into effect in August 2010. Histogenics has obligations to supply CT3 to Angiotech under certain terms and conditions, and Angiotech is entitled to use any data and results obtained from any clinical studies conducted by Histogenics with respect to CT3.

Histogenics paid \$1.0 million to Angiotech to make the license grant under the agreement exclusive. In addition, Histogenics paid four annual patent fees of \$50,000 each as of December 31, 2018. Histogenics is also obligated to pay an additional fee of \$3.0 million within 30 days after Histogenics receives regulatory approval from the FDA for a licensed product. As further consideration for the license, Histogenics also agreed to pay royalties at percentage rates of single digits of net sales of NeoCart and certain other products. Histogenics was able to reduce royalties from percentage rates of net sales in the double digits to this rate after making revenue share reduction payments that totaled \$2.0 million.

The agreement terminates on the earlier of May 12, 2035 and expiration of all royalty payment obligations under the agreement. Either party has the right to terminate the agreement if the other party materially breaches the agreement and fails to cure such breach within 30 days from the date of notice of such breach (ten days in the case of non-payment). Histogenics may also terminate the agreement by giving at least one year's notice. Angiotech may also terminate the agreement if Histogenics or any of its affiliates or sublicensees challenge the validity of Angiotech's patents rights or rights to improvements (or directly or indirectly support any such challenge), or if Histogenics is acquired by or merge with a third party that has developed or is marketing, or has an affiliate that has developed or is marketing, a competitive product prior to such acquisition or merger and the resulting or surviving entity post-acquisition or merger fails to either continue to develop or sell licensed product at a level reasonably similar to the development or sale that was occurring prior to the acquisition or merger, during the six-month period following the acquisition or merger. Competitive product means, in a given country, (1) a drug or biologic approved for marketing or in Phase 3 clinical development, (2) a 510(k), or foreign equivalent, device approved for marketing, or (3) an FDA Premarket Approval, or foreign equivalent, device

approved for marketing or in pivotal study clinical development, other than a licensed product, that acts (or is being developed to act) for one or more target label indications substantially similar to one or more approved or target label indications for a licensed product.

### ***Intrexon Corporation***

In September 2014, Histogenics entered into an Exclusive Channel Collaboration (“ECC”) with Intrexon Corporation (“Intrexon”) governing a “channel collaboration” arrangement in which Histogenics intended to use Intrexon’s proprietary technology towards the design, identification, culturing and/or production of genetically modified cells (“Technology”). The ECC granted Histogenics an exclusive worldwide license to utilize Intrexon’s Technology to develop and commercialize allogeneic genetically modified chondrocyte cell therapeutics for the treatment or repair of damaged articular hyaline cartilage in humans.

In December 2018, Histogenics and Intrexon entered into a mutual termination and release agreement (the “Mutual Termination Agreement”) pursuant to which Histogenics and Intrexon mutually agreed to terminate ECC. Pursuant to the ECC, Histogenics was responsible for the research and development costs incurred by Intrexon associated with the development of product candidates under the collaboration. As of December 21, 2018, the date of termination, Histogenics had accrued approximately \$3.0 million of research and development expenses under the ECC (the “Accrued Expenses”). In connection with the Mutual Termination Agreement, in lieu of payment of the Accrued Expenses, Histogenics agreed to pay Intrexon an aggregate of up to \$1.5 million, with \$0.375 million paid at the time of entering into the Mutual Termination Agreement and \$1.125 million payable within one year following any submission of a BLA to the FDA for NeoCart. Histogenics adjusted the accrued expenses to reflect a \$1.125 million balance as of December 31, 2018 and recorded a gain on extinguishment of liability of \$1.5 million.

### **Competition**

The cell therapy and regenerative medicine sector is characterized by innovative science, rapidly advancing technologies and a strong emphasis on proprietary products. While Histogenics believes that its technology, development experience, scientific knowledge and intellectual property portfolio provide Histogenics with competitive advantages, Histogenics faces potential competition from many different sources, including major pharmaceutical, specialty pharmaceutical, biotechnology and regenerative medicine companies, academic institutions, governmental agencies and public and private research institutions.

The competitive landscape in the field of articular cartilage repair in the U.S. is emerging and has stimulated a substantial amount of interest from companies developing tissue repair solutions. Companies have employed a variety of approaches to meet the goals of cartilage repair. The approaches, which represent the scientific evolution of the field, can be generally categorized in five ways: (1) non-cell-based, such as ArthroSurface’s HemiCAP and Anika’s Hyalofast; (2) uncultured cell-based (with or without scaffold), such as Zimmer’s DeNovo NT, Arthrex’s BioCartilage and Osiris’ Cartiform, distributed exclusively with Arthrex; (3) cultured cell-based (without scaffold), such as ISTO’s RevaFlex; (4) cultured cell- and scaffold-based, such as Vericel’s MACI and the Aesculap division of B. Braun Medical’s NovoCart 3D; and (5) cultured cell- and scaffold-based incorporating tissue engineering, such as NeoCart.

In Japan, a historical cultured cell-based product, known as JACC is sold by Japan Tissue Engineering Co., Ltd (J-TEC). This product has some of the same limitations of first-generation autologous chondrocyte implantation products in the U.S. including limited efficacy, lengthy surgery and extended patient rehabilitation. Several cultured cell and cultured cell and scaffold combinations are in various stages of clinical development in Japan, with the earliest potential new competitive entries in 2023.

## **Government Regulation**

### ***Regulatory Background on Autologous Cellular Products***

The FDA does not apply a single regulatory scheme to human tissues and the products derived from human tissue. On a product-by-product basis, the FDA may regulate such products as drugs, biologics, or medical devices, in addition to regulating them as human cells, tissues, or cellular or tissue-based products (HCT/Ps), depending on whether or not the particular product triggers any of an enumerated list of regulatory factors. A fundamental difference in the treatment of products under these classifications is that the FDA generally permits HCT/Ps that do not trigger any of those regulatory factors to be commercially distributed without marketing approval. In contrast, products that trigger those factors, such as if they are more than minimally manipulated when processed or manufactured, are regulated as drugs, biologics, or medical devices and require FDA approval. The FDA has designated NeoCart as a biologic under the jurisdiction of the Center for Biologics Evaluation and Research and market access or approval will require BLA approval.

In 1997, the FDA began requiring a BLA for autologous cellular products and approved the already-marketed Carticel contingent on further clinical trials. In 2000, Carticel's indication narrowed to second-line therapy for patients with inadequate response to prior treatment. As of December 2011, the FDA requires evidence of clinical efficacy against approved and validated endpoints and standard of care control arm as outlined in their final guidance on the subject of cartilage repair.

The grant of marketing authorization in the European Economic Area (EEA) for products containing viable human tissues or cells such as NeoCart is governed by Regulation 1394/2007/EC on advanced therapy medicinal products, read in combination with Directive 2001/83/EC of the European Parliament and of the Council, commonly known as the Community code on medicinal products. Regulation 1394/2007/EC lays down specific rules concerning the authorization, supervision and pharmacovigilance of gene therapy medicinal products, somatic cell therapy medicinal products and tissue engineered products. Manufacturers of advanced therapy medicinal products must demonstrate the quality, safety and efficacy of their products to the European Medicines Agency (EMA), which is required to provide an opinion regarding the application for marketing authorization. The European Commission grants or refuses marketing authorization in light of the opinion delivered by the EMA.

Applicants for marketing authorization for medicinal products in the EEA are required to submit applications for marketing authorization based on the ICH Common Technical Document and must demonstrate the safety, quality and efficacy of the medicinal product for which the marketing authorization is sought. The application must include the results of pre-clinical tests and clinical trials conducted with the medicinal product. The conduct of clinical trials in the EEA is governed by Directive 2001/20/EC which imposes obligations and procedures that are similar to those provided in applicable U.S. laws. The obligations provided in the European Union (EU) Good Clinical Practice rules and EU Good Laboratory Practice must also be respected during conduct of the trials. Clinical trials must be approved by the competent regulatory authorities and the competent Ethics Committees in the EU Member States in which the clinical trials take place. Moreover, applicants are required to demonstrate that studies have been conducted with the medicinal product in the pediatric population as provided by a Pediatric Investigation Plan approved by the Pediatric Committee of the EMA. Alternatively, confirmation that the applicant has obtained a waiver or deferral for the conduct of these studies must be provided.

### ***Reimbursement***

In both domestic and foreign markets, sales of any regulatory-approved products depend in part upon the availability of reimbursement from third-party payors. Third-party payors include government health programs, such as Medicare and Medicaid, private health insurers and managed care providers, and other organizations. Reimbursement policy involves coding, coverage and payment decisions and its business strategy is to produce the necessary information for optimal decision-making by payors.

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**Coding:** While reimbursement policy for NeoCart is uncertain at this point, Histogenics believe that the existing Current Procedural Terminology, Healthcare Commission Procedure Coding System and International Classification of Diseases, Ninth Edition coding options for ACI are sufficiently broad that they could apply to NeoCart.

**Coverage:** Histogenics' goal is to demonstrate improved health outcomes (e.g., improved patient outcomes and quality of life on several parameters, lower total costs including lower overall utilization of healthcare services and faster return to work) for patients receiving NeoCart compared to microfracture, an important element in securing coverage decisions by payors (Medicare and private payors).

**Payment:** Analysis of recent trends in ACI coverage (discharge data) suggest that patients between 18 and 64 years of age constitute the majority of the market for ACI, resulting in a market dominated by private payors. Only 10% to 20% of ACI patients are estimated to be 65 years of age and older. While limited data is available for private payor reimbursement of ACI, these payors typically reimburse inpatient procedures with bundling mechanisms similar to Medicare Severity Diagnosis Related Groups. In addition, some private payors also tend to use Medicare rates as benchmarks when setting their own fee schedules.

### ***Government Regulation Overview***

#### **United States**

##### **Overview**

In the United States, the FDA regulates biological products under the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act and related regulations. Biological products are also subject to other federal, state, local, and foreign statutes and regulations. The FDA and comparable regulatory agencies in state and local jurisdictions and in foreign countries impose substantial requirements upon the clinical development, manufacture and marketing of biological products. These agencies and other federal, state, local, and foreign entities regulate research and development activities and the testing, manufacture, quality control, safety, effectiveness, packaging, labeling, storage, distribution, record keeping, reporting, approval, advertising and promotion of its products. Failure to comply with the applicable U.S. regulatory requirements at any time during the product development process, including clinical testing, approval process or after approval may subject an applicant to administrative or judicial sanctions.

Government regulation may delay or prevent marketing of product candidates for a considerable period of time and impose costly procedures upon its activities. The testing and approval process requires substantial time, effort, and financial resources, and Histogenics cannot be certain that the FDA or any other regulatory agency will grant approvals for NeoCart or any future product candidates on a timely basis, if at all. The FDA's policies may change and additional government regulations may be enacted that could prevent or delay regulatory approval of NeoCart or any future product candidates or approval of new disease indications or label changes. Histogenics cannot predict the likelihood, nature or extent of adverse governmental regulation that might arise from future legislative, judicial, or administrative action, either in the United States or abroad.

##### **Marketing Approval**

The process required by the FDA before biological products may be marketed in the United States generally involves the following:

- completion of nonclinical laboratory and animal tests according to good laboratory practices, and applicable requirements for the humane use of laboratory animals or other applicable regulations;
- submission to the FDA of an Investigational New Drug Application ("IND") which must become effective before human clinical trials may begin;

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- performance of adequate and well-controlled human clinical trials according to the FDA’s regulations commonly referred to as good clinical practices (“GCP”), and any additional requirements for the protection of human research patients and their health information, to establish the safety and efficacy of the proposed biological product for its intended use or uses;
- submission to the FDA of a BLA for marketing approval that includes substantive evidence of safety, purity, and potency from results of nonclinical testing and clinical trials;
- satisfactory completion of an FDA pre-approval inspection of manufacturing facilities where the biological product is produced to assess compliance with good manufacturing practices (“GMP”) to assure that the facilities, methods and controls are adequate to preserve the biological product’s identity, strength, quality and purity and, if applicable, the FDA’s current good tissue practices (“GTP”) for the use of human cellular and tissue products to prevent the introduction, transmission or spread of communicable diseases;
- potential FDA audit of the nonclinical study sites and clinical trial sites that generated the data in support of the BLA; and
- FDA review and approval, or licensure, of the BLA, which must occur before a biological product can be marketed or sold.

### **U.S. Biological Products Development Process**

Before testing any biological product candidate in humans, the product candidate enters the nonclinical testing stage. Nonclinical tests include laboratory evaluations of product chemistry, toxicity and formulation, as well as animal studies to assess the potential safety and activity of the product candidate. The conduct of the nonclinical tests must comply with federal regulations and requirements including good laboratory practices.

Prior to commencing the first clinical trial, the clinical trial sponsor must submit the results of the nonclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and a proposed clinical protocol, to the FDA as part of an initial IND. Some nonclinical testing may continue even after the IND is submitted. The IND automatically becomes effective 30 days after receipt by the FDA unless the FDA, within the 30-day time period, raises concerns or questions about the conduct of the clinical trial and places the clinical trial on a clinical hold. In such case, the IND sponsor must resolve any outstanding concerns with the FDA before the clinical trial may begin. Further, an Institutional Review Board (“IRB”) for each site proposing to conduct the clinical trial must review and approve the plan for any clinical trial before it commences at that site. An IRB is charged with protecting the welfare and rights of study subjects and considers such items as whether the risks to individuals participating in the clinical trials are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the form and content of the informed consent that must be signed by each clinical trial subject or his or her legal representative and must monitor the clinical trial until completed. The FDA or IRB may impose clinical holds on a biological product candidate at any time before or during clinical trials due to safety concerns or non-compliance. If the FDA imposes a clinical hold, trials may not recommence without FDA or IRB authorization and then only under terms authorized by the FDA and IRB. Accordingly, Histogenics cannot be sure that submission of an IND will result in the FDA allowing clinical trials to begin or that, once begun, issues will not arise that will result in the suspension or termination of such trials.

Clinical trials involve the administration of the biological product candidate to healthy volunteers or patients under the supervision of qualified investigators, generally physicians not employed by or under the trial sponsor’s control. Clinical trials are conducted under protocols detailing, among other things, the objectives of the clinical trial, dosing procedures, subject selection and exclusion criteria, and the parameters to be used to monitor subject safety, including stopping rules that assure a clinical trial will be stopped if certain adverse events should occur. Each protocol and any amendments to the protocol must be submitted to the FDA as part of the IND and to the IRB.



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For purposes of BLA approval, human clinical trials are typically conducted in three sequential phases that may overlap:

- Phase 1—The biological product is initially introduced into healthy human patients and tested for safety. In the case of some products for severe or life-threatening diseases, especially when the product may be too inherently toxic to ethically administer to healthy volunteers, the initial human testing is conducted in patients. These trials may also provide early evidence on effectiveness.
- Phase 2—These trials are conducted in a limited number of patients in the target population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance and optimal dosage. Multiple Phase 2 clinical trials may be conducted by the sponsor to obtain information prior to beginning larger and more expensive Phase 3 clinical trials.
- Phase 3—Phase 3 trials are undertaken to provide statistically significant evidence of clinical efficacy and to further evaluate dosage, potency and safety in an expanded patient population at multiple clinical trial sites. They are performed after preliminary evidence suggesting effectiveness of the product has been obtained, and are intended to establish the overall benefit-risk relationship of the investigational product and to provide an adequate basis for product approval and labeling.

Post-approval clinical trials, sometimes referred to as Phase 4 clinical trials, may be conducted after initial marketing approval. These trials may be required by the FDA as a condition of approval and are used to gain additional experience from the treatment of patients in the intended therapeutic indication, particularly for long-term safety follow-up. The FDA now has express statutory authority to require post-market clinical trials to address safety issues. All of these trials must be conducted in accordance with GCP requirements in order for the data to be considered reliable for regulatory purposes.

During all phases of clinical development, regulatory agencies require extensive monitoring and auditing of all clinical activities, clinical data and clinical trial investigators. Annual progress reports detailing the results of the clinical trials must be submitted to the FDA. Written IND safety reports must be promptly submitted to the FDA and the investigators for serious and unexpected adverse events; any findings from other studies, tests in laboratory animals or in vitro testing that suggest a significant risk for human patients; or any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. The sponsor must submit an IND safety report within 15 calendar days after the sponsor determines that the information qualifies for reporting. The sponsor also must notify the FDA of any unexpected fatal or life-threatening suspected adverse reaction within seven calendar days after the sponsor's initial receipt of the information.

Phase 1, Phase 2 and Phase 3 clinical trials may not be completed successfully within any specified period, if at all. Regulatory authorities, a data safety monitoring board or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the participants are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the biological product has been associated with unexpected serious harm to patients.

Histogenics' ongoing and planned clinical trials for its product candidates may not begin or be completed on schedule, if at all. Clinical trials can be delayed for a variety of reasons, including delays in:

- obtaining regulatory approval to commence a trial;
- reaching agreement with third-party clinical trial sites and their subsequent performance in conducting accurate and reliable trials on a timely basis;
- obtaining IRB approval to conduct a trial at a prospective site;
- recruiting patients to participate in a trial; and
- supply of the biological product.

Typically, if a biological product is intended to treat a chronic disease, as is the case with NeoCart, safety and efficacy data must be gathered over an extended period of time, which can range from six months to three years or more. Success in early stage clinical trials does not ensure success in later stage clinical trials. Data obtained from clinical activities is not always conclusive and may be susceptible to varying interpretations, which could delay, limit or prevent regulatory approval.

Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the physical characteristics of the biological product as well as finalize a process for manufacturing the product in commercial quantities in accordance with GMP requirements. To help reduce the risk of the introduction of adventitious agents with the use of biological products, the Public Health Service Act emphasizes the importance of manufacturing control for products whose attributes cannot be precisely defined. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, the sponsor must develop methods for testing the identity, strength, quality, potency and purity of the final biological product. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the biological product candidate does not undergo unacceptable deterioration over its shelf life.

### **U.S. Review and Approval Processes**

In order to obtain approval to market a biological product in the United States, a BLA must be submitted to the FDA that provides data establishing to the FDA's satisfaction the safety, purity and potency of the investigational biological product for the proposed indication. The application includes all data available from nonclinical studies and clinical trials, including negative or ambiguous results as well as positive findings, together with detailed information relating to the product's manufacture and composition, and proposed labeling, among other things. The testing and approval processes require substantial time and effort, and there can be no assurance that the FDA will accept the BLA for filing and, even if filed, that any approval will be granted on a timely basis, if at all.

Under the Prescription Drug User Fee Act ("PDUFA"), each BLA must be accompanied by a significant user fee and after approval, an approved biologic will also be subject to a program fee. The FDA adjusts the PDUFA user fees on an annual basis. According to the FDA's fee schedule, the user fee for an application requiring clinical data, such as a BLA, will be \$2.4 million for 2018. Fee waivers or reductions are available in certain circumstances, including a waiver of the application fee for the first application filed by a small business. Additionally, no user fees are assessed on BLAs for products designated as orphan drugs, unless the product also includes a non-orphan indication.

The FDA has 60 days from its receipt of a BLA to determine whether the application will be accepted for filing based on the FDA's threshold determination that the application is sufficiently complete to permit substantive review. The FDA may refuse to file any BLA that it deems incomplete or not properly reviewable at the time of submission and may request additional information. In this event, the BLA must be resubmitted with the additional information. The resubmitted application also is subject to review before the FDA accepts it for filing. After the BLA is accepted for filing, the FDA reviews the BLA to determine, among other things, whether the proposed product is safe and potent, or effective, for its intended use, and has an acceptable purity profile, and whether the product is being manufactured in accordance with GMPs to assure and preserve the product's identity, safety, strength, quality, potency, and purity, and biological product standards. The FDA may refer applications for novel biological products or biological products that present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved and, if so, under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Before approving a BLA, the FDA will inspect the facilities at which the product is manufactured. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance

with GMP requirements and adequate to assure consistent production of the product within required specifications. For a human cellular or tissue product, the FDA also will not approve the product if the manufacturer is not in compliance with the GTP. These are FDA regulations that govern the methods used in, and the facilities and controls used for, the manufacture of HCT/Ps, which are human cells or tissue intended for implantation, transplant, infusion, or transfer into a human recipient. The primary intent of the GTP requirements is to ensure that cell and tissue based products are manufactured in a manner designed to prevent the introduction, transmission and spread of communicable disease. FDA regulations also require tissue establishments to register and list their HCT/Ps with the FDA and, when applicable, to evaluate donors through screening and testing. Additionally, before approving a BLA, the FDA may inspect one or more clinical sites to assure that the clinical trials were conducted in compliance with IND study requirements and GCP. To assure GMP, GTP and GCP compliance, an applicant must incur significant expenditure of time, money and effort. If the FDA determines the manufacturing process or manufacturing facilities are not acceptable, it typically will outline the deficiencies and often will require the facility to take corrective action and provide documentation evidencing the implementation of such corrective action. This may significantly delay further review of the application. If the FDA finds that a clinical site did not conduct the clinical trial in accordance with GCP, the FDA may determine the data generated by the clinical site should be excluded from the primary efficacy analyses provided in the BLA and request additional testing or data. Additionally, notwithstanding the submission of any requested additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

The FDA also has authority to require a Risk Evaluation and Mitigation Strategy (“REMS”) from manufacturers to ensure that the benefits of a biological product outweigh its risks. A sponsor may also voluntarily propose a REMS as part of the BLA. The need for a REMS is determined as part of the review of the BLA. Based on statutory standards, elements of a REMS may include “dear doctor letters,” a medication guide, more elaborate targeted educational programs, and in some cases restrictions on distribution. These elements are negotiated as part of the BLA approval, and in some cases may delay the approval date. Once adopted, REMS are subject to periodic assessment and modification.

After the FDA completes its initial review of a BLA, it will communicate to the sponsor that the biological product will either be approved, or it will issue a complete response letter to communicate that the BLA will not be approved in its current form. The complete response letter usually describes all of the specific deficiencies in the BLA identified by the FDA. The deficiencies identified may be minor, for example, requiring labeling changes, or major, for example, requiring additional clinical trials. Additionally, the complete response letter may include recommended actions that the applicant might take to place the applicant in a condition for approval. If a complete response letter is issued, the applicant may either resubmit the BLA, addressing all of the deficiencies identified in the letter, or withdraw the application.

The FDA may not grant approval on a timely basis, or at all. Histogenics may encounter difficulties or unanticipated costs in its efforts to secure necessary governmental approvals, which could delay or preclude Histogenics from marketing its products. The testing and approval process for a biological product usually takes several years to complete.

One of the performance goals agreed to by the FDA under PDUFA is to review 90% of standard BLAs within ten months of the 60-day filing date and 90% of priority BLAs within six months of the 60-day filing date, whereupon a review decision is to be made. The FDA does not always meet its PDUFA goal dates for standard and priority BLAs and its review goals are subject to change from time to time. The review process and the PDUFA goal data may be extended by three months if the FDA requests or the BLA applicant otherwise provides additional information or clarification regarding information already provided in the submission within the last three months before the PDUFA goal date.

Even if a product candidate receives regulatory approval, the approval may be limited to specific disease states, patient populations and dosages, or the indications for use may otherwise be limited, which could restrict the commercial value of the product. Further, the FDA may require that certain contraindications, warnings, or

precautions be included in the product labeling. The FDA may impose restrictions and conditions on product distribution, prescribing or dispensing in the form of a risk management plan, or otherwise limit the scope of any approval. In addition, the FDA may require Phase 4 post-marketing clinical trials, designed to further assess a biological product's safety and effectiveness, and testing and surveillance programs to monitor the safety of approved products that have been commercialized. Further, even after regulatory approval is obtained, later discovery of previously unknown problems with a product may result in the imposition of new restrictions on the product or even complete withdrawal of the product from the market. Delay in obtaining, or failure to obtain and maintain, regulatory approval for NeoCart, or obtaining approval but for significantly limited use, would harm Histogenics' business.

#### **FDA Post-Approval Requirements**

Maintaining substantial compliance with applicable federal, state, local and foreign statutes and regulations requires the expenditure of substantial time and financial resources. Rigorous and extensive FDA regulation of biological products continues after approval, particularly with respect to GMP. Histogenics may rely, in the future, on third parties for the production of clinical and commercial quantities of any future products that Histogenics may commercialize. Manufacturers of Histogenics' products are required to comply with applicable requirements in the GMP regulations, including quality control and quality assurance and maintenance of records and documentation. Histogenics cannot be certain that Histogenics or its present or future suppliers will be able to comply with the GMP and other FDA regulatory requirements. Other post-approval requirements applicable to biological products include reporting of GMP deviations that may affect the identity, potency, purity and overall safety of a distributed product, record-keeping requirements, reporting of adverse effects, reporting updated safety and efficacy information and complying with electronic record and signature requirements. After a BLA is approved, the product also may be subject to official lot release. As part of the manufacturing process, the manufacturer is required to perform certain tests on each lot of the product before it is released for distribution. If the product is subject to official release by the FDA, the manufacturer submits samples of each lot of product to the FDA together with a release protocol showing a summary of the history of manufacture of the lot and the results of all of the manufacturer's tests performed on the lot. The FDA also may perform certain confirmatory tests on lots of some products, such as viral vaccines, before releasing the lots for distribution by the manufacturer. In addition, the FDA conducts laboratory research related to the regulatory standards on the safety, purity, potency and effectiveness of biological products.

Discovery of previously unknown problems or the failure to comply with the applicable regulatory requirements, by Histogenics or its suppliers, may result in restrictions on the marketing of a product or withdrawal of the product from the market as well as possible civil or criminal sanctions and adverse publicity. FDA sanctions could include refusal to approve pending applications, suspension or revocation of an approval, clinical hold, warning or untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, mandated corrective advertising or communications with doctors, debarment, restitution, disgorgement of profits or civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on Histogenics.

Biological product manufacturers and other entities involved in the manufacture and distribution of approved biological products are required to register their facilities with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with GMPs and other laws. In addition, changes to the manufacturing process or facility generally require prior FDA approval before being implemented and other types of changes to the approved product, such as adding new indications and additional labeling claims, are also subject to further FDA review and approval.

#### **Labeling, Marketing and Promotion**

The FDA closely regulates the labeling, marketing and promotion of biological products, including direct-to-consumer advertising, promotional activities involving the internet, and industry-sponsored scientific and educational activities. While doctors are free to prescribe any product approved by the FDA for any use, a

company can only make claims relating to safety and efficacy of a biological product that are consistent with FDA approval, and a company is allowed to market a biological product only for the particular use and treatment approved by the FDA. In addition, any claims Histogenics makes for its products in advertising or promotion must be appropriately balanced with important safety and risk information and otherwise be adequately substantiated. Failure to comply with these requirements can result in adverse publicity, warning letters, corrective advertising, injunctions, seizures, potential civil and criminal penalties and exclusion from government healthcare programs.

#### **Anti-Kickback and False Claims Laws**

In the United States, the research, manufacture, distribution, sale and promotion of biological products are potentially subject to regulation by various federal, state and local authorities in addition to the FDA, including the Centers for Medicare & Medicaid Services, other divisions of the U.S. Department of Health and Human Services (for example, the Office of Inspector General), the U.S. Department of Justice, state Attorneys General, and other federal, state and local government agencies. For example, sales, marketing and scientific/educational grant programs must comply with the Anti-Kickback Statute, the False Claims Act, the privacy regulations promulgated under the Health Insurance Portability and Accountability Act and similar state laws. Pricing and rebate programs must comply with the Medicaid Drug Rebate Program requirements of the Omnibus Budget Reconciliation Act, and the Veterans Health Care Act. If products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. All of these activities are also potentially subject to federal and state consumer protection and unfair competition laws.

As noted above, in the United States, Histogenics is subject to complex laws and regulations pertaining to healthcare “fraud and abuse,” including the Anti-Kickback Statute, the False Claims Act and other state and federal laws and regulations. The Anti-Kickback Statute makes it illegal for any person, including a biological product manufacturer (or a party acting on its behalf), to knowingly and willfully solicit, receive, offer, or pay any remuneration that is intended to induce the referral of business, including the purchase or order of an item for which payment may be made under a federal healthcare program, such as Medicare or Medicaid. Violations of this law are punishable by up to five years in prison, criminal fines, administrative civil money penalties and exclusion from participation in federal healthcare programs. In addition, many states have adopted laws similar to the Anti-Kickback Statute. Some of these state prohibitions apply to the referral of patients for healthcare services reimbursed by any insurer, not just federal healthcare programs such as Medicare and Medicaid. Due to the breadth of these federal and state anti-kickback laws and the potential for additional legal or regulatory change in this area, it is possible that Histogenics’ future sales and marketing practices or its future relationships with physicians might be challenged under anti-kickback laws, which could harm Histogenics. Because Histogenics intend to commercialize products that could be reimbursed under a federal healthcare program and other governmental healthcare programs, Histogenics plans to develop a comprehensive compliance program that establishes internal controls to facilitate adherence to the rules and program requirements to which Histogenics will or may become subject.

The False Claims Act prohibits anyone from, among other things, knowingly presenting, or causing to be presented, for payment to federal programs (including Medicare and Medicaid) claims for items or services, including biological products, that are false or fraudulent. Although Histogenics likely would not submit claims directly to payers, manufacturers can be held liable under these laws if they are deemed to “cause” the submission of false or fraudulent claims by, for example, providing inaccurate billing or coding information to customers or promoting a product off-label. In addition, Histogenics’ future activities relating to the reporting of wholesaler or estimated retail prices for its products, the reporting of prices used to calculate Medicaid rebate information and other information affecting federal, state and third-party coverage and reimbursement for its products and the sale and marketing of its products, are subject to scrutiny under this law. For example, pharmaceutical companies have been prosecuted under the False Claims Act in connection with their off-label promotion of drugs. Penalties for a False Claims Act violation include three times the actual damages sustained by the government, plus mandatory civil penalties of between \$5,500 and \$11,000 for each separate false claim,

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the potential for exclusion from participation in federal healthcare programs, and, although the federal False Claims Act is a civil statute, conduct that results in a False Claims Act violation may also implicate various federal criminal statutes. If the government were to allege that Histogenics was, or convict Histogenics of, violating these false claims laws, Histogenics could be subject to a substantial fine and may suffer a decline in its stock price. In addition, private individuals have the ability to bring actions under the False Claims Act and certain states have enacted laws modeled after the False Claims Act.

There are also an increasing number of state laws that require manufacturers to make reports to states on pricing and marketing information. Many of these laws contain ambiguities as to what is required to comply with the laws. In addition, beginning in August 2013, a similar federal requirement requires manufacturers to track and report to the federal government certain payments made to physicians and teaching hospitals made in the previous calendar year. These laws may affect Histogenics' sales, marketing, and other promotional activities by imposing administrative and compliance burdens on Histogenics. In addition, given the lack of clarity with respect to these laws and their implementation, its reporting actions could be subject to the penalty provisions of the pertinent state, and soon federal, authorities.

### Other Regulations

Histogenics is also subject to numerous federal, state and local laws relating to such matters as safe working conditions, manufacturing practices, environmental protection, fire hazard control and disposal of hazardous or potentially hazardous substances. Histogenics may incur significant costs to comply with such laws and regulations now or in the future.

### **EU and EEA**

Marketing authorization in the EU for products containing viable human tissues or cells such as NeoCart is governed by Regulation 1394/2007/EC on advanced therapy medicinal products, read in combination with Directive 2001/83/EC of the European parliament and of the Council, commonly known as the Community code on medicinal products. Regulation 1394/2007/EC establishes specific rules concerning the authorization, supervision and pharmacovigilance of gene therapy medicinal products, somatic cell therapy medicinal products and tissue engineered products. Manufacturers of advanced therapy medicinal products must demonstrate the quality, safety and efficacy of their products to the EMA which is required to provide an opinion regarding the application for marketing authorization. The European Commission grants or refuses marketing authorization in light of the opinion delivered by the EMA.

Applicants for marketing authorizations for medicinal products in the EEA are required to submit applications for marketing authorization in a form that is based on the ICH Common Technical Document, and must demonstrate the safety, quality and efficacy of the medicinal product for which the marketing authorization is sought. The application must include the results of pre-clinical tests and clinical trials conducted with the medicinal product.

The conduct of clinical trials in the EEA is governed by Directive 2001/20/EC which imposes obligations and procedures that are similar to those provided in applicable U.S. laws. The EU Good Clinical Practice rules and EU Good Laboratory Practice obligations must also be respected during conduct of the trials. Clinical trials must be approved by the competent regulatory authorities and the competent Ethics Committees in the EU Member States in which the clinical trials take place.

Moreover, applicants are required to provide evidence that studies have been conducted with the medicinal product in the pediatric population as provided by a Pediatric Investigation Plan approved by the Pediatric Committee of the EMA. Alternatively, confirmation that the applicant has obtained a waiver or deferral for the conduct of these studies must be provided. Cell-based products must also comply with Directive 2004/23/EC of the European Parliament and of the Council of March 31, 2004 on setting standards of quality and safety for the

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donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells (Tissues and Cells Directive). This Directive describes the conditions and quality requirements which must be applied when sourcing the cells intended for manufacturing of the cell-based medicinal product. The EU Member States have transposed the Tissues and Cells Directive into their national laws.

Locally different interpretations of the Tissue and Cells Directive have occurred during adoption of the national legal implementations by individual EU Member States. This has led to some inconsistency of approach leading to additional complexity in complying with the all-over requirements in this already difficult regulatory field.

Given the specific nature of cell-based products, the clinical development paths are less standardized than for classic pharmaceutical or biological products. Phase 1 studies are often not relevant, in particular for autologous cell-based products, since cells often need to be directly implanted into a tissue defect only present in patients. As cellular therapy Phase 3 clinical trials are very complex to organize, often limited numbers of patients can be enrolled and follow up times can be very long, so that the design and execution of these large confirmatory trials might not always be possible to the classical extent. Upfront discussions and agreement with the regulatory authorities are an important criterion to success. It is also expected that new regulatory guidance will become available in the near future, more clearly describing the regulatory expectations.

### **Employees**

As of June 30, 2019, Histogenics did not have any employees. Histogenics has engaged Mr. Adam Gridley, its former Chief Executive Officer and current President, Mr. Stephen Kennedy, its former Chief Operating Officer, and certain former key employees as consultants to assist with its ongoing operations and in order to consummate the merger. Mr. Gridley has retained his statutory titles of president, treasurer and secretary of Histogenics while he continues to provide consulting services to Histogenics, and remains a director of Histogenics. Histogenics has never had a work stoppage, and none of its employees are represented by a labor organization or under any collective bargaining arrangements.

### **Corporate Information**

Histogenics was originally incorporated as a Massachusetts corporation in 2000. In 2006, Histogenics underwent a corporate reorganization pursuant to which Histogenics was incorporated as a Delaware corporation. Histogenics' principal offices are currently located at c/o Gunderson Dettmer, One Marina Park Drive, Suite 900, Boston, Massachusetts 02210, Attn: HSGX Corporate Secretary, and its telephone number is (781) 312-5013. Histogenics' website address is [www.histogenics.com](http://www.histogenics.com). Histogenics' website and the information contained on, or that can be accessed through, its website shall not be deemed to be incorporated by reference in, and are not considered part of, this proxy statement/prospectus/information statement. You should not rely on any such information in making your decision whether to purchase Histogenics common stock.

### **Available Information**

Histogenics files annual, quarterly, and current reports, proxy statements, and other documents with the SEC under the Exchange Act. The SEC maintains an Internet website, [www.sec.gov](http://www.sec.gov), that contains reports, proxy and information statements, and other information regarding issuers, including Histogenics, that file electronically with the SEC.

Copies of each of Histogenics' filings with the SEC on Form 10-K, Form 10-Q and Form 8-K and all amendments to those reports, can be viewed and downloaded free of charge at its website, [www.histogenics.com](http://www.histogenics.com) as soon as reasonably practicable after the reports and amendments are electronically filed with or furnished to the SEC.

Histogenics' code of ethics, other corporate policies and procedures, and the charters of its Audit Committee, Compensation Committee and Nominating/Corporate Governance Committee are available through its website at [www.histogenics.com](http://www.histogenics.com).

## OCUGEN BUSINESS

### OVERVIEW

Ocugen is a clinical stage biopharmaceutical company focused on discovering, developing and commercializing a pipeline of innovative therapies, including gene therapies and biologicals, to address rare and underserved eye diseases.

Ocugen is developing a modifier gene therapy platform for unmet medical needs in the area of retinal diseases, including inherited retinal diseases (“IRDs”). Ocugen’s modifier gene therapy platform is novel in that it targets nuclear hormone receptor (“NHR”) genes that have the potential to restore homeostasis to the retina and may target multiple genes that are associated with a range of IRDs. Unlike single-gene replacement therapies, which only target one genetic mutation, Ocugen believes that its gene therapy platform, through its use of NHRs, may impact multiple genes that are associated with a range of genetically diverse diseases. Ocugen’s first gene therapy candidate, OCU400 received Orphan Drug Designation (“ODD”), from the Food and Drug Administration (the “FDA”), for the treatment of *NR2E3* mutation-associated retinal degenerative disease. OCU400 uses an adeno-associated virus vector. Ocugen is planning to initiate a Phase 1/2a clinical trial for OCU400 in the next two years.

Ocugen has a late-stage, Phase 3 program, OCU300, that has also received ODD from the FDA. OCU300 is a small molecule therapeutic currently in Phase 3 clinical development for patients with ocular graft-versus-host disease (“oGVHD”). OCU300 is the first and only product candidate to receive ODD for the treatment of oGVHD. Ocugen estimates the current prevalence of patients suffering from oGVHD in the United States to be approximately 50,000. The final manufacturing processes for OCU300 has been scaled up by Ocugen’s existing contract manufacturer at a cGMP facility located in the United States to support potential commercialization, and chemistry, manufacturing and control (“CMC”) development is ongoing.

OCU300 is formulated using Ocugen’s proprietary nanoemulsion technology, OcuNanoE—Ocugen’s ONE Platform™ (“OcuNanoE™”). Ocugen is the first and only company to use nanoemulsion technology in the ophthalmology space, and Ocugen believes that OcuNanoE™ provides additional protection to the ocular surface. Ocugen’s technology delivers the active drug with the use of defined narrow-range globules with an average diameter of less than 100 nanometers. Ocugen believes this provides the potential for enhanced efficacy compared to traditional formulations.

Ocugen is developing OCU310 for patients with dry eye disease (“DED”), which is also formulated using OcuNanoE™. Ocugen has completed a Phase 3 clinical trial for OCU310 that was initiated in September 2018 with the first patient dosed in December 2018. Although the trial showed that OCU310 is well-tolerated, as demonstrated by no adverse events regarded as “severe,” it did not meet its co-primary endpoints for symptom and sign. However, a pre-specified exploratory efficacy endpoint of reduction in redness (sign) from the baseline visit, measured by a Validated Bulbar Redness score, was significantly better for OCU310 relative to placebo at both Day 14 and Day 28. Post-hoc analysis of the Phase 3 clinical trial is ongoing, subsequent to which a consultation with the FDA will be sought. Ocugen is evaluating its options and timing for the continued development of OCU310, including partnering for future clinical trials.

Ocugen is developing OCU200, a novel fusion protein, that is currently in preclinical development for treating wet age-related macular degeneration (“wet AMD”). Ocugen expects to initiate a Phase 1/2 clinical trial for OCU200 within the next two years. In addition, Ocugen plans to expand the therapeutic applications of OCU200 beyond wet AMD to potentially include diabetic retinopathy (“DR”), diabetic macular edema (“DME”), macular edema following retinal vein occlusion (“RVO”), and myopic choroidal neovascularization (“mCNV”). Ocugen’s novel biologic, OCU100 for the treatment of retinitis pigmentosa (“RP”) has received ODD in the United States and the European Union.



## OCUGEN'S STRATEGY

Ocugen believes that its product candidates have the potential to address unmet medical needs in retinal and ocular surface diseases. Key elements of its strategy include:

- **Advancing OCU400 into clinical development.** Ocugen intends to advance OCU400 into and through clinical development for the treatment of *NR2E3* mutation-associated retinal degenerative disease. In addition to OCU400, Ocugen will also explore additional nuclear hormone receptor-based product candidates for multiple eye disease indications.
- **Advancing the development of OCU300 to approval.** Based on results from an investigator-initiated Phase 1/2 clinical study and its eligibility to utilize the streamlined 505(b)(2) regulatory pathway, Ocugen has initiated Phase 3 registration trials using OCU300 as a first-in-class treatment for ocular redness and discomfort in patients with oGVHD. While the clinical trials are progressing and are a prerequisite for the NDA submission, Ocugen is continuing CMC development for OCU300, including process validation and stability studies of registration batches. Since OCU300 has ODD, it may be eligible for seven-year market exclusivity.
- **Establishing internal sales capabilities to commercialize its product candidates in the United States.** Ocugen owns or exclusively licenses worldwide rights to all indications for its product candidates. Ocugen may partner commercialization rights for OCU300. If Ocugen chooses not to partner commercialization rights for OCU300, it may build a commercial team of up to 100 marketing and sales representatives in support of OCU300, which Ocugen either may hire directly or engage through a contract sales organization. The team may include specialty sales and managed care representatives, medical science liaisons, telemarketers, and customer service personnel. Allogeneic stem cell transplantation is conducted in a small number of medical centers nationwide, with the top 58 bone marrow transplant centers accounting for 75% of all allogeneic transplant procedures in the United States (National Marrow Donor Program). As a result, these representatives would be able to efficiently target and personally focus on those hematologists, oncologists, and ophthalmologists who are actively involved in hematopoietic stem cell transplant, or HSCT, and who routinely treat patients with oGVHD throughout the United States.
- **Exploring potential partnerships with leading pharmaceutical and biotechnology companies to maximize patient access, global reach and the value of its product candidates.** Ocugen currently plans to explore licensing the commercialization rights to its product candidates or other forms of collaboration with qualified potential partners in certain key markets outside of the United States, including Europe, Japan and emerging markets.
- **Evaluating the potential of OCU310 moving forward.** Based on results from its first Phase 3 clinical trial of OCU310 in DED, Ocugen continues to perform post-hoc analysis of the Phase 3 data and explore further development or partnership opportunities.
- **Advancing preclinical biological programs into clinical development.** Ocugen has programs targeting wet AMD and RP in preclinical development. Ocugen intends to advance these programs into clinical development within the next two years as follows:
  - Advance OCU200 into and through clinical development for wet AMD.
  - Advance orphan drug designated OCU100 into and through clinical development for RP.
- **Leveraging its proprietary OcuNanoE™ nanoemulsion formulation as a drug delivery technology for ocular surface disorders.** Ocugen believes its proprietary OcuNanoE™ nanoemulsion formulation may improve drug distribution and penetration into ocular tissues and may have a favorable impact on certain ocular disease states. Ocugen is exploring the use of its OcuNanoE™ technology to develop product candidates targeting other eye diseases.

## OCUGEN'S PIPELINE

### MODIFIER GENE THERAPY PLATFORM

#### **OCU400 for Treatment of *NR2E3* Mutation-Associated Retinal Degenerative Disease**

Ocugen is developing OCU400, which has received ODD, for the treatment of *NR2E3* mutation-associated retinal degenerative disease. OCU400 is the first product candidate being developed with its gene therapy platform utilizing NHRs. NHRs have long been known to play a critical role in modulating cellular homeostasis by regulating basic biological processes including development, metabolism, circadian cycle, and energy homeostasis. OCU400 is comprised of *NR2E3*, a NHR gene with the potential to be used as a gene therapeutic for the treatment of retinal degenerative diseases including subsets of RP. Ocugen plans to initiate a Phase 1/2a clinical trial in the next two years. In addition, Ocugen intends to explore broader therapeutic indications using NHRs, such as Leber Congenital Amaurosis (“LCA”), Bardet-Biedl Syndrome (“BBS”) and Rhodopsin Mutation-Associated Retinal Degeneration. Preclinical studies conducted by Dr. Neena Haider’s lab at The Schepens Eye Research Institute, an affiliate of Harvard Medical School, and others have shown that *NR2E3* may partially or fully rescue photoreceptors from degeneration in IRD.

### OCULAR SURFACE DISEASES

#### **OCU300 for Patients with oGVHD**

OCU300 is a late-stage product candidate for which Ocugen has initiated a randomized, double-masked, placebo-controlled, Phase 3 trial for the treatment of ocular redness and ocular discomfort in patients with oGVHD. There currently are no FDA approved products for oGVHD. The active ingredient in OCU300 is brimonidine tartrate. Brimonidine tartrate is an imidazoline compound that acts as a specific  $\alpha_2$ -adrenergic agonist. OCU300 is a twice-daily, steroid-free, preservative-free eye drop of brimonidine tartrate (0.18%) OcuNanoE™ nanoemulsion. In addition to the existing ODD designation for oGVHD, Ocugen is eligible to utilize the streamlined 505(b)(2) NDA regulatory pathway for the approval of OCU300 in the United States. Ocugen believes that the 505(b)(2) NDA regulatory pathway provides it with a potential path to market by allowing Ocugen to rely on certain information from studies conducted by third parties. Ocugen initiated the first of two identical, pivotal Phase 3 trials of OCU300 in June 2018 and the first patient was dosed in December 2018.

Preclinical and early clinical studies have demonstrated the potential value of OCU300 for the treatment of ocular redness and discomfort in patients with oGVHD. Because each of the early clinical studies had a very small sample size, these studies were not considered sufficiently powered. However, some results met the cut-off for statistical significance, which is denoted by p-values. The p-value is the probability that the reported result was achieved by chance (e.g., a p-value of <0.01 means that there is a less than 1.0% chance that the observed effect was due to chance). Generally, a p-value less than 0.05 is considered statistically significant in an adequately powered study. It is possible to have a positive result based on a p-value less than 0.05 in a study that is not adequately powered due to a small sample size. In this case, the result should be regarded as a signal to be confirmed in a larger, adequately powered study. Key highlights include:

- Preclinical proof-of-concept activity in a mouse model;
- IND-enabling preclinical studies; and
- Two early investigator-initiated clinical studies in patients with oGVHD:
  - Retrospective hypothesis-generating analysis in which most patients on brimonidine tartrate therapy for at least six months reported subjective ocular symptom benefits, though not powered for statistical significance; and
  - Phase 1/2 placebo-controlled study topline data of brimonidine tartrate demonstrating a significant reduction in ocular redness ( $p < 0.05$ ) in patients on brimonidine tartrate therapy for three months.

oGVHD is a severe chronic autoimmune disease that occurs in up to 60% of HSCT recipients and represents a critical unmet medical need. The disease is driven by the invasion of HSCT derived leukocytes onto the ocular surface, resulting in fibrosis and excessive production of extracellular matrix (“ECM”) proteins. The donor leukocytes subsequently launch an autoimmune assault on the tear producing glands, cornea, conjunctiva and eyelid of the recipient. oGVHD can cause irreparable damage to these ocular tissues, thereby decreasing the secretion and stability of tear film. Prolonged inflammation can result in ocular pain and discomfort, corneal ulceration, cicatricial conjunctivitis, blepharitis, and vision loss. Ocugen believes brimonidine tartrate may address oGVHD in the following ways:

- Reducing ocular surface blood flow;
- Disrupting leukocyte extravasation to the ocular tissue;
- Suppressing leukocyte activation;
- Providing anti-nociceptive (analgesic) properties; and
- Reducing fibrosis and suppressing excessive ECM formation.

### **OCU310 for Patients with DED**

Ocugen is developing OCU310 for relief from the signs and symptoms of DED. OCU310 is a twice-daily, steroid-free, preservative-free eye drop of brimonidine tartrate (0.2%) OcuNanoE™ nanoemulsion.

In 2018, Ocugen conducted a Phase 2 placebo-controlled proof-of-concept clinical study, in which patients with DED were dosed with brimonidine tartrate 0.2%, with and without loteprednol etabonate 0.2%, twice a day for 84 days. The study met its primary endpoint of tolerability. Several prospectively defined, exploratory endpoints for common signs and symptoms of DED showed positive results. Brimonidine monotherapy resulted in a positive treatment effect compared to placebo at the 28-day and 84-day time points in the Symptom Assessment in Dry Eye, or SANDE, symptom endpoint. Brimonidine monotherapy also showed numerical improvement at the 84-day time point in the conjunctival staining sign endpoint. Steroid combination therapy also showed improvement in both sign and symptom endpoints relative to placebo. These results were presented at the 2018 Annual Meeting of The American Academy of Ophthalmology (“AAO”). Based on the results of this study, Ocugen proceeded with the monotherapy product (brimonidine tartrate 0.2% OcuNanoE™) without loteprednol for its Phase 3 clinical trials.

Ocugen evaluated OCU310 in one Phase 3 trial, which was initiated in September 2018, and the first patient was dosed in December 2018. OCU310 was evaluated in a randomized, double-masked, placebo-controlled Phase 3 trial for safety and efficacy. Although the trial showed that OCU310 is well-tolerated, as demonstrated by no adverse events regarded as “severe,” it did not meet its co-primary endpoints for symptom and sign. However, a pre-specified exploratory efficacy endpoint of reduction in redness (sign) from the baseline visit, measured by a Validated Bulbar Redness score, was significantly better for OCU310 relative to placebo at both Day 14 and Day 28. Post-hoc analysis of the Phase 3 clinical trial is ongoing, subsequent to which a consultation with the FDA will be sought. Ocugen is evaluating its options and timing for the continued development of OCU310, including partnering for future clinical trials.

DED is a chronic disease affecting the tears and ocular surface that can result in tear film instability, inflammation, discomfort, visual disturbance and ocular surface damage. DED can cause long-term damage to the ocular surface. Due to the impact of DED on tear film stability, the condition can affect the performance of common vision-related activities, such as reading, using a computer and driving, and can lead to complications associated with visual impairment.

It is estimated that there are approximately 35 million adult patients affected by DED in the United States. Of the estimated 16 million patients who have been diagnosed with DED, Ocugen estimates that approximately

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1 million patients receive an on-label FDA approved prescription therapy. Since the launch of Xiidra®, the DED market has grown due to new therapies and increased disease awareness. There may be additional opportunities for Ocugen to address acute exacerbations suffered by the majority of dry eye patients as well as to provide non-steroidal therapies for DED more generally.

Ocugen believes there is a significant opportunity for OCU310 to address unmet medical needs. Ocugen believes that OCU310 may have several key features, including:

- Multiple modes of action:
  - Direct analgesic effect (relieves ocular pain/discomfort);
  - Direct anti-inflammatory effects;
- Improved tolerability profile; and
- Symptomatic relief as early as 28 days following the initiation of treatment.

### **ITS PROPRIETARY OCUNANOETM —OCUGEN'S ONE PLATFORMTM**

Ocugen has core capabilities in ophthalmic drug delivery and plans to leverage its proprietary OcuNanoE™ nanoemulsion formulation to deliver drugs more efficiently to relevant ocular tissues. OcuNanoE™ is also designed to provide protection to the ocular surface. Data from a preclinical study suggests that brimonidine formulated with OcuNanoE™ may enhance drug distribution and penetration into the lacrimal gland, which is critical for tear film production. Ocugen has applied this technology to create a nanoemulsion formulation of brimonidine tartrate, resulting in the development of its two clinical product candidates, OCU300 (brimonidine 0.18%, OcuNanoE™) and OCU310 (brimonidine 0.2%, OcuNanoE™). OCU300 and OCU310 are sterile-filtered, preservative-free and steroid-free, which have been designed to avoid certain side effects. Ocugen also believes its technology may be leveraged to formulate additional active molecules and to treat additional ocular surface disorders.

### **PRECLINICAL BIOLOGICAL PIPELINE**

Ocugen is evaluating several preclinical product candidates for ophthalmic diseases, including wet AMD and RP.






#### **OCU200 for Patients with Wet AMD**

Ocugen is developing OCU200 for the treatment of wet AMD. AMD is a degeneration of the macula of the retina that leads to impairment and loss of central vision. Wet AMD results from growth of abnormal blood vessels under the retina and macula, resulting in edema, tissue damage and rapid loss of central vision. If untreated, neovascularization in wet AMD patients typically results in significant vision loss and the formation of a scar under the macular region of the retina. Available FDA approved treatments for wet AMD include the intravitreal injection of either Lucentis® or Eylea®, which target vascular endothelial growth factor (“VEGF”). However, studies suggest that these therapies have limited success both with respect to an increase in non-responders, reduced effectiveness over a period of time, and persistent fluid accumulation in the sub-retinal space even after long-term treatment. Given these limitations, Ocugen believes that unmet medical needs still exist. OCU200 is a novel fusion protein consisting of two human proteins, transferrin and tumstatin, which are present normally in retinal tissues. In a preclinical *in-vitro* cell culture study, OCU200 compared to tumstatin alone and an anti-VEGF antibody reduced cell invasion of the basement membrane by endothelial cells, which suggested that OCU200 may reduce new blood vessel formation. In an *in-vivo* rat study in laser induced choroidal neovascularization, or CNV, OCU200 reduced lesion size and inhibited CNV to a greater extent than tumstatin alone and an anti-VEGF antibody. OCU200 is currently in preclinical development for treating wet AMD. Eventually, Ocugen plans to expand the therapeutic applications of OCU200 beyond wet AMD, to potentially include diabetic retinopathy, diabetic macular edema, macular edema following retinal vein occlusion, and myopic choroidal neovascularization.

**OCU100 for Patients with Retinitis Pigmentosa**

Ocugen is developing OCU100 for the treatment of RP, which is a class of diseases that leads to the progressive degeneration of the retina and blindness, with multiple modes of inheritance, and can arise in syndromic or nonsyndromic forms. To date, mutations in more than 200 genes are associated with RP. However, there are many more genes and mutations that have yet to be identified, with known mutations only accounting for approximately 60% of all RP cases. There is no FDA approved treatment for RP. OCU100 is a protein-based biologic comprised of a recombinant form of the N-terminal segment (1-326 amino residues) of human lens epithelial derived growth factor, or LEDGF, which may rescue photoreceptors from retinal degeneration. An *in-vivo* preclinical study suggests that intravitreal injections of OCU100 could improve the survival of retinal cells, which Ocugen believes may slow or stop the progression of disease in individuals with RP, regardless of genetic background.

Ocugen’s current product pipeline candidates are outlined below:

	Indication	Preclinical	Phase 1	Phase 2	Phase 3
<b>MODIFIER GENE THERAPY PLATFORM</b>					
OCU400 <i>NR2E3-AAV</i>	<i>NR2E3</i> Mutation-Associated Retinal Degeneration Orphan - US				
	Leber Congenital Amaurosis (LCA)				
	Bardet-Biedl Syndrome (BBS)				
	Rhodopsin Mutation-Associated Retinal Degeneration				
OCU410 <i>RORA-AAV</i>	Dry AMD				
<b>RETINAL DISEASES</b>					
OCU200 Turnstatin-Transferrin	Wet AMD				
	Diabetic Macular Edema				
	Diabetic Retinopathy				
OCU100 LEDGF 1-326	Retinitis Pigmentosa Orphan - US & EU				
<b>OCULAR SURFACE DISEASES</b>					
OCU300 Brimonidine 0.18% OcuNanoE™	oGVHD Orphan - US				
OCU310 Brimonidine 0.2% OcuNanoE™	Dry Eye Disease				

**COMPETITIVE STRENGTHS**

Ocugen’s key competitive strengths include:

- **Intellectual Property Portfolio.** Ocugen holds the worldwide commercial rights for its current product candidates. Its intellectual property portfolio contains patents and pending patent applications related to composition of matter, pharmaceutical compositions and methods of use for its product candidates. Ocugen strives to protect the proprietary technology that Ocugen believes is important to its business, including seeking and maintaining patents for its product candidates and OcuNanoE™ platform. Ocugen has patent protection for OCU300 and OCU310 in the United States through at least 2036.

Ocugen seeks to protect its proprietary and intellectual property positions by filing U.S. and foreign applications for its clinical programs, OCU300 and OCU310, preclinical development programs, OCU400, OCU200 and OCU100, as well as technology platforms critical to the development and

implementation of its business strategy. To the best of its knowledge, as of June 2019, Ocugen had exclusive rights or owned rights to: (i) 3 issued patents and a total of 16 pending U.S. and foreign patent applications related to OCU300 and OCU310; (ii) a total of 1 issued patent and a total of 2 pending applications related to OCU400; (iii) a total of 25 issued U.S. and foreign patents and a total of 2 pending patent applications related to OCU200; and (iv) a total of 3 issued U.S. and foreign patents and a total of 8 pending U.S. and foreign patent applications related to OCU100.

- **Licensing Arrangements with Leading Institutions.** Ocugen has three licensing agreements with leading academic and medical institutions that cover its five product candidates. In February 2016, Ocugen entered into an exclusive worldwide license agreement with University of Illinois at Chicago to develop brimonidine tartrate for the treatment of ocular surface diseases which is used in its OCU300 and OCU310 programs. In December 2017, Ocugen entered into an exclusive worldwide license agreement with The Schepens Eye Research Institute, an affiliate of Harvard Medical School, for patent rights for NHRs, including the OCU400 program. In March 2014, Ocugen entered into an exclusive worldwide license agreement with the University of Colorado for the transferrin-tumstatin fusion protein technology for OCU200 and the LEDGF peptides technology for OCU100 program. Ocugen has built a strong global patent portfolio with 31 U.S. or foreign issued patents and 29 patent applications, including patents licensed from the University of Illinois at Chicago, the University of Colorado and The Schepens Eye Research Institute.
- **Experienced Management Team.** Ocugen's management team has a combined experience of over 200 years with a proven track record of success in developing, launching and managing the life cycle of many biopharmaceuticals at leading pharmaceutical companies (including Pfizer and Merck) and biotechnology companies. Ocugen believes that the experience of its management team and its broad network of relationships with leaders within the industry and the medical community provides it with insight into product development and identification of product opportunities to address underserved eye diseases.

## OVERVIEW OF EYE DISEASES

The human eye consists of two major parts: the posterior segment, or the back of the eye, and the anterior segment, or the front of the eye.

The posterior segment mainly consists of the vitreous humor, retina, choroid, and optic nerve. Common retinal degenerative diseases affecting the back of the eye include RP, AMD, diabetic retinopathy, diabetic macular edema, proliferative vitreoretinopathy, retinal vein occlusion and posterior uveitis. These diseases frequently result in damage to the vasculature, photoreceptors and retinal pigment epithelium and can lead to a loss of function and an irreversible loss of vision. The most common treatments for these diseases involve the administration of biologic agents, including protein and gene therapeutics. Delivery of these biologic agents to the target ocular space is critical for the clinical efficacy of a given product. Clinicians generally have only two options to deliver these biologic agents to the target ocular space: either by injection into the intravitreal space or by subretinal injection. No topical therapeutics to treat back of the eye diseases have been approved.

The anterior segment of the eye consists of the ocular surface (including the cornea, conjunctiva, eye lids, meibomian glands and lacrimal glands), aqueous humor, iris, ciliary body and lens. Common diseases affecting the anterior segment are DED, glaucoma, allergic conjunctivitis, anterior uveitis and cataracts. In addition, the ocular surface is significantly affected in oGVHD. Drug delivery to the anterior segment of the eye typically involves topical eye drops. The anterior segment is coated with the tear film which is composed of the inner mucin layer, the middle aqueous component and the outer lipid layer. The mucin layer is derived from goblet cells from conjunctiva and lacrimal glands; the aqueous layer is derived from lacrimal glands; and the lipid layer is derived from meibomian glands. About 90% of topical drugs applied to the anterior segment are lost through the nasolacrimal duct and conjunctiva into systemic circulation. The rest of the drug is expected to reach the target tissues. Therefore, in treating diseases in the anterior segment, it is crucial for topically administered drops

to have enhanced residence time on the eye surface and adequate penetration to ensure that the drug reaches the target tissues, such as lacrimal gland.

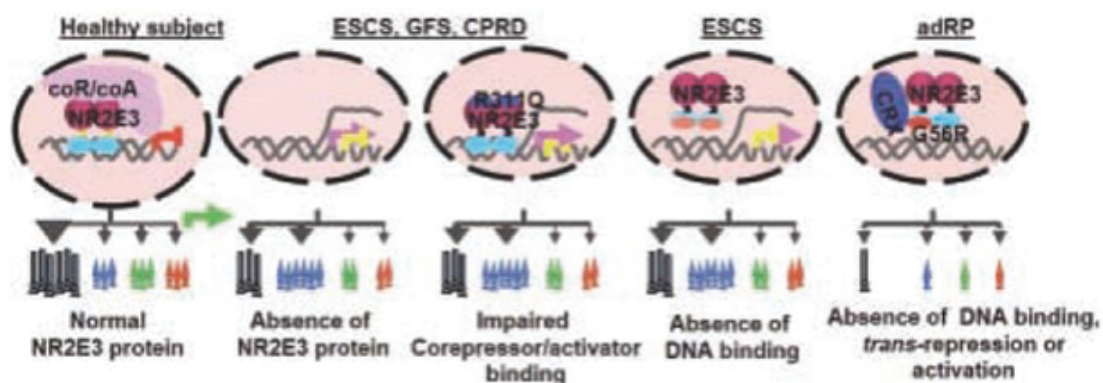
**PRODUCT CANDIDATE FOR MODIFIER GENE THERAPY PLATFORM**

**OCU400 for the Treatment of NR2E3 Mutation-Associated Retinal Degenerative Disease**

OCU400 is the first product candidate developed with its gene therapy platform utilizing NHRs, which have long been known to play a critical role in modulating cellular homeostasis by regulating basic biological processes including development, metabolism, circadian cycle, and energy homeostasis. OCU400 is comprised of NR2E3, a NHR gene expressed in adeno-associated viral vector that has the potential to be used as a gene therapeutic for the treatment of NR2E3 mutation-associated retinal degenerative disease. Ocugen had a pre-IND meeting with the FDA in February 2019 and received guidance on IND-enabling preclinical studies to support the Phase 1/2a study.

In addition, Ocugen intends to continue to explore broader therapeutic indications using NHRs. Preclinical studies conducted by Dr. Neena Haider and others have shown that NR2E3 is a dual activator/repressor and member of the NHR family and that, with other transcription factors, modulates cell fate and differentiation of rod and cone photoreceptor cells. Specifically, NR2E3 regulates cone cell proliferation in retinal progenitors and promotes rod differentiation in postmitotic differentiating rod photoreceptors (Figure 1) likely by suppressing cone genes while activating rod-specific genes. NR2E3 has been shown to be a key factor in regulating retinal progenitor cells to produce the appropriate number of blue cones and also in directing proper rod cell differentiation. Delivery of NR2E3 efficiently ameliorated clinical, morphological, and functional defects associated with retinal degeneration in a mouse model lacking functional NR2E3. It has also been demonstrated that the mechanism of rescue at the molecular and functional level is through the re-regulation of key genes within the NR2E3-directed transcriptional network. Ocugen believes that these studies suggest that NR2E3 may partially or fully rescue photoreceptors from degeneration in patients with IRDs. Accordingly, Ocugen believes that study of OCU400 treatment for NHR associated IRDs is warranted.

**Figure 1 Schematic representation of the potential mechanism impacting NR2E3 retinal degeneration.** coR/coA—corepressor or coactivator; ESCS—Enhanced S-cone syndrome; GFS—Goldman Favre syndrome; adRP—autosomal dominant retinitis pigmentosa; rod photoreceptors in grey and cone photoreceptors are in blue, green, and red.



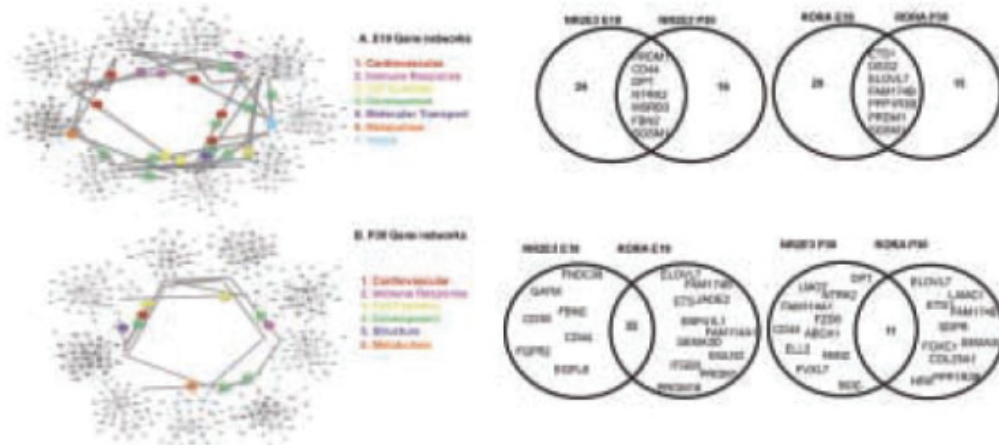
NHR technology represents a novel gene modifier therapy platform that has the potential to restore retinal integrity and function across a range of genetically diverse IRDs and other degenerative retinal diseases, leading to multiple potential product opportunities. NHR technology encompasses the targeted delivery and expression of certain NHRs that are expressed naturally in retinal tissue. It has shown potential to rescue many genetic defects

and may lead to vision-sparing therapies for rare IRDs such as enhanced S-cone syndrome, Goldman-Favre syndrome and RP, as well as other forms of retinal and macular degeneration, providing Ocugen with significant potential long-term value.

Dr. Haider’s lab and others have shown the preclinical phenotypic outcome results from a mutational load on a biological system that includes the primary mutation and other factors such as modifier alleles impacting the normal homeostatic state. As modifier genes may be capable of modifying disease states in the retina, they may provide a viable therapeutic option with broad applicability.

Therapeutic NHRs have been identified for their potential ability to modify disease progression through the regulation of key gene networks that can restore retinal homeostasis and rescue the defects caused by inherited gene mutations. The use of genetic modifiers represents a broadened means of potentially treating a variety of retinal degenerative diseases, as compared to single-gene replacement therapy. While single-gene replacement therapies have shown tremendous promise in rare retinal diseases, they are highly specific and cannot ameliorate a multitude of disease-causing genetic defects. On the other hand, NHRs play a vital role in regulating retinal cell development, maturation, metabolism, visual cycle function and survival (**Figure 2**).

**Figure 2 Interacting NR2E3 and RORA Associated Gene Networks.**

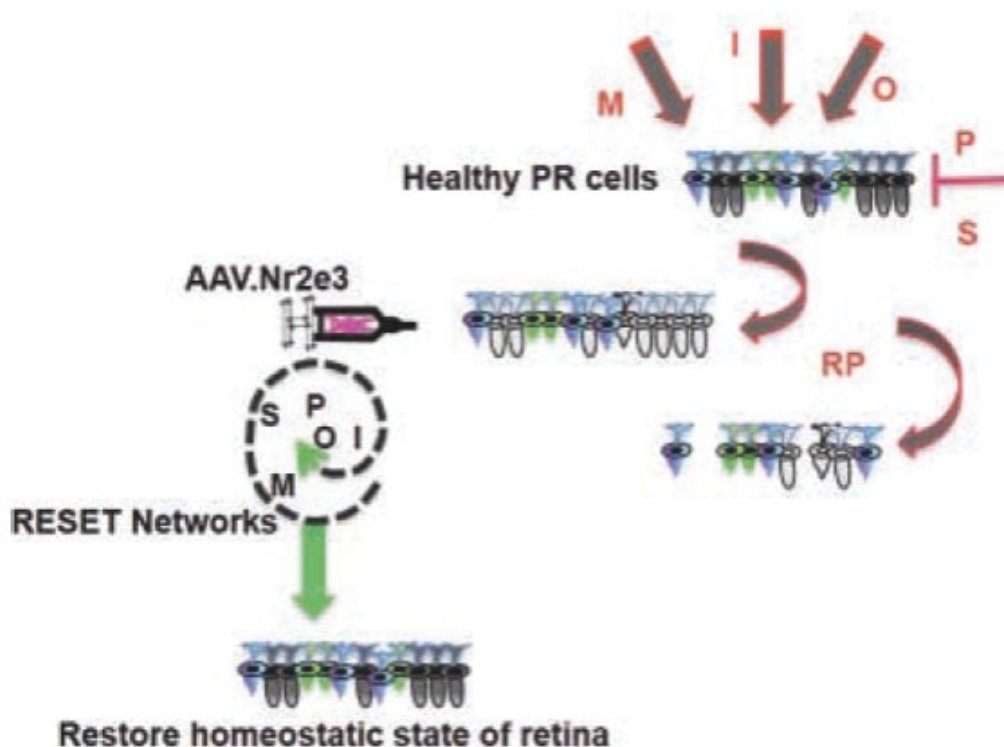


**(A)** IPA analysis of E18 targets identified nine gene networks with seven biological classifications. **(B)** IPA analysis of P30 targets identified nine gene networks with six biological classifications. Venn Diagrams show unique and overlapping gene targets of NR2E3 and RORA at E18 and P30. Comparisons of RORA E18/P30 or NR2E3 E18/P30 show less overlap than RORA/NR2E3 at E18 or RORA/NR2E3 at P30.

Disease outcome is a result of a primary mutation as well as modifier alleles. NR2E3 is a master regulator of several key pathways in retinal development and function. NR2E3 potentially prevents and attenuates disease by resetting the homeostatic state of key gene networks in the presence of a primary mutation (**Figure 3**).



**Figure 3 Schematic representation of potential *NR2E3* mediated therapy.** *NR2E3* potentially resets key gene networks that contribute to retinal degeneration in RP. RP—retinitis pigmentosa; PR—photoreceptor cells; Gene networks: M—Metabolism; I—Inflammation; O—oxidative stress; P—photoreceptor genes; S—cell survival.



*NR2E3* regulates multiple transcriptional networks, such as cell survival, metabolism, inflammation and phototransduction, that impact RP. *NR2E3* and *NR1D1* are cofactors that modulate many of the same gene networks. It was also demonstrated preclinically that *RORA* offers a protective allele in AMD where loss of photoreceptor cells leads to blindness. *NR2E3* regulates the expression of both *NR1D1* and *RORA*. Thus, the nuclear receptors work in overlapping networks to modulate normal retinal development and function. These receptors impact gene expression of hundreds of genes and numerous networks and, as such, may be potent modifiers of retinal disease and degeneration.

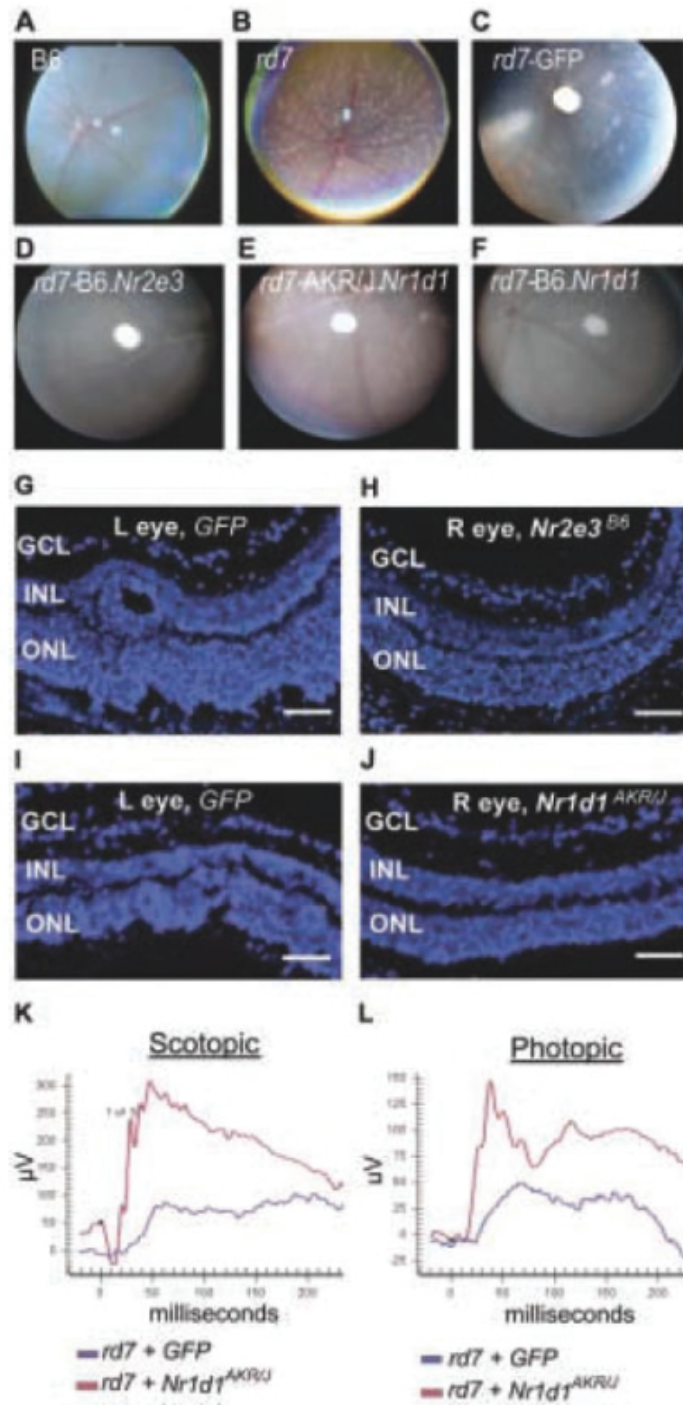
While there are several gene replacement clinical trials in progress, these treatments only address a few known RP genes and rely on identifying the primary mutation, which is not possible for approximately 40% of all RP patients. Additionally, the severity and progression of RP disease is greatly impacted by the genetic background in which the mutation is present.

*NR1D1*, an important NHR gene, regulates many processes, such as differentiation, metabolism and the circadian rhythms. Recently, various preclinical studies demonstrated a role for *NR1D1* in the retina. *NR1D1* forms a complex with *NR2E3*, *CRX* and *NRL*, key transcriptional regulators of retinal development and function. Importantly, *NR1D1* binds the *NR2E3* protein directly and acts synergistically to regulate transcription of photoreceptor-specific genes. Thus, *NR1D1* is a strong candidate to potentially modify the effects of *NR2E3*-associated retinal degeneration (**Figures 4 and 5**).

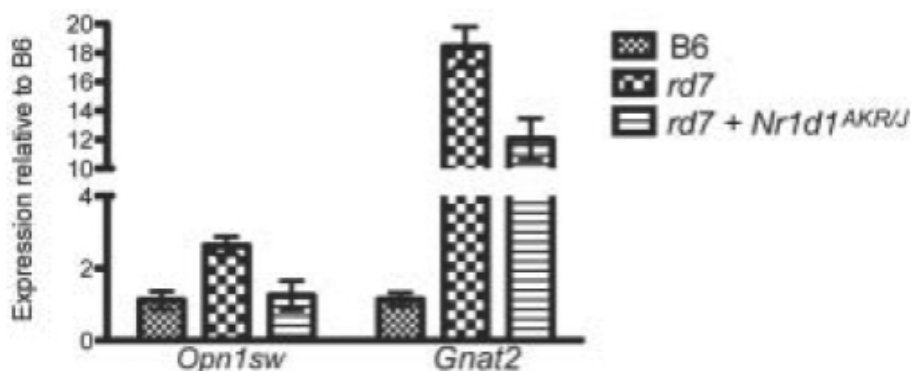
**Figure 4 Gene delivery of *Nr1d1* suppresses pan-retinal spotting, retinal dysplasia and function in *Nr2e3<sup>rd7/rd7</sup>* mice.** (A–F) Fundus photographs of control and rd7 injected retinas: (A) B6 (uninjected), (B) rd7 (uninjected), (C) GFP injected, (D) GFP.*Nr2e3<sup>B6</sup>* injected, (E) GFP.*Nr1d1<sup>AKR/J</sup>* injected, (F) GFP.*Nr1d1<sup>B6</sup>* injected. (G–J) DAPI staining (blue) shows rescue of defects in retinal morphology 30 days after electroporation into rd7 neonatal retinas.

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(G) GFP control, (H) *Nr2e3*<sup>B6</sup> injected, (I) GFP control, (J) *Nr1d1*<sup>AKR/J</sup> injected. L: left, R: right, GCL: ganglion cell layer, INL: inner nuclear layer, ONL: outer nuclear layer. Scale bar = 50  $\mu$ m. (K, L) Representative scotopic (K) and photopic (L) electroretinograms from animals four months after injection with GFP (blue) or GFP.*Nr1d1*<sup>AKR/J</sup> (red).



**Figure 5 Expression of phototransduction genes *Opn1sw* and *Gnat2* is rescued in rd7 retinas upon *Nr1d1* delivery.** Quantitative real time PCR (Polymerase chain reaction) shows that *Nr1d1* delivery results in down-regulation of the phototransduction genes *Opn1sw* and *Gnat2* in rd7 retinas (mean  $\pm$  SD of mean, n = 3, p<0.05), to near normal level in a preclinical model.



### Overview of Inherited Retinal Diseases

IRDs are caused by genetic mutations that are passed down within families and lead to progressive disease, severe visual impairment and blindness. Treating these conditions has been a significant challenge due to the sheer volume of potential therapeutic gene targets. Gene replacement therapy is a promising approach to provide a sustained restoration effect of normal retinal function for a mutated gene, but such therapies can only address one gene at a time, limiting their effectiveness. Developing a custom gene therapy for genetic defects in each of the more than 200 known genes linked to RP would not only be expensive but also may not be possible due to size, class, or localization that will impact delivery of the gene. Not all genes and disease expressions are amenable to gene therapy, and for the approximately 40% of patients whose genetic mutations remain unknown, there are few or no therapeutic options. Modifier gene therapy to ameliorate multiple forms of RP without requiring knowledge of the mutated gene, may provide a robust and feasible treatment for RP.

RP is a group of heterogeneous, pleiotropic IRDs that affect approximately one in every 4,000 individuals. Currently, there is no cure for RP and over 40% of RP cannot be genetically diagnosed. RP is heterogeneous and varies greatly in age of onset, rate of progression, and even genetic etiology, yet a common pathology of photoreceptor (PR) cell degeneration develops.

In addition to RP, no effective treatments are available for a large number of other retinal degenerative diseases including treatments specifically for dry AMD.

### Current treatments for IRDs

There is currently no approved treatment which slows or stops the progression of multiple forms of RP. Proposed treatments for RP include gene-replacement therapy, retinal implant devices, retinal transplantation, stem cells, vitamin therapy, and other pharmacological treatments. Gene-replacement therapies are promising but are limited to treating just a single mutation and therefore cannot address the multiple mutations implicated by RP. In addition, while gene therapies may provide a new functional gene, they do not necessarily eliminate the underlying genetic defect which may still cause stress and toxic effects. Therefore, the development of gene specific replacement therapy is highly challenging, especially when multiple and unknown genes are involved.

The FDA recently approved a gene therapy treatment (Luxturna™, Spark Therapeutics) for the treatment of biallelic RPE65 mutation-associated retinal dystrophy, which is one of at least 45 genes that could result in RP.

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As a result, there remains a significant unmet medical need for a treatment with application across multiple genetic forms of RP as well as other ocular degenerative diseases.

### ***Preclinical studies of OCU400***

Ocugen is currently studying human and mouse NHRs expressed in adeno-associated viral vectors in animal models representing various forms of human RP diseases. If these studies are successful, Ocugen plans to initiate current Good Manufacturing Practices (“cGMP”) production for clinical supplies and commence IND enabling non-clinical studies.

Ocugen plans to initiate a Phase 1/2a clinical trial targeting one IRD in next two years.

## **PRODUCT CANDIDATES FOR THE TREATMENT OF OCULAR SURFACE DISEASES**

### **OCU300 for the Treatment of Ocular Redness and Discomfort in Patients with Ocular Graft-versus-Host Disease**

Ocugen is developing its clinical product candidate, OCU300, for the treatment of ocular redness and ocular discomfort in patients with oGVHD. OCU300 is a brimonidine tartrate eye drop formulated as a topical nanoemulsion. Brimonidine tartrate is an  $\alpha_2$ -adrenergic receptor agonist and is approved for other ophthalmic indications. It has 1,000 times higher selectivity for  $\alpha_2$ -adrenergic receptors than  $\alpha_1$  adrenergic receptors.

In order to treat oGVHD, a viable product must have the ability to interrupt the pathological process of the disease, which can involve the local infiltration of inflammatory cells, the activation of leukocytes, fibrosis, the production of ECM proteins and the disruption of tear production. Ocugen believes brimonidine tartrate can treat oGVHD in the following ways:

- ***Reducing ocular surface blood flow.*** As an  $\alpha_2$ -adrenergic agonist, brimonidine tartrate may cause significant vasoconstriction leading to the reduction of blood flow to the ocular surface thereby potentially reducing local pressure, edema and inflammation.
- ***Disrupting leukocyte extravasation to the ocular tissue.*** Brimonidine tartrate may inhibit the infiltration of activated leukocytes by modulating endothelial cell activity.
- ***Suppressing leukocyte activation.*** Although inhibition of T lymphocytes has not been studied with brimonidine tartrate, activation of  $\alpha_2$ -receptors (with another  $\alpha_2$ -adrenergic agonist) has been shown to suppress the reactivation of T lymphocytes. However, induction of neutrophil apoptosis with brimonidine tartrate has been reported in acute inflammation.
- ***Providing antinociceptive (analgesic) properties.*** Brimonidine tartrate may antagonize or suppress the excitatory response of phenylephrine and nonadrenaline. As an  $\alpha_2$ -adrenergic agonist, brimonidine tartrate may attenuate pro-inflammatory cytokine release from leukocytes, which in turn may attenuate neuritis-induced pain.
- ***Reducing fibrosis and suppressing excessive ECM formation.*** Fibrosis in oGVHD is characterized by an excessive number of CD34+ fibroblasts, excessive fibrosis and the over accumulation of ECM in the lacrimal glands leading to the dysfunction of this exocrine gland. Brimonidine tartrate has been shown to attenuate the TGF- $\beta$ 1-induced production of ECM proteins, which in turn leads to the decrease in the synthesis of fibronectin and collagens in human fibroblasts.

By potentially attenuating autoimmune activity and inflammation, brimonidine tartrate may allow the ocular surface and tear film producing glands to avoid further atrophy and to heal from damage sustained during the HSCT pre-conditioning regimen. In addition, brimonidine tartrate may alleviate heightened ocular pain through its antinociceptive and anti-inflammatory properties, which in turn, may potentially make the drug more tolerable and more effective. Brimonidine tartrate is approved for other indications by the FDA and has demonstrated a favorable safety profile via topical ocular delivery.

### ***Overview of Ocular Graft-versus-Host Disease***

oGVHD is a severe ocular autoimmune disease that occurs in up to 60% of allogeneic HSCT recipients. It is recognized by the National Institutes of Health and clinical experts as a distinct organ manifestation of chronic graft-versus-host disease and in August 2017, the FDA granted ODD to OCU300 for the treatment of oGVHD. oGVHD is a predictable manifestation of chronic graft-versus-host disease that occurs exclusively in patients undergoing allogeneic HSCT. oGVHD is etiologically driven by an autoimmune mechanism and initiates immediately after bone marrow transplant completion with the encroachment of autoimmune cells onto the ocular surface. HSCT-derived leukocytes (*i.e.*, T lymphocytes and neutrophils) invade the ocular surface of HSCT recipients, resulting in excessive production of ECM proteins, and fibrosis. The donor leukocytes subsequently launch an autoimmune assault on the recipient eye's tear producing glands, cornea, conjunctiva, and eyelid. The disease typically affects all major ocular surface tear film glands (*i.e.*, the lacrimal gland, conjunctiva, and meibomian gland), as well as the cornea.

If left untreated, oGVHD can cause irreparable ocular surface damage and significant vision loss. The disease is most commonly associated with severe dry eye signs and symptoms, including visual hazing, reduction in visual acuity, photophobia, excessive ocular redness caused by hyperemia and telangiectasia, foreign body sensation, and heightened ocular pain. In more severe cases, oGVHD can cause lens opacification, significant corneal epithelium degeneration and melting, including the development of corneal ulcers and corneal perforation. Patients with severe oGVHD may require multiple corneal grafts or surgeries to improve visual acuity.

Patients with oGVHD experience significant vision-related impairment leading to an overall decrease in their quality of life. Of the clinical symptoms reported with oGVHD, ocular pain is the one that most severely impacts the quality of life. In fact, the pain scores in oGVHD patients are comparable to those of patients suffering from ocular chemical burns. Furthermore, patients with oGVHD have difficulties in performing both near-vision activities and distance-vision activities, both centrally and peripherally, and suffer from cases of vision-related mental health decline. The majority of patients with oGVHD become disabled and are unable to work and have reduced social functioning.

### ***Absence of Approved Treatments for oGVHD Provides a Market Opportunity***

According to the Center for International Blood and Marrow Transplant Research (“CIBMTR”), the number of allogeneic transplant recipients in the United States in 2016 was 8,539, a 20% increase since 2010. Up to 60% of these patients are expected to develop oGVHD, which equates to approximately 5,000 new cases of oGVHD in the United States per year based on the current number of patients undergoing HSCT in the United States. A recent study using data from CIBMTR projected that there would be 105,000 surviving allogeneic HSCT recipients in the United States by 2020, which is anticipated to grow to a total of 234,000 survivors by 2030.

There are currently no FDA approved drug products for the treatment of oGVHD. oGVHD, if left untreated, can cause significant vision loss and irreparable ocular surface damage. In addition to direct harm to individuals suffering from oGVHD, the disease is associated with a significant economic impact on both patients and society. It has been estimated that the combined direct medical costs (*e.g.*, prescription therapy, procedures, physician visits) and indirect costs (*e.g.*, lost wages/productivity) resulting from oGVHD in the United States aggregate to approximately \$18,000 per patient per year.

### ***Data from Preclinical and Clinical Studies***

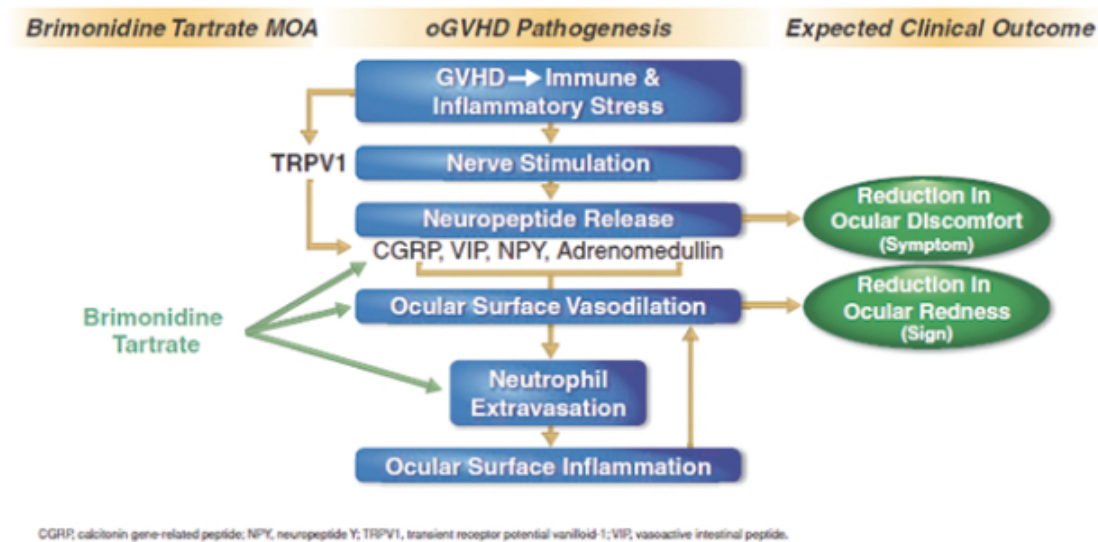
#### ***The interrelationship between oGVHD pathogenesis and mechanism of action of brimonidine tartrate***

Ocugen postulates that the potential mechanism of action of brimonidine tartrate blocks specific steps in the pathogenesis of oGVHD, and by extension, specific intended clinical outcomes. This, in turn, provides a rationale for selecting endpoints in late-stage clinical studies. These potential interrelationships are summarized in **Figure 6**. As noted in the figure, brimonidine tartrate's activity as an  $\alpha_2$ -adrenergic agonist may interrupt and/

or mitigate various steps in the pathologic process of oGVHD, thereby potentially decreasing ocular redness and ocular discomfort.

The disease is driven by the invasion of HSCT derived leukocytes onto the ocular surface, resulting in fibrosis and excessive production of ECM proteins. The donor leukocytes subsequently launch an autoimmune assault on tear producing glands, cornea, conjunctiva, and the eyelid of the recipient. oGVHD can cause irreparable damage to these ocular tissues, thereby decreasing the secretion and stability of tear film. Prolonged inflammation can result in ocular pain and discomfort, corneal ulceration, cicatricial conjunctivitis, blepharitis, and vision loss.

**Figure 6 Brimonidine tartrate potential mechanism of action and expected clinical outcome**



Ocugen’s preclinical data, data from the literature supporting the potential of brimonidine tartrate in both *in-vitro* and *in-vivo* animal studies, data from a prospective clinical study and a retrospective clinical study are summarized below. In the discussion below, statistical significance is denoted by p-values. The p-value is the probability that the reported result was achieved purely by chance (*e.g.*, a p-value of <0.01 means that there is a less than a 1.0% chance that the observed effect was due to chance). Generally, a p-value less than 0.05 is considered statistically significant.

*Preclinical Study: Mouse Model*

In 2018, Ocugen completed a preclinical study that assessed the effect of OCU300 in a mouse model on corneal surface inflammation and damage, as well as lacrimal gland pathology, which are the hallmarks of oGVHD pathology. Goblet cell loss in the conjunctiva was also measured. Ocugen used an established DED mouse model which shares a number of pathophysiological properties of oGVHD in humans.

For this study, C57BL/6 mice were exposed to a desiccating environment (controlled air flow at 15 liters/min and 5% humidity) combined with transdermal administration of scopolamine for a period of two weeks. Treatments were started one day prior to exposure to the desiccating environment and continued throughout the induction treatment period. OCU300 (brimonidine tartrate 0.18%) and appropriate control compounds were topically instilled at 10 µl in each eye, twice a day. At the end of the study corneal surface inflammation and damage was assessed by fluorescein staining. Lacrimal gland pathology was scored by a qualitative assessment of the extent of immune cell infiltration and parenchymal damage based on hematoxylin and eosin, or H&E, staining. The number of goblet cells in the conjunctiva was quantified using stereological counting of PAS-stained sections.

As shown in Figure 7 below, the protective effect of OCU300 against corneal epithelial damage in comparison to untreated control, placebo nanoemulsion control and brimonidine tartrate 0.2% is demonstrated in a mouse DED model. OCU300 showed statistically significant protection against corneal epithelial cell damage in comparison to untreated and placebo controls ( $p < 0.05$ ) and a commercial brimonidine tartrate solution ( $p < 0.01$ ). These results indicate that OCU300 may provide significantly better protection for corneal epithelial damage than placebo (vehicle) and a marketed brimonidine tartrate. The difference between OCU300 and brimonidine tartrate 0.2% provides support for the potential importance of its nanoemulsion formulation in contributing to the treatment of oGVHD. In addition, OCU300 significantly reduced the lacrimal gland pathology compared to the untreated control group ( $p < 0.01$ ). Goblet cell data showed a numerical improvement trend compared to the untreated control group.

**Figure 7 Effect of OCU300 OcuNanoE™ against corneal epithelial damage in comparison to a placebo nanoemulsion, cyclosporine, lifitegrast and a commercial brimonidine tartrate using a mouse DED model. \* $P < 0.05$ , \*\* $P < 0.01$**

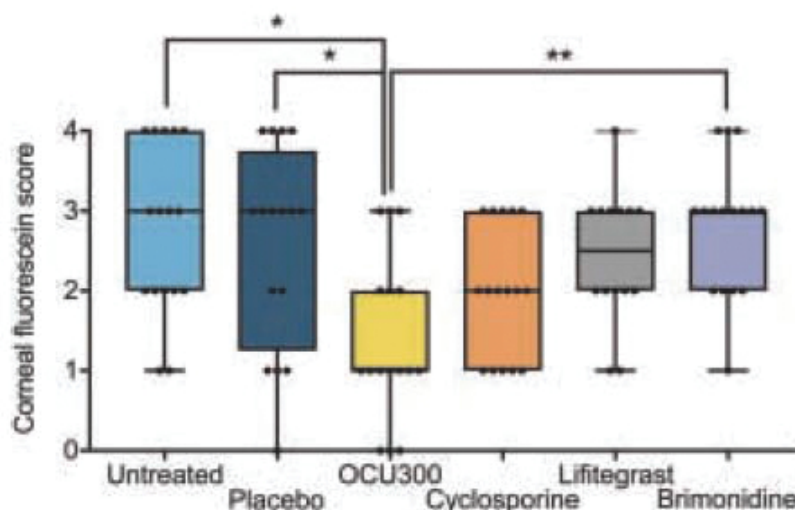


Figure showing medians, interquartile ranges, and min/max fluorescein scores by treatment.

*Preclinical Study: Demonstration of OCU300 Ocular Distribution in Dutch-Belted Rabbits*

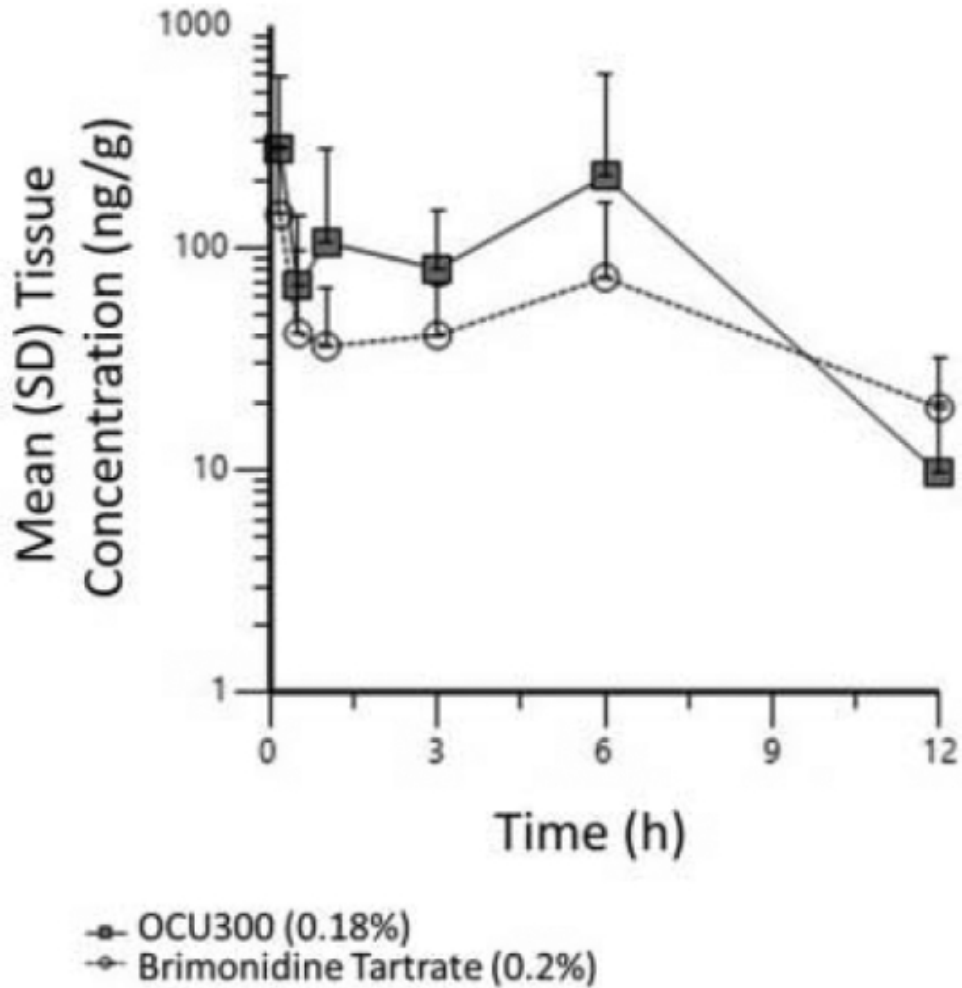
In 2018, Ocugen completed a preclinical ocular distribution study in dutch-belted rabbits that analyzed the distribution of brimonidine tartrate after the topical treatment with OCU300 in comparison to a brimonidine tartrate 0.2% solution.

Tear film is composed of the inner mucin layer, the middle aqueous component and the outer lipid layer. The mucin layer is derived from goblet cells from the conjunctiva and lacrimal glands; the aqueous layer is derived from the lacrimal glands; and the lipid layer is derived from the meibomian glands. One drawback of topical treatment of ocular redness and discomfort in patients with oGVHD is that approximately 90% of topical drugs applied to the anterior segment of the eye is lost into systemic circulation. The rest of the drug must reach a minimum threshold concentration in the target tissues, such as the lacrimal glands, conjunctiva and cornea, in order to exert the functional characteristics of the therapeutics. Therefore, treatment of oGVHD requires the stabilization of tear film and targeting of the drug molecule at sufficient concentrations to the lacrimal functional unit, which is primarily responsible for the tear film production and stability. OCU300 is formulated with Ocugen’s proprietary OcuNanoE™ which is designed with a nanoemulsion formulation that Ocugen believes

decreases the drainage rate, prolongs precorneal residence time and increases the drug concentration in the lacrimal tissues.

Figure 8 provides brimonidine tartrate concentration in the lacrimal gland following a single dose with OCU300 versus brimonidine tartrate 0.2% solution. Dutch-belted rabbits were dosed with either OCU300 or a brimonidine tartrate 0.2% solution and the lacrimal glands were removed at various intervals of time and analyzed for the content of brimonidine tartrate. Results are represented as ng/gm in the Y-axis. The preclinical study showed that, after a single dose, brimonidine tartrate levels in the dutch-belted rabbits were numerically higher in the group treated with OCU300 compared to brimonidine tartrate levels in the group treated with brimonidine tartrate 0.2% solution for up to six hours, which provides support for the relative increased distribution of OCU300 in the lacrimal gland.

**Figure 8 Brimonidine tartrate content (ng/gm) in the lacrimal gland after a single dose administration of OCU300 versus brimonidine tartrate 0.2%.**



In summary, Ocugen’s data reported in the preclinical study supports the thesis that OCU300 distributes brimonidine tartrate to the lacrimal gland to a greater extent than a formulation without OcuNanoE™.



### Scientific Literature to Delineate MOA of Brimonidine Tartrate

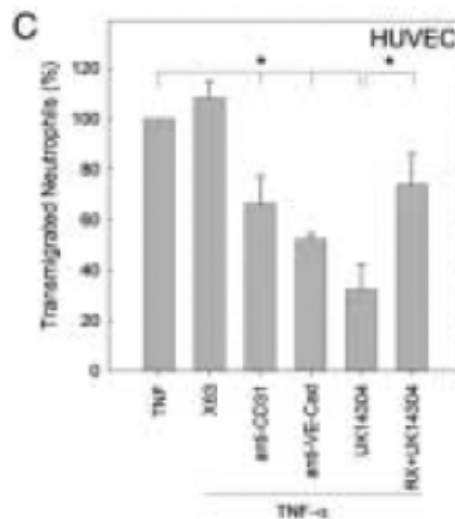
#### Brimonidine tartrate's vasoconstriction properties and inhibition of local edema

Brimonidine tartrate is a potent vasoconstrictor. In an *ex vivo* human skin biopsy neural inflammation model, brimonidine tartrate was shown to significantly inhibit vasodilation of human blood vessels exposed to capsaicin. Further, in an *ex vivo* model, brimonidine tartrate was shown to attenuate the vasodilation of subcutaneous vessels with a diameter of less than 200 micrometers, approximately 13 times larger than typical capillaries of the conjunctiva, suggesting brimonidine tartrate may have vasoconstriction effects on conjunctival vessels. Supowit et al. demonstrated that brimonidine tartrate attenuates the release of calcitonin gene-related peptide, a key neurotransmitter in the dorsal root ganglia neurons of adult rats that, in turn, mediates inflammation and vasodilation. In an *in vivo* mouse ear inflammation model, brimonidine tartrate inhibited ear edema by up to 76%.

#### Inhibition of activated leukocyte migration

$\alpha_2$ -adrenergic agonists, such as brimonidine tartrate, are thought to disrupt leukocyte extravasation into inflamed tissue by modulating endothelial cell activity. Herrera-Garcia et al. demonstrated in a preclinical model that brimonidine tartrate significantly decreased neutrophil trans-endothelial migration ( $p < 0.05$ ). Brimonidine tartrate also restricted macromolecular and ion transport in human umbilical vein endothelial cells, or HUVECs. In addition, brimonidine tartrate decreased ICAM-1-mediated VE-cadherin phosphorylation on HUVEC cells (ICAM-1 and VE-cadherin play crucial roles in leukocyte extravasation via the destabilization of endothelial cell adherens junctions). The authors additionally demonstrated that brimonidine tartrate restricted L-selectin shedding and CD11b up-regulation in pre-treated neutrophils activated with IL-8, both critical steps in neutrophil extravasation into inflamed tissue.

**Figure 9 Brimonidine tartrate (UK14304) disrupts neutrophil trans-endothelial migration in HUVEC cell culture**



Data represent mean  $\pm$  SD from three independent experiments (percentage of migrated neutrophils) compared with cell migration in TNF- $\alpha$ -activated neutrophils, which was considered 100% \* $p < 0.05$ .

#### $\alpha_2$ -adrenergic agonists potently disrupt leukocyte activation

$\alpha_2$ -adrenergic agonists are also thought to suppress leukocyte reactivity and activation and may cause leukocyte apoptosis at high concentrations. This effect may particularly be seen with T cell lymphocytes and neutrophils.

Notably, clonidine (an  $\alpha$  agonist) markedly diminishes leukocyte proliferation and interferes with the release of TNF  $\alpha$ , IFN-g, IL-1 $\alpha$ , IL-1b, IL-4 and IL-6. Clonidine shifts leukocyte cytokine activity to an anti-inflammatory profile, suggesting that both brimonidine tartrate and clonidine may have leukocyte inhibitory properties. Herrera-Garcia et al. demonstrated that brimonidine tartrate significantly decreased the recruitment and accumulation of neutrophils in an acute inflammation mouse model ( $p < 0.01$ ), suggesting that suppression of activated leukocytes may be one of the key mechanisms of action of brimonidine tartrate in oGVHD.

### *Potential ocular antinociceptive activity*

Brimonidine tartrate is believed to act as an ocular antinociceptive via its antagonistic effects on nociceptive receptor signaling. The compound has been shown in a preclinical model to significantly suppress the stimulation of nociceptive receptors in the murine cerebral cortex by antagonizing the pro-inflammatory effects of norepinephrine and phenylephrine. Nociceptive neuron activation in ocular surface tissue is linked to elevated ocular pain, photophobia, ocular discomfort, and ocular surface inflammation. Calcitonin gene-related peptide, or CGRP, and substance P are two neuropeptides linked to chronic ocular surface inflammation and hyperemia; nociceptive corneal nerves release CGRP and substance P when the cornea is wounded. The neural inflammatory peptides spur the recruitment of immune cells onto the ocular surface and the up-regulation of pro-inflammatory cytokines and hyperalgesia. Nociceptive neurons that release CGRP are found in the conjunctiva and eyelid including the meibomian glands. An immunohistochemical study on primate meibomian tissue confirmed the presence of CGRP and substance P releasing nociceptive nerves.

### *Mediation of fibroblast activity and production of ECM proteins*

Brimonidine tartrate may alleviate ocular surface fibrosis and stimulate corneal wound healing. Hong et al. demonstrated in a preclinical model that brimonidine tartrate down-regulated TGF-beta activity in human Tenon's fibroblasts suggesting that brimonidine tartrate acts as an anti-fibrotic compound. It is possible that brimonidine tartrate may alleviate hyperkeratinization and fibrotic conditions found in the meibomian glands, lacrimal glands, conjunctiva, and cornea in oGVHD patients. It has also been shown that fibroblasts, excessive fibrosis, and over accumulation of ECM proteins in the lacrimal glands play a role in the dysfunction of the lacrimal gland.

### **OCU300 Early Clinical Studies**

Two early clinical studies were completed by a principal investigator at the University of Illinois at Chicago (Dr. Sandeep Jain). The first study was an exploratory study, which included retrospective analyses. The second study was a prospective Phase 1/2 placebo-controlled study. While there are limitations to these two studies, the study results informed Ocugen's choice of endpoint assessments for its current ongoing Phase 3 clinical trial.

### *Retrospective exploratory study in patients with oGVHD*

In 2015, Dr. Jain performed a retrospective analysis on the topical use of brimonidine tartrate 0.15% in 18 patients, or a total of 36 eyes, with oGVHD and related Meibomium Gland Dysfunction (MGD) who complained of persistent ocular discomfort despite aggressive topical therapy with lubricants and anti-inflammatory agents. Patients were evaluated using a subjective endpoint (Subject Global Assessment, or SGA) as well as a clinical endpoint (Clinical Global Impression, or CGI). All included patients had ocular discomfort, along with clinical signs of MGD, such as eyelid margin telangiectasia, eyelid margin excoriation, ocular surface keratinization and poor or no expression of meibomian gland secretion upon digital pressure.

One drop of a commercially available brimonidine tartrate 0.15% solution was instilled twice a day on the ocular surface of each eye. At the 6-month follow-up visit, patients were asked to assess their overall change in comfort from baseline using the 5-point SGA scale, while Dr. Jain completed the 7-point CGI scale. As a hypothesis-generating, exploratory study using retrospective analyses, the study was not powered for statistical significance due to a small sample size. There was no control group.

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The eye drops were well-tolerated. No patients complained of allergic symptoms or reactions or discontinued brimonidine tartrate use during the study.

Approximately 90%, or 16 out of the 18 patients, reported a subjective benefit from brimonidine tartrate, with SGA scores of “Much Improved” (N=10) or “Improved” (N=6). Results of clinical examination of the meibomium gland were consistent with subject-reported benefits and included reduced eyelid margin telangiectasia; reduced eyelid margin excoriation; and improved expression of meibomian gland secretion upon digital pressure.

### *Prospective Phase 1/2 placebo-controlled study*

The second study was designed as a prospective randomized, placebo-controlled, double-blind Phase 1/2 study, in which a total of 51 patients with oGVHD were to be enrolled at one clinical site. Subjects were randomly assigned 1:1:1 to three treatment groups (placebo, brimonidine tartrate 0.15% or brimonidine tartrate 0.075%), with 17 subjects planned per group. The brimonidine tartrate solution that was used in the study was different than the formulation Ocugen is using in its Phase 3 clinical trials. Although the study was terminated early due to slow enrollment, important information was collected around key signs, such as redness.

The primary endpoint analysis showed similar tolerability between the combined brimonidine tartrate dose level groups and the artificial tears group (five and six subjects, respectively) at week 12.

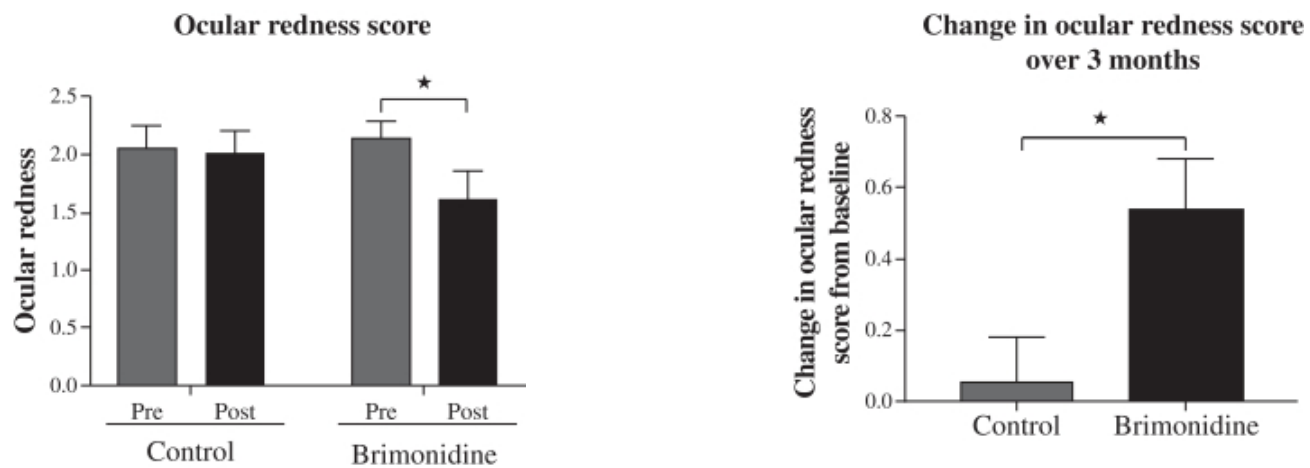
As part of an exploratory endpoint assessment, data were available for a subset of eight patients, or a total of 16 eyes, who received either brimonidine tartrate 0.15% (three patients or six eyes) or artificial tears (five patients, ten eyes) and had paired ocular redness scale, or ORS, assessments for pre-dose and three-months (12 weeks) post-dose. ORS was measured using a Keratograph 5M according to the manufacturer’s instruction.

Statistical significance is denoted by p-values. The p-value is the probability that the reported result was achieved purely by chance (e.g., a p-value of <0.01 means that there is a less than 1.0% chance that the observed effect was purely due to chance). Generally, a p-value less than 0.05 is considered statistically significant in an adequately powered study. As shown in the figure on the left below, for within group comparisons, the difference in mean ORS from pre- to post-dosing was significant at the  $p < 0.05$  level for the brimonidine tartrate group, but not for the control group. Moreover, as shown in the figure to the right below, for between-group comparisons, the difference in mean ORS at three-months (post-dosing) was significantly higher ( $p < 0.05$ ) for the brimonidine tartrate group relative to the control group in an analysis that assumed independence between eyes within a subject. Although most cases of oGVHD eventually involve both eyes, the pathologic process affects each eye in a slightly different way over a slightly different time, so that independent assessments of each eye are necessary at all study visits. These assessments are compared back to baseline for each eye. This same comparison had a p-value = 0.0921 in an analysis that accounted for the correlation between eyes within a subject. Looking at only one eye per patient, the worst eye, the numbers are too low for statistical significance, but there is a two-fold difference between the control and brimonidine groups in the change in redness score three months post dosing and therefore the results are still supportive.

It is possible to have a positive result based on a p-value less than 0.05 in a study that is not adequately powered due to a small sample size. In this case, the result should be regarded as a signal to be confirmed in a larger, adequately powered study. In summary:

- 1) A difference in ocular redness score is observed if all eyes are included, and
- 2) A positive trend (2x) in favor of brimonidine is observed when accounting for the correlation between two eyes (worst eye analysis).

**Figure 10 Ocular redness score in oGVHD patients receiving either brimonidine tartrate 0.15% or artificial tears (control)**



\* P value (<0.05)

Moreover, in a subset of 6 subjects (12 eyes) with chronic ocular and systemic GVHD, “discomfort”, as measured by SGA, was noted to be “Improved” in 3 subjects (50%) and “About the Same” in the remaining 3 subjects (50%), without any evidence of worsening, over the 3-month study.

#### **Ongoing OCU300 Phase 3 Clinical Trials**

A registration trial for OCU300 was initiated in June 2018 and the first patient was dosed in December 2018. As of May 2019, Ocugen has enrolled approximately 20% of patients into the first study. Ocugen plans to conduct two identical trials. These studies will test OCU300 brimonidine tartrate (0.18%) OcuNanoE™ Ophthalmic Solution against placebo (ophthalmic buffered saline) for safety and efficacy based on reducing ocular redness and ocular discomfort after 84 days of treatment. The primary objective of each study is “To evaluate the safety, tolerability, and efficacy of brimonidine tartrate nanoemulsion eye drops in patients with ocular Graft-vs-Host Disease (oGVHD)”. The study has two primary endpoints, ocular discomfort and ocular redness, which are also supported by the International Chronic Ocular Graft-vs-Host-Disease Consensus Group (Ogawa et al., 2013). That is, two of the Consensus Group’s four criteria include ocular pain/discomfort (as measured by the OSDI scale) and ocular redness (as measured by a conjunctival injection scale).

The pivotal trials will enroll approximately 60 patients in each study, randomized 2:1 (active: placebo). Subjects will be permitted to continue their existing ocular treatments. The trials are designed to measure the efficacy of OCU300 compared to placebo, dosed twice daily for approximately three months. After a baseline visit, patients will be observed during three additional visits, at Day 28, Day 56, and Day 84.

The co-primary endpoints of the Phase 3 trials are:

- Ocular redness based on a 100-point Validated Bulbar Redness scale measuring change in appearance from baseline to Day 84; and
- Ocular discomfort based on a 10-point Visual Analog Scale measuring change in intensity from baseline to Day 84. This scale is designed to capture the type of severe discomfort or pain often seen with oGVHD patients and has been validated as an assessment of pain intensity in multiple populations. Moreover, it has been recommended as the primary endpoint for use in clinical trials for chronic pain.

A sample size re-estimation is planned after data are collected on approximately the first 50% of enrolled subjects.

Through these clinical trials Ocugen will also conduct standard safety assessments.

These trials are intended to support the indication of the “treatment of ocular redness and ocular discomfort in patients with oGVHD”, using the FDA’s 505(b)(2) regulatory pathway. In addition to these trials, Ocugen may need to conduct additional OCU300 development work before submitting an NDA to the FDA for product candidate approval.

Severe ocular inflammation is a key factor in the pathogenesis oGVHD. Ocular inflammation, in turn, contributes to ocular redness and discomfort. As a result, ocular redness and discomfort are markers of inflammation in patients with oGVHD. By choosing ocular redness and ocular discomfort as co-primary endpoints, Ocugen is indirectly assessing brimonidine tartrate’s anti-inflammatory properties. There are no products available that can adequately relieve the debilitating discomfort of oGVHD. Ocugen believes that a treatment that can reduce ocular redness (and hence inflammation) while relieving ocular discomfort would significantly enhance the quality of life for patients suffering from oGVHD.

In addition to its potential overall anti-inflammatory properties, brimonidine tartrate may have a direct effect on both ocular redness and discomfort. First, as an  $\alpha_2$ -adrenergic agonist, brimonidine tartrate may cause significant vasoconstriction leading to the reduction of blood flow to the ocular surface, thereby reducing redness. Second, brimonidine tartrate may act as an ocular analgesic by interrupting nociceptive pathways. Brimonidine tartrate has been shown to significantly suppress the stimulation of nociceptive receptors in the murine cerebral cortex by antagonizing the effects of norepinephrine and phenylephrine. Nociceptive neuron activation in ocular surface tissue is linked to elevated ocular pain, photophobia, and ocular discomfort.

### **OCU310 for the Treatment of Dry Eye Disease**

Ocugen’s OCU310 is being developed as a non-steroidal solution to provide patients suffering from DED with relief from the signs and symptoms of their disease. OCU310 is an investigational twice-daily, steroid-free, preservative-free eye drop of brimonidine tartrate 0.2% formulated with OcuNanoE™. OCU310 is expected to compete against Restasis®, Xiidra® and various over-the-counter products.

Ocugen believes that OCU310 has a favorable profile for the management of DED, including the following potential attributes:

- ***Favorable drug distribution profile.*** As discussed in the context of OCU300 above, based upon a preclinical study, Ocugen believes its brimonidine tartrate nanoemulsion formulation enhances distribution of brimonidine tartrate in the lacrimal glands.
- ***Favorable tolerability profile.*** OCU310 is sterile filtered and does not contain preservatives, therefore reducing the likelihood of allergic adverse events and ocular inflammation that sometimes result from the topical administration of ophthalmic formulations that contain preservatives, such as benzalkonium chloride.
- ***Time to onset of relief.*** Ocugen believes that OCU310 has the potential for symptomatic relief in patients with DED as early as 28 days following the initiation of treatment. In its Phase 2 clinical trial, patients treated with brimonidine tartrate monotherapy reported reductions in DED symptoms within 28 days of initiation of treatment based on topline results.
- ***Multiple modes of action.*** Ocugen believes that OCU310 has the potential to have a direct analgesic effect and reduce ocular surface inflammation via multiple modes of action on inflamed ocular surface tissue and activated leukocytes:
  - ***Leukocyte inhibition.*** Brimonidine tartrate may inhibit leukocyte extravasation and activation in ocular surface tissue, a notable mechanistic modality.

- **Suppression of leukocyte activation.** Although inhibition of T lymphocytes has not been studied with brimonidine tartrate, activation of  $\alpha_2$ -receptors (with another  $\alpha_2$ -adrenergic agonist) has been preclinically shown to suppress the reactivation of T lymphocytes. Induction of neutrophil apoptosis with brimonidine tartrate has been reported preclinically in acute inflammation.
- **Attenuation of proinflammatory cytokine release.** As an  $\alpha_2$ -adrenergic agonist, brimonidine tartrate may attenuate pro-inflammatory cytokine release from leukocytes, which in turn may attenuate neuritis-induced pain.
- **Vasoconstrictive properties.** As an  $\alpha_2$ -adrenergic agonist, brimonidine tartrate may significantly cause vasoconstriction leading to the reduction of blood flow to the ocular surface, which, in turn, may reduce local pressure, edema and inflammation. In this manner, OCU310 has the potential to reduce redness of the ocular surface.

### **Overview of Dry Eye Disease**

DED is a common ocular disorder involving the aberrant production, composition and instability of tear film, which results in damage to the ocular surface and is correlated with symptoms of ocular discomfort. DED is also recognized as keratoconjunctivitis sicca, sicca syndrome, keratitis sicca, xerophthalmia, dysfunctional tear syndrome, ocular surface disease or dry eye. DED is caused by chronic instability of precocular tear film.

Tear film instability can be triggered by insufficient tear production or by poor tear film quality that results in increased tear evaporation. DED is typically categorized into two groups: 1) aqueous tear deficient DED and 2) evaporative DED. DED is a result of changes to the lacrimal functional unit, or LFU. The LFU is composed of the lacrimal glands, cornea, eyelids, meibomian glands, conjunctiva, goblet cells and ocular nerves. The LFU is responsible for the sustained production of adequate tear film to consistently lubricate the ocular surface. Structural changes to the LFU can induce tear film instability and insufficiency, which in turn can lead to tear hyperosmolarity. Chronic osmotic stress from tear film can activate stress associated pathways in ocular surface epithelial cells, thereby triggering a pro-inflammatory response that involves a mix of chemokines, cytokines, and matrix metalloproteinases. The subsequent maturation of antigen-presenting cells on the ocular surface leads to the migration, activation and expansion of autoreactive T cell lymphocytes as well as other leukocytic classes in the LFU. The constant recruitment of pro-inflammatory leukocytes onto the ocular surface inflicts epithelium damage in the form of small abrasions and epithelium barrier defects. These abrasions can eventually progress to superficial punctuate keratitis, squamous metaplasia, ECM deposits, decreased goblet cell differentiation, increased epithelial cell turnover (epitheliopathy) and significant ocular surface nerve damage and neuropathy.

As DED progresses, lacrimal gland obstruction, meibomian gland orifice obstruction, thickened eyelid margins, cloudy, solid, or granular meibum secretion, eyelid telangiectasia and meibomian gland dysfunction become common clinical features. In advanced cases, dry eye disease can cause fibrotic thickening of the cornea and conjunctiva, filamentous keratitis, mucoid clumping, trichiasis, symblepharon, keratinization of the eyelids and meibomian glands, corneal and conjunctival erosion and thinning, corneal and conjunctival neovascularization, corneal and conjunctival scarring, corneal ulceration and corneal perforation. In addition, prolonged ocular surface inflammation can lead to moderate or absolute loss/atrophy of the meibomian glands, lacrimal glands and conjunctival goblet cells, and subsequently a dramatic reduction in tear film production and the onset of permanent DED.

The prevalence of DED increases with age. The most common causes of DED are contact lens usage, autoimmune disorders, systemic drug effects and refractive surgeries, particularly in middle-aged and older adults. Other contributing factors include fever, allergens, low humidity, wind, commercial travel and prolonged digital device usage. DED also occurs in a higher percentage of women than men, especially in women entering menopause or pregnancy as hormone imbalances during menopause or pregnancy can cause lacrimal gland and ocular surface inflammation and tear film abnormalities.

Common signs and symptoms of DED include eye redness, ocular pain, burning and stinging sensation, foreign body sensation, pruritus, itchy or scratchy eye sensation, tired eyes, enhanced eye pressure, photophobia, painful mucous discharge and, in some cases, epiphora. DED typically affects eyes bilaterally. DED can impact visual function especially during visually intensive activities and can decrease overall quality of life.

*Market Size and Limitations of Approved Treatments for DED Provides Market Opportunity*

DED is among the most common ocular morbidities with approximately one in four of all patients who visit ophthalmic clinics reporting symptoms to their physician. Based on a prevalence rate of 14.5% of the adult population, it is estimated that approximately 35 million patients have dry eye symptoms in the United States. Of these patients, it has been reported that approximately 16 million have been diagnosed with DED. Of the estimated 16 million patients who have been diagnosed with DED, Ocugen estimates that approximately 1 million patients receive an FDA approved on-label prescription therapy. The DED market has grown since 2016 due to new therapies entering the market and increased disease awareness. Ocugen believes, however, that an unmet medical need still exists for a large population of patients.

DED also imposes a substantial economic burden on patients, the health care system, and society as a consequence of direct medical costs related to health care professional visits, pharmacologic therapies, surgical procedures, and indirect costs related to loss of work days and reduced productivity. It has been estimated that the direct medical cost of the disease in the United States is \$3.8 billion annually and the overall societal cost of the disease in the United States is \$55 billion annually, primarily attributable to lost work time.

There are currently FDA approved marketed products for DED, including Restasis® and Xiidra®, which had sales of approximately \$2.5 billion in the United States for the 12-month period ended June 30, 2018. Restasis® 0.05% contains cyclosporine and is indicated to increase tear production in patients whose tear production is presumed to be suppressed due to ocular inflammation associated with keratoconjunctivitis sicca. The most common adverse reaction following use of Restasis® is ocular burning.

Xiidra® 5% is a lymphocyte function-associated antigen antagonist (lifitegrast) indicated for the treatment of the signs and symptoms of DED. Per the Xiidra® prescribing information, the most common adverse reactions, reported in 5 to 25% patients, are instillation site irritation, dysgeusia (an unusual taste sensation) and decreased visual acuity.

In addition to Restasis® and Xiidra®, clinicians typically prescribe artificial tear eye drops and topical corticosteroids for DED. Antibiotics (tetracyclines and macrolides), non-steroidal anti-inflammatory agents, autologous serum drops, omega fatty acids, mucin secretagogues, and anti-inflammatory agents are also used to combat DED symptoms. In addition, prosthetic scleral lenses (i.e. PROSE) that also serve as supplemental tear reservoirs are increasingly being prescribed to enhance ocular surface hydration in patients with chronic DED. Hot eyelid compresses are often utilized to treat meibomian gland dysfunction, a primary driver of evaporative DED. In advanced cases of DED, punctal plugs can be installed to block tear drainage. In severe cases of dry eye, tarsorrhaphy surgery, tear duct cauterization, or amniotic membrane transplant might be required to reduce tear evaporation.

Overall, given the complexity, severity and frequency of DED and the limited modes of action by which Restasis®, Xiidra® and other available treatments currently treat dry eyes, Ocugen believes that there is a medical need for other dry eye therapies, particularly those with potential multiple modes of action that may be effective for a wider dry eye population.

**Data from Preclinical and Clinical Studies of OCU310**

*Preclinical Study of Brimonidine Tartrate*

As discussed above in “Preclinical Study: Mouse Model,” Ocugen assessed the effect of OCU300 (brimonidine tartrate 0.18%) in a preclinical study using an established DED mouse model. The results from this study indicate

that brimonidine tartrate formulated with OcuNanoE™ may provide significantly better protection against corneal epithelial cell damage in comparison to a commercially available brimonidine tartrate and other control groups.

### **OCU310 Phase 2 Clinical Study**

In 2017, Ocugen conducted a Phase 2 placebo-controlled, proof-of-concept clinical study where patients with DED were dosed with brimonidine tartrate 0.2%, with and without loteprednol etabonate 0.2%, twice a day for 84 days. The brimonidine tartrate solution that was used in this study was different than the formulation Ocugen used in its Phase 3 clinical trial. The primary endpoint of this study was to establish whether subjects with DED receiving brimonidine tartrate 0.2% eye drops, alone or in combination with loteprednol etabonate 0.2%, twice a day for 84 days had tolerability scores that were similar to subjects on placebo. Several prospectively defined exploratory endpoints for common signs and symptoms also were assessed to allow for the selection of the primary endpoints for Phase 3 clinical trials. These exploratory endpoints were used to investigate the effect of brimonidine tartrate 0.2% topical eye drop solution, alone or in combination with loteprednol etabonate 0.2%, in treating the signs and symptoms of DED, allowed Ocugen to select endpoints for Phase 3 clinical trials.

As part of this randomized, placebo-controlled, double-blind study, 84 patients at three clinical sites were randomly assigned to one of three groups:

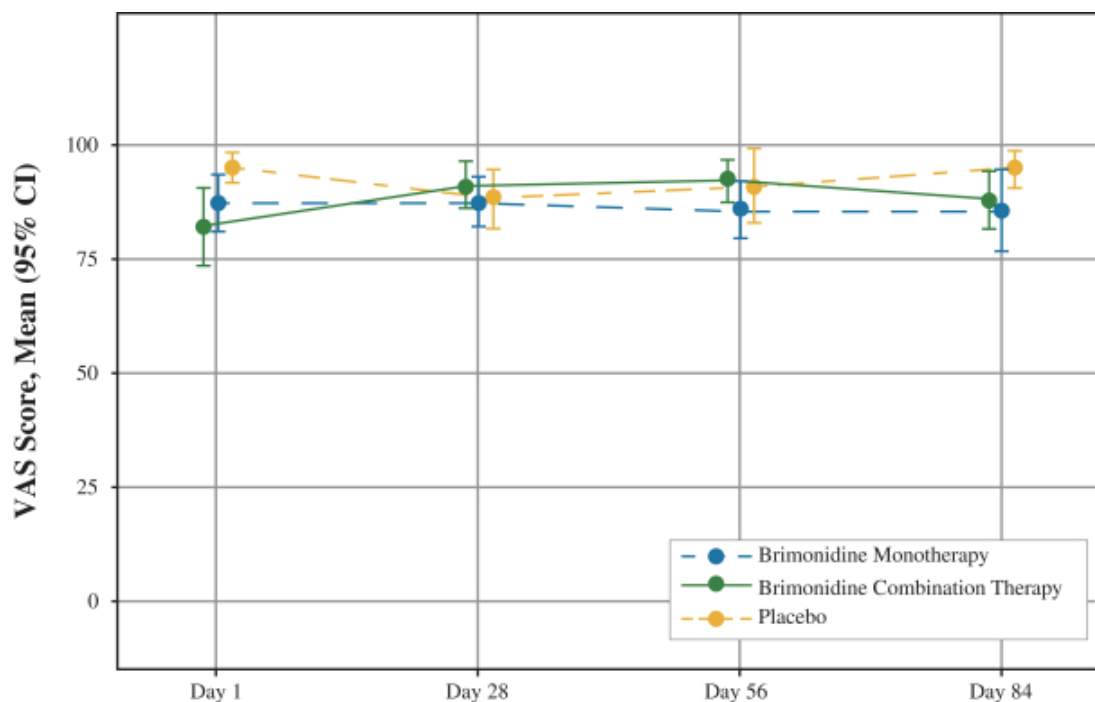
- **Brimonidine Tartrate/Loteprednol Combination (Brimonidine Combination) therapy.** Brimonidine tartrate 0.2% was administered to patients as eye drops, followed by loteprednol ophthalmic suspension (0.2%), separated by five to ten minutes, two times a day for 84 days.
- **Brimonidine Tartrate Monotherapy (Brimonidine Monotherapy).** Brimonidine tartrate 0.2% was administered to patients as eye drops followed by placebo, separated by five to ten minutes, two times a day for 84 days.
- **Placebo.** Lubricant eye drops (sodium carboxymethylcellulose, 0.25%) were administered to patients followed by a second application, separated by five to ten minutes, two times a day for 84 days.

### **Primary Endpoint**

The primary tolerability endpoint was Test Substance Tolerance measured by a Visual Analog Scale (“VAS”) at Day 1 (post-dose), Day 28, Day 56 and Day 84 (primary endpoint assessment). The VAS is a 100-millimeter horizontal line representing a scale from 0 to 100, with 0 indicating the study drug was “completely intolerable” and 100 indicating the study drug was “easily tolerable.” Patients were asked to rate their tolerance to the administration of the study drug based on this scale by placing a single slash mark across the horizontal line between the end labeled 0, or “completely intolerable,” and 100, or “easily tolerable.” As illustrated in **Figure 11**, overall tolerability scores, as measured by VAS, were high for all treatment group (range of means, 82.1-95.0 on a VAS scale of 0 to 100). At Day 84, there was not a statistically significant difference in tolerability scores between treatment groups. As a result, the primary endpoint of the study was met. That is, brimonidine tartrate 0.2% and placebo eye drops were similarly well tolerated.



**Figure 11 Tolerability Visual Analogue Scale (VAS) Scores by Treatment and Visit (Safety Population)**



**Note: Mean and a 95% confidence interval have been plotted.**

*Other Endpoints*

While not powered for statistical significance for efficacy for the exploratory endpoints, several of these prospectively defined exploratory endpoints showed positive results and allowed Ocugen to select primary endpoints for Phase 3 clinical trials. In Phase 3 trials supporting an indication in relief of signs and symptoms of DED, the FDA expects the sponsor to demonstrate the efficacy of the product candidate on both DED signs and symptoms.

Symptom Assessment

Ocugen used SANDE (Symptom Assessment iN Dry Eye), which is a short questionnaire based on VAS that quantifies both severity and frequency of dry eye symptoms, to assess the symptoms of DED. It is designed to specifically capture the frequency and severity of “dryness” and “irritation” in patients with DED. While not adequately powered for efficacy, some SANDE endpoints had a p-value of less than 0.05. For example, the change in overall SANDE score from baseline through subsequent visits, showed that both the brimonidine tartrate/loteprednol combination and brimonidine tartrate monotherapy treatment groups were superior to the placebo group with respect to overall SANDE score improvement from baseline on Day 28 (p=0.0077 and p=0.0101, respectively) and, with respect to the monotherapy only, again on Day 84 (p=0.0150). Moreover, both groups were numerically better when comparing change from baseline scores to placebo on Day 56.

In summary, both brimonidine combination and brimonidine monotherapy appear to reduce dry eye symptoms by Day 28, and the benefit continues through Day 84. In this study, statistically significant efficacy results should be regarded as positive signals to be confirmed in larger, adequately powered studies.

### Sign Assessment

Ocugen used conjunctival staining scores using lissamine green dye to assess the signs of DED in patients receiving brimonidine combination therapy, brimonidine tartrate monotherapy and placebo. In the Phase 2 study, the change in conjunctival staining scores using lissamine green dye at the baseline and Day 84 visits favored the active treatment groups. Ocular surface staining was not done at the intervening visits on Day 28 and Day 56. The brimonidine combination and brimonidine tartrate monotherapy groups each showed numerical improvement when compared to the placebo group for the overall conjunctival lissamine green staining score at Day 84.

Based on the results of this study, Ocugen believes that there is no significant incremental benefit in adding loteprednol to brimonidine tartrate, when compared to using brimonidine tartrate alone, in treating patients with DED. Given that ocular steroids, such as loteprednol, can be associated with adverse effects such as cataracts, increased ocular pressure and ocular rebound inflammation, Ocugen is proceeding with the monotherapy product (Brimonidine 0.2% OcuNanoE™) without loteprednol in Phase 3.

### *Safety*

Overall, there were few adverse events in Ocugen's Phase 2 study. These were generally split evenly across treatment groups, providing additional evidence of tolerability. Adverse events generally were mild in severity and consistent with the commercial product inserts. Brimonidine tartrate 0.2% eye drops, alone or in combination with loteprednol 0.2%, administered two times a day for twelve weeks, were well tolerated in the study. There were two Serious Adverse Events (SAEs), both unrelated to the study drug. There were no meaningful differences between treatment groups for visual acuity (as measured by Snellen eye chart). Intraocular pressure, or IOP, measurements remained within normal range (7-21 mm Hg) during the study, for all subjects in all treatment groups.

A safety follow-up visit was conducted at Day 105, three weeks after discontinuation of all study medication. No SAEs were reported at this visit.

In summary, there were few adverse events in this study. They were generally mild in severity, split across treatment groups, and consistent with information in the commercial product inserts.

### *Conclusion*

Ocugen's Phase 2 study met its primary endpoint of showing similarity in Test Substance Tolerance for brimonidine tartrate (with or without loteprednol) relative to placebo at Day 84. This endpoint was also achieved at the earlier post-baseline visits on Day 28 and Day 56. These tolerability data were also supported by the low incidence of ocular adverse events in the study.

### ***OCU310 Phase 3 Clinical Trial***

A Phase 3 trial for OCU310 was initiated in September 2018 and the first patient was dosed in December 2018. Ocugen has completed the first clinical trial. In this Phase 3 trial, OCU310 brimonidine tartrate (0.2%) OcuNanoE™ was tested versus placebo (ophthalmic buffered saline) for safety and efficacy based on relieving the signs and symptoms of DED after 28 days of treatment.

The trial enrolled 252 patients randomized 1:1 (active: placebo), of which 248 were evaluable in the primary analysis population (intent-to-treat). Subjects were permitted to continue their existing ocular treatments, except for corticosteroid-containing eye drops, which were exclusionary within 14 days prior to the screening visit and throughout the study. The trial was designed to measure the efficacy of OCU310 compared to placebo, all dosed twice daily. Given the potential therapeutic benefits of brimonidine tartrate observed in the Phase 2 study, the Phase 3 efficacy and safety results were assessed after 28 days of treatment (primary endpoint assessment visit).

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After a baseline visit, patients were observed during two additional visits, at Day 14 and Day 28. The primary objective of the study was “To evaluate the safety, tolerability, and efficacy of Brimonidine Nanoemulsion Eye Drops in Patients with Dry Eye Disease (DED)”.

The primary endpoints of the Phase 3 trials were:

- Change from baseline to four weeks (Day 28) in SANDE score; and
- Change from baseline to four weeks (Day 28) in lissamine green conjunctival staining scores. This endpoint would be considered in a hierarchical fashion if statistical success is first demonstrated for SANDE at Day 28.

Through this clinical trial, Ocugen also conducted standard safety assessments.

### *Results*

Demographic characteristics were balanced across treatment groups. The clinical trial showed that OCU310 is well-tolerated. Overall, 18.3% of OCU310-treated patients and 8.7% of Placebo-treated patients experienced an adverse event in the study, of which 9.5% and 3.2% respectively, were either definitely or possibly related to the study drug. The majority of adverse events were classified as mild; no adverse event was classified as severe. There were no deaths or SAEs reported.

There were no meaningful differences between treatment groups for visual acuity (as measured by Snellen eye chart). Intraocular pressure, or IOP, measurements remained within normal range (7-22mm Hg) during the study.

The trial did not meet either of its primary endpoints for symptom (SANDE) and sign (lissamine green conjunctival staining). However, reduction in redness (sign) from the baseline visit, a pre-specified exploratory efficacy endpoint measured by a Validated Bulbar Redness score, was significantly better for OCU310 relative to placebo at both Day 14 ( $p=0.006$ ) and Day 28 ( $p=0.02$ ). This is consistent with the mechanism of action of brimonidine tartrate as an  $\alpha_2$ -agonist with anti-inflammatory properties.

Post-hoc analysis of the Phase 3 clinical trial is ongoing, subsequent to which a consultation with the FDA will be sought. Ocugen is evaluating its options and timing for the continued development of OCU310, including through partnering or future clinical trials.

### **Its proprietary OcuNanoE—Ocugen’s ONE Platform™**

Ocugen has developed a proprietary drug delivery system that it believes is suitable for the delivery of drugs to the target tissues of the anterior segment of the eye for the treatment of ocular surface diseases such as DED and oGVHD. Its proprietary OcuNanoE™ nanoemulsion formulation has shown positive results in preclinical studies and enhanced lacrimal gland drug distribution. It is manufactured as a sterile-filtered, preservative-free and steroid-free product, which is designed to avoid the side effects related to the use of steroids and preservatives.

Ocugen believes that its proprietary formulation has the following attributes:

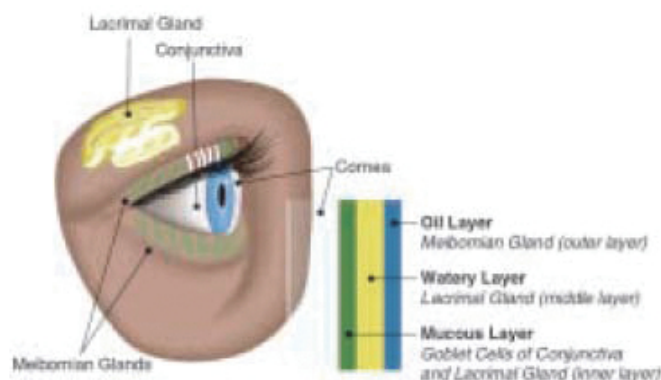
- Oil in water nanoemulsion;
- Capable of formulating water-soluble drug molecules in the aqueous portion of the nanoemulsion;
- Capable of formulating water insoluble (lipiphilic) drug molecules in the oil portion of the nanoemulsion;
- Capable of delivering drug molecules to ocular tissues based upon a preclinical study;
- Defined narrow range globules with average diameter of less than 100 nanometers;

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- Capable of filter sterilization without having to use non-scalable processes and/or preservatives; and
- Suitable for commercial scale manufacturing.

As illustrated in **Figure 12** below, tear film is composed of the inner mucin layer, the middle aqueous component and the outer lipid layer. The mucin layer is derived from goblet cells from the conjunctiva and lacrimal glands; the aqueous layer is derived from the lacrimal glands; and the lipid layer is derived from the meibomian glands. About 90% of topical drugs applied to the anterior segment of the eye is lost into systemic circulation. The rest of the drug must reach a minimum threshold concentration in the target tissues, such as the lacrimal glands, conjunctiva and cornea, in order to exert the functional characteristics of the therapeutic. Therefore, treatment of diseases associated with the front of the eye, such as DED and oGVHD, requires the stabilization of tear film and targeting the drug molecule at sufficient concentrations to the lacrimal functional unit which is primarily responsible for the tear film production and stability.

**Figure 12 Tear film in Human Eye**



Given the structure of tear film and the human eye, Ocugen believes that its formulation has several novel properties, which may enable it to improve drug distribution and penetration:

- it contains lipid components that may act as the lipid layer of the tear film both in its functional characteristics and its charge distribution;
- it may mimic the charge characteristics of mucin and glycocalyx components present in the inner mucin layer, thus, potentially allowing the drug molecules to be carried to the site of action without binding to the mucin layer; and
- it is a reproducible nanosized (less than 100 nanometers) emulsion which may enable the drug molecules to be transported through the interstitial cells to reach the specific target tissues.

In a DED mouse model study, Ocugen demonstrated that its nanoemulsion technology significantly reduced corneal epitheliopathy using brimonidine tartrate formulated with OcuNanoE™ as compared to brimonidine formulated without OcuNanoE™. While a significant portion of conventionally formulated ophthalmic drugs are rapidly eliminated via the tear film, Ocugen believes that its nanoemulsion technology is capable of achieving higher concentration on the surface of the eye, thereby potentially enabling the active drug substance to reach cells in the underlying ocular tissue at higher therapeutic levels. Its proprietary OcuNanoE™ nanoemulsion was developed to decrease the drainage rate, prolong precorneal residence time and increase the drug concentration in the lacrimal gland.

To date, Ocugen has applied its OcuNanoE™ technology to create a nanoemulsion formulation of brimonidine tartrate resulting in the development of its two clinical product candidates, OCU300, brimonidine tartrate

(0.18%) OcuNanoE™ for the treatment of ocular redness and ocular discomfort in patients suffering from oGVHD, and OCU310, brimonidine tartrate (0.2%) OcuNanoE™ for the relief of signs and symptoms of DED. Ocugen also believes this technology may be useful to treat other ocular surface disorders.

## **RETINAL DISEASES**

Ocugen is also evaluating several other product candidates for an array of ophthalmic conditions. Ocugen has two biological preclinical programs in development, OCU200 for the treatment of wet AMD and OCU100 for the treatment of RP. Ocugen has exclusively in-licensed a broad range of rights for these preclinical programs. Ocugen has not submitted any IND applications for these programs and there can be no assurance that an IND will be submitted.

### **OCU200 for the Treatment of Wet Age-Related Macular Degeneration**

OCU200 is a biologic product candidate in preclinical development for treating wet AMD, a severely sight-threatening disease caused by the abnormal growth and infiltration of new, leaky blood vessels into the retina from both choroidal and retinal vasculature systems. OCU200 is a novel fusion protein consisting of two human proteins, transferrin and tumstatin, that are endogenously present normally in retinal tissues.

Tumstatin is an endogenous angiogenesis inhibitor derived from the C terminus non-collagenous domain (NC1) of collagen IV present in the basement membrane. Tumstatin is the active component of OCU200 and potentially plays a pivotal role in antagonizing ocular neovascularization through the inhibition of several key signaling pathways involved in angiogenesis, including VEGF, and by inducing endothelial cell apoptosis. Importantly, tumstatin may selectively target the actively proliferating epithelial cells involved in angiogenesis by antagonizing  $\alpha$ Vb3 integrin signaling, leaving healthy vasculature unharmed. In the absence of any pathological condition, a strict balance is maintained between angiogenic (such as VEGF) and antiangiogenic molecules (such as tumstatin). During hypoxia and ischemia, the balance between angiogenic and antiangiogenic molecules is disturbed, thereby causing neovascularization.

Transferrin is a ubiquitous iron-binding serum protein involved in regulating iron levels. It binds a transferrin receptor that is highly expressed in the posterior sections of the retina, particularly in the retinal pigment epithelial cells and in the sub-retinal choroidal layer where wet AMD is clinically recognized to first occur before pathologically spreading inward during disease progression. Transferrin potentially helps in the localization of OCU200 in the posterior ocular tissues and increases the interaction between tumstatin and  $\alpha$ Vb3 integrin receptor.

Current therapies for wet AMD focus on reducing new blood vessel formation (neovascularization) through inhibition of a single key regulator, VEGF, an approach that has demonstrated limited long-term effectiveness in clinical studies. OCU200 is designed to address the limitations of current therapies by targeting multiple mechanisms associated with ocular neovascularization. This multifactorial approach centers around antagonizing  $\alpha$ Vb3 integrin signaling.

### ***Overview of Wet Age-Related Macular Degeneration***

AMD is a degeneration of the macula of the retina that leads to impairment and loss of central vision. There are two categories of AMD: “dry” AMD, which involves the slow deterioration of the retina with submacular drusen, atrophy, loss of macular function and central vision impairment; and “wet” AMD, which involves the growth of abnormal blood vessels under the retina and macula, resulting in edema, tissue damage and rapid loss of central vision. If untreated, neovascularization in wet AMD patients typically results in significant vision loss and the formation of a scar under the macular region of the retina. Most cases begin as dry AMD and may progress to wet AMD.

Wet AMD is a leading cause of blindness in people over the age of 55 in the United States and the European Union. The incidence of wet AMD increases substantially with age, and Ocugen expects that the number of cases of wet AMD will increase with the growth of the elderly population in the United States. It has been estimated that approximately 11 million patients in the United States have some form of AMD of which, 1.1 million, or 10 percent, suffer from wet AMD. Additionally, roughly 200,000 new cases of wet AMD are diagnosed each year in the United States.

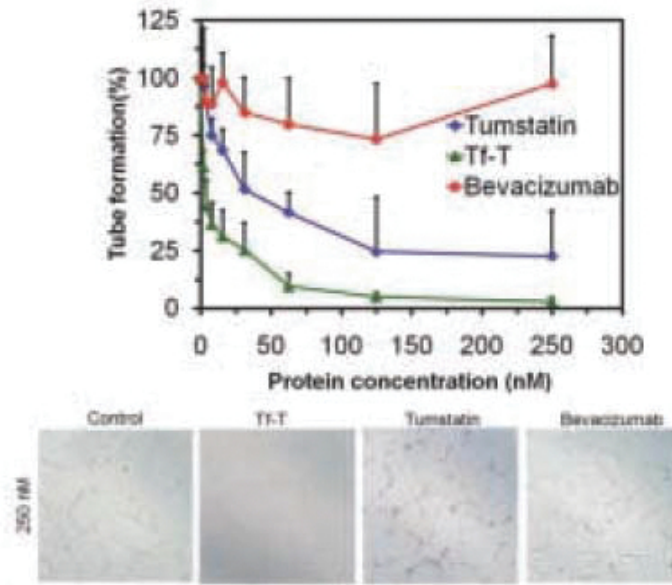
*Current treatments for wet AMD*

Current FDA approved therapeutics for wet AMD include intravitreal injection of either Lucentis® or Eylea,® which target VEGF, one of the key proteins involved in neovascularization. Their effect is limited to restraining the activity of VEGF in vascular hyperpermeability and angiogenesis. Bevacizumab (Avastin™), the parent antibody from which ranibizumab was derived, is also used as an off-label treatment. Though these products have been effective in mitigating the disease symptoms, they have substantial limitations based on clinical studies. For example, a significant percentage of patients do not respond to therapy and experience continuous deterioration of vision; long-term repeated dosing results in reduced effectiveness; persistence of fluid in subretinal space of 30-50% patients even after 1-2 years of treatment; and lack of apoptotic activity. Given the above limitations of these existing treatments, Ocugen believes that a substantial unmet medical need still exists.

***Preclinical studies of OCU200***

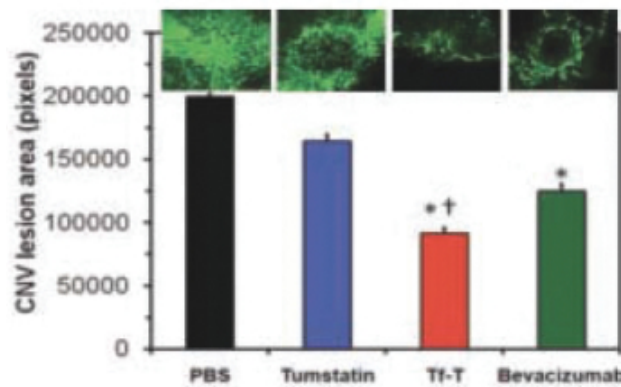
Based on preclinical studies, OCU200 may reduce new blood vessel formation to a greater extent than tumstatin alone and anti-VEGF therapy. This potential was shown in an *in-vitro* cell culture model, which is based on an inhibition of endothelial cells tube formation in an extracellular basement membrane matrix (Matrigel®), demonstrating anti-angiogenic activity (Figure 19), and in *in-vivo* laser induced CNV rat and mouse models (Figure 20). In addition to anti-angiogenic activity, OCU200 also promoted apoptosis in an *in-vitro* cell culture assay (Figure 21). The induction of apoptosis in an *in-vitro* cell culture assay could also have an inhibitory effect on the progression of neovascularization. These encouraging results, coupled with published literature on an  $\alpha$ Vb3 integrin antagonist's curtailment of retinal and choroidal neovascularization in an animal model, highlights the potential for OCU200 to deliver disease modification for wet AMD and other high-need retinal neovascular diseases, such as diabetic macular edema, diabetic retinopathy and retinal vein occlusion.

**Figure 13** OCU200 (Tf-T) inhibits the tube formation in RF/6A cells (endothelial cells) in an *in-vitro* cell culture-based assay. RF/6A cells were plated on Matrigel®-coated plates along with different concentrations of OCU200 (Tf-T), tumstatin, and bevacizumab protein. (A) Plot for the inhibition of tube formation by tumstatin, Tf-T, and bevacizumab is shown. Data is expressed as mean ± S.D. for 3 biological replicates. (B) Representative images of RF/6A cell tube formation is shown at 250 nM.

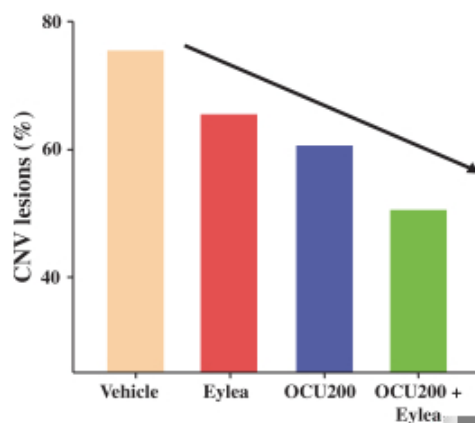


**Figure 14: OCU200 (Tf-T) Reduces Lesion Area Significantly more than Anti-VEGF Therapy in a Choroidal Neovascularization animal Models.** **A)** *In vivo* assessment of OCU200 in laser burn rat CNV model. A quantitative comparison of the treatments indicated decreased laser induced lesion area in rat eyes treated with Tf-T as compared to bevacizumab and tumstatin. Data is expressed as mean ± S.D. \* indicates  $p < 0.05$  when compared to PBS and/or tumstatin treatment. † indicates  $p < 0.05$  when compared to bevacizumab. **B)** Mice CNV model. OCU200 treatments indicated a trend in decreased number of CNV lesions. Data expressed as percentage of CNV lesions on Day 10 after treatment. Laser induction & treatment start on Day 0.

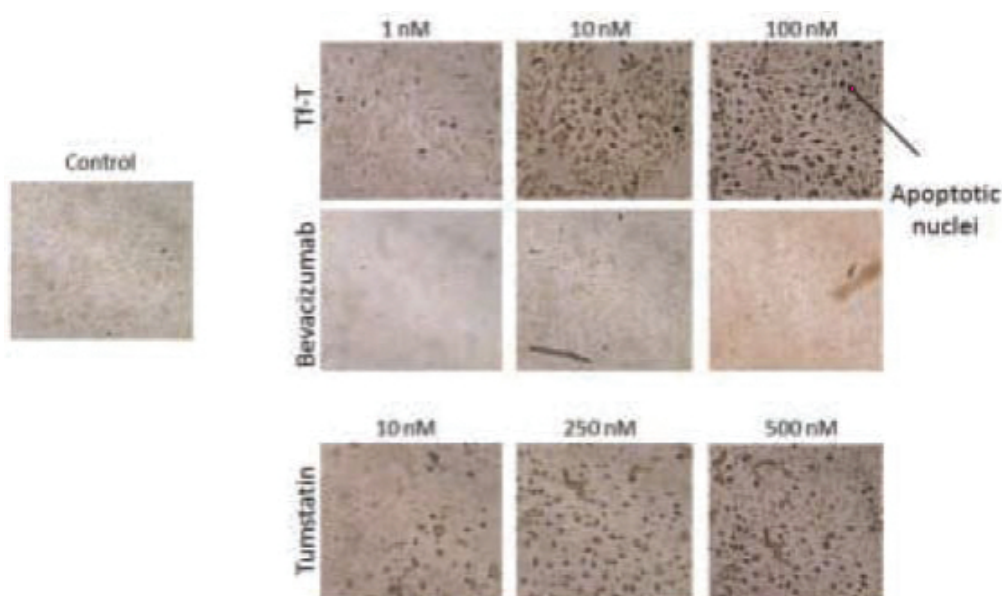
**Figure 14 A.**



**Figure 14 B.**



**Figure 15** OCU200 (Tf-T) and tumstatin induced apoptosis in RF/6A cells in an *in vitro* assay. Bevacizumab had no effect on RF/6A apoptosis. Arrows point towards apoptotic cell nuclei.



Ocugen has identified a promoter, linker and mammalian host cell for the recombinant production of OCU200 for preclinical, clinical, and commercialization needs. The production of stable cell lines followed by cGMP manufacturing activities are in progress, while Ocugen is studying recombinantly expressed OCU200 in animal models. Based on its preclinical results, Ocugen believes that OCU200 may offer an improved therapeutic option and has the potential to show synergistic effect in combination with existing therapeutics with multi-mode mechanisms.

Eventually, Ocugen plans to expand the therapeutic applications of OCU200 beyond wet AMD, and potentially include diabetic retinopathy (DR), diabetic macular edema (DME), macular edema following retinal vein occlusion (RVO), and myopic choroidal neovascularization (mCNV). These patients suffer from retinal/choroidal



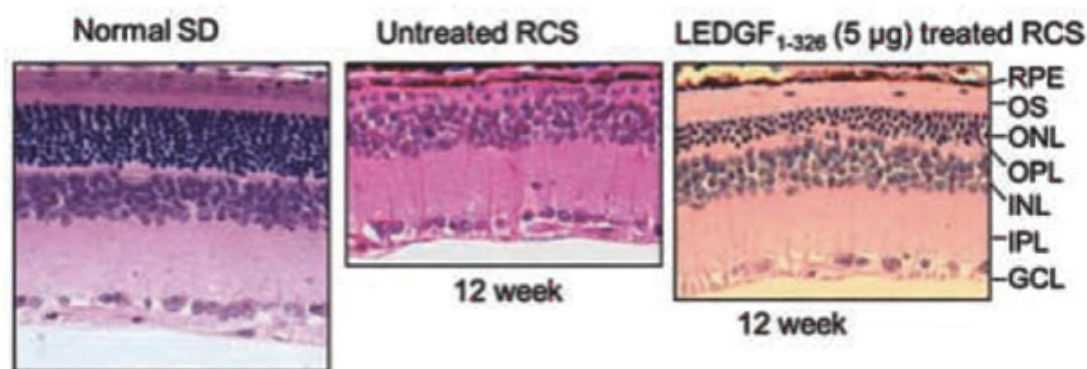
complications in the back of the eye which may have a sudden and debilitating impact on visual acuity, eventually leading to blindness. Anti-VEGF therapeutics have been recently approved for the treatment of these retinal disorders. Ocugen believes that OCU200 may also be a promising therapy for the treatment of DR, DME, RVO and mCNV for the reasons outlined for the treatment of wet AMD.

### **OCU100 for the Treatment of Retinitis Pigmentosa**

OCU100 is a recombinant form of N-terminal segment (1-326 amino residues) derived from human LEDGF, which has been shown preclinically to rescue photoreceptors from degeneration. In May 2014, Ocugen was granted ODD from the FDA for the use of OCU100 as a treatment for RP and in August 2017, Ocugen was granted Orphan Medicinal Product Designation from the European Commission. A pre-IND meeting with the FDA was held in 2015 to gain guidance on the development pathway, including IND enabling studies and Phase 1 and Phase 2 clinical studies. Ocugen currently is conducting IND enabling studies.

OCU100 contains the key functional domains required to facilitate transport into the nucleus and activate stress response pathways. Results of proof of concept testing from an *in-vivo* RCS rat model suggest that OCU100 could improve the survival of retinal cells. Ocugen believes that these results indicate that OCU100 could slow or stop disease progression in individuals with RP as shown in **Figure 16**.

**Figure 16 OCU100 reduced degeneration of photoreceptor in RCS model of retinal degeneration**



LEDGF originally was isolated by researchers at the National Eye Institute and has been shown preclinically to enhance photoreceptor and retinal pigment epithelial cell survival. Ocugen is also investigating LEDGF's regenerative potential. LEDGF is a naturally occurring survival factor which is up regulated under stress conditions. LEDGF binds to stress response elements within the nucleus to potentially enhance cell survival. Researchers have found preclinically that LEDGF activates the natural stress response mechanisms which include heat shock proteins, antioxidant proteins, and detoxification enzymes. Ocugen believes OCU100, which contains a truncated form of LEDGF, may be a potential therapeutic for RP.

### **Overview of Retinitis Pigmentosa**

RP is a clinically and genetically heterogeneous group of inherited retinal disorders characterized by dysfunction and death of photoreceptor cells which leads to the progressive degeneration of the retina, causing vision loss and blindness. RP is the leading cause of inherited blindness in the United States. According to the Foundation Fighting Blindness, most people with RP are legally blind by age 40, with a central visual field of less than 20 degrees in diameter. The onset and pace of RP disease progression varies significantly. RP initially manifests as night blindness due to the onset of rod photoreceptor degeneration in the retina. Early stages of RP include the

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loss of mid-peripheral vision, which restricts movement and orientation in low light environments and delays visual adjustment from dark to light settings. As the disease progresses, the far-peripheral visual field and the central visual field of RP patients deteriorate as scotomas expand outward into the peripheral retina and inward into the macula. The gradual loss of cone photoreceptors and retinal pigment epithelium cells further impairs visual acuity and color vision, eventually leading to irreversible blindness.

In general, the diagnosis of RP is established when the following findings are present:

- Bilateral involvement (can be asymmetric);
- Impairment of night vision and loss of peripheral vision;
- Rod dysfunction evidenced by elevated rod final threshold on dark adaptation and/or rod responses on electroretinography testing that are either reduced in b-wave amplitude and prolonged in implicit time or are essentially non-detectable; and
- Progressive loss in photoreceptor function.

RP is a rare disease with a prevalence of approximately one in 4,000. Approximately 100,000 people in the United States and 1.5 million globally are afflicted by the disease. Currently there is no FDA approved drug treatment for RP, representing an area of significant unmet medical need.

### *Current treatments for RP*

To date, there is no approved treatment for RP. RP is a complex genetic disorder with mutations in over 200 genes. The functions of these genes span phototransduction, vitamin A metabolism, cytoskeleton, protein trafficking, cell-cell interaction, maintenance of cilia, pH regulation, phagocytosis, RNA splicing, and others. Because of the multiplicity of mechanisms involved in RP, a therapeutic agent that is effective across a broad spectrum of genetic mutations is highly desirable.

Proposed treatments for RP include gene-replacement therapy, retinal implant devices, retinal transplantation, stem cells, vitamin therapy, and other pharmacological treatments. Gene-replacement therapies are promising but are limited to treating just a single mutation and therefore cannot address the multiple mutations implicated by RP. In addition, while gene therapies may provide a new functional gene, they do not necessarily eliminate the underlying genetic defect which may still cause stress and toxic effects. As a result, there is a significant unmet medical need for a treatment with application across multiple genetic forms of RP. Ocugen believes that OCU100 targets multiple cellular and molecular pathways associated with the degeneration of the retina, such as oxidative stress, inflammatory and phagocytosis pathways.

### *Preclinical studies of OCU100*

RP is caused by mutations in a diverse set of genes involved in cellular growth, inflammation, survival, cellular organization and metabolism. Ocugen is conducting gene network analyses to understand the pathways regulated by OCU100. Based on these analyses, Ocugen will select a set of patients whom Ocugen believes could benefit from OCU100 and experience improved cell survival and signaling and overall vision processing.

Ocugen currently is conducting IND enabling studies of OCU100.

## **COMPETITION**

The biopharmaceutical industry, including gene therapy, is characterized by rapidly advancing technologies, intense competition and a strong emphasis on intellectual property. Ocugen faces competition from many different sources, including large and specialty pharmaceutical and biotechnology companies, academic institutions, governmental agencies and public and private research institutions.

Competitors include established, emerging, and growing companies such as Valeant Pharmaceuticals International, Inc., Allergan, Inc., Santen, Inc., Shire Plc, Regeneron Pharmaceuticals, Inc., Genentech, Inc. and Spark Therapeutics, Inc. Additionally, Ocugen is aware of several companies focusing on developing ocular surface, retinal and gene therapies for various indications including Kala Pharmaceuticals, Inc., Ophthotech Corporation, Aldeyra Therapeutics, Ocular Therapeutix, and Applied Genetic Technologies Corporation. Many of Ocugen's competitors have significantly greater financial resources to support research and development, manufacturing, preclinical testing, and clinical trials, as well as regulatory and marketing efforts. These organizations also compete with Ocugen in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites, patient registration for clinical trials, and in acquiring technologies necessary for its programs. Smaller or early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of its competitors.

Ocugen's commercial opportunity could be reduced or eliminated if its competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any products that Ocugen may develop. Its competitors may also obtain FDA or other regulatory approval for their products more rapidly than Ocugen. In addition, its ability to compete may be affected as insurers or other third-party payers seek to encourage the use of more cost-effective products.

## **MANUFACTURING**

Ocugen utilizes its in-house expertise and know-how to develop and scale up its manufacturing processes before these processes are transferred to third-party contract manufacturers and testing labs to understand and establish controls of critical process parameters and critical quality attributes. Ocugen also has personnel with deep product development experience who actively manage the third-party contract manufacturers producing OCU300 and OCU310, and other products that are in the development pipeline.

Ocugen's OCU300 and OCU310 product candidates (using its proprietary OcuNanoE™ nanoemulsion formulation) are currently manufactured at an established contract manufacturing facility located in the United States. The drug substance containing nanoemulsion is sterilized by 0.2-micron filtration and is filled into sterile single-use vials. The final process has been successfully scaled up to support commercial manufacturing. Labeling and packaging of vials also occurs at the same third-party manufacturer. Its third-party manufacturers and testing labs are subject to FDA inspections from time to time.

### *Commercial Supply Agreements for OCU300 and OCU310*

Ocugen is currently working with third parties to finalize its commercial supply agreements and has negotiated an arrangement with a third-party manufacturer to supply brimonidine tartrate (drug substance). Ocugen intends to use the current third-party contract manufacturing organization to supply the commercial drug products, and to perform label/pack activities for it. Similarly, Ocugen will continue to use current third-party testing labs for release and stability testing of its commercial products.

## **LICENSE AGREEMENTS**

Ocugen is a party to license agreements under which it licenses patents, patent applications, technical information and other intellectual property for OCU400, OCU300, OCU310, OCU200 and OCU100. Certain diligence and financial obligations are tied to these agreements. Ocugen considers the following agreements to be material to its business.

### *License Agreement with University of Colorado*

In March 2014, Ocugen entered into an exclusive license agreement with the University of Colorado ("CU"), which was amended in January 2017 and clarified by a letter of understanding in November 2017 (the exclusive

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license agreement, as amended and clarified, is referred to as the “CU Agreement”). The CU Agreement gives Ocugen an exclusive, worldwide, sublicensable license to patents for OCU100 and OCU200 to make, have made, use, import, offer to sell, sell, have sold, and practice the licensed products in all therapeutic applications. Under the CU Agreement, Ocugen must use commercially reasonable efforts to develop, manufacture, sublicense, market and sell the licensed products.

Pursuant to the terms of the CU Agreement, Ocugen paid CU an initial fee of \$26,179 and issued 247,000 shares of common stock. Commencing in 2017, Ocugen pays CU an annual royalty payment. The CU Agreement also requires the payment of certain regulatory milestones, aggregating \$1.5 million, and low single-digit percentage earned royalties on net sales.

The CU Agreement will expire on the later of the expiration date of the last to expire licensed patent (expected in 2032) or the end of any relevant statutory or regulatory exclusivity period. Ocugen may terminate the CU Agreement upon 60 days’ prior written notice. CU may terminate the CU Agreement upon 60 days’ notice if Ocugen fails to make payments within 60 days of such payment’s due date, breaches and does not cure any diligence obligation, provides any materially false report or otherwise materially breaches and does not cure any material provision of the CU Agreement.

### *License Agreement with University of Illinois at Chicago*

In February 2016, Ocugen entered into an exclusive license agreement (the “UIC Agreement”) with the University of Illinois at Chicago (“UIC”). This agreement gives Ocugen an exclusive, worldwide, non-transferable, sublicensable license to patents and patent rights for OCU300 and OCU310 to make, have made, use, import, sell, and offer for sale products claimed by and/or incorporating or derived from the licensed patents. Under this agreement, Ocugen must use commercially reasonable efforts to develop and bring products to market. Pursuant to the terms of the UIC Agreement, Ocugen paid UIC a signing fee of \$15,000. Commencing in 2019, Ocugen also pays UIC an annual minimum payment and reimburses UIC for reasonable documented patent costs and expenses. The UIC Agreement also requires the payment of certain regulatory and commercial milestones, aggregating \$1.25 million and low to mid-single-digit percentage royalties on annual net sales of products that fall under the licensed patent rights.

The UIC Agreement will expire on the later of the expiration date of the last to expire licensed patents (expected in 2036), when Ocugen provides notice to UIC that use of the technical information has ceased or the end of any relevant statutory or regulatory exclusivity period. Ocugen may terminate the license upon 90 days’ prior written notice. UIC may terminate the UIC Agreement if Ocugen fails to make payments within thirty days of receiving a written notice of missed payment, breaches any provision of the UIC Agreement and does not cure such breach within 30 days, breaches any obligation under any other agreement between Ocugen and UIC and does not cure such breach within 45 days, makes any materially false report, becomes bankrupt or insolvent, or takes any action that causes a lien or encumbrance to be placed on the licensed patent rights or technical information.

### *License Agreement with The Schepens Eye Research Institute, Inc.*

In December 2017, Ocugen entered into an exclusive license agreement (the “SERI Agreement”) with The Schepens Eye Research Institute, Inc. (“SERI”). The SERI Agreement gives Ocugen an exclusive, worldwide, sublicensable license to patent rights, biological materials and technical information for nuclear hormone receptor genes *NR1D1*, *NR2E3* (OCU400), *RORA*, *NUPR1*, and *NR2C1*. Under the SERI Agreement, Ocugen may make, have made, use, offer to sell, sell and import licensed products.

Under this agreement, Ocugen must use commercially reasonable efforts to bring one or more licensed products to market as soon as reasonably practicable.

Pursuant to the terms of the SERI Agreement, Ocugen paid SERI an upfront fee of \$39,681 to reimburse SERI for patent expenses prior to the effective date of the SERI Agreement and an initial license fee of \$125,000. The

SERI Agreement requires Ocugen to pay an annual license maintenance fee. The SERI Agreement also requires the payment of certain regulatory and commercial milestones, aggregating \$16.5 million and low single-digit percentage royalties on annual net sales of products that fall under the licensed patent rights.

SERI maintains control of patent preparation, filing, prosecution and maintenance. After the first anniversary of the execution date of the SERI Agreement, Ocugen has the right, but not the obligation, to assume responsibility for and control of the prosecution and maintenance of the licensed patent rights, at its sole cost and expense. If Ocugen does not exercise this option, it must pay SERI's out-of-pocket expenses related to the filing, prosecution and maintenance of the licensed patent rights. In the event that SERI decides to discontinue the prosecution or maintenance of the licensed patent rights, Ocugen has the right, but not the obligation, to file for, or continue to prosecute, maintain or enforce such licensed patent rights.

The SERI Agreement will expire on the expiration date of the last to expire licensed patents right (expected in 2034). Ocugen may terminate the license upon 180 days' prior written notice. SERI may immediately terminate the SERI Agreement if Ocugen ceases to carry on its business with respect to the licensed patent rights, fails to make payments within thirty days of receiving a written notice of missed payment, fails to comply with its diligence obligations, defaults on its obligation to procure and maintain insurance, one of Ocugen's officers is convicted of felony related to the licensed products, Ocugen breaches any material obligation of the agreement and does not cure such breach within 90 days or if it becomes bankrupt or insolvent.

## **INTELLECTUAL PROPERTY**

Ocugen has obtained patent protection for all of its product candidates. It intends to maintain and defend its patent rights to protect its technology, inventions, processes and improvements that are commercially important to the development of its business. Ocugen cannot be sure that any of its existing patents or patents that it obtains in the future will be commercially useful in protecting its technology, or that patents will be issued for any pending patent applications or patent applications that it files in the future. Ocugen's commercial success also depends in part on its non-infringement of the patents and proprietary rights of third parties.

As of June 2019, Ocugen's patent portfolio included five U.S. issued patents, 27 foreign issued patents, eight U.S. patent applications and 20 foreign patent applications. Ocugen has licensed 28 patents from CU relating to OCU100 and OCU200 which cover the U.S., Australia, Albania, Austria, Belgium, Canada, Czech Republic, Denmark, Finland, France, Germany, Great Britain, Ireland, Italy, Japan, the Netherlands, Norway, Poland, Portugal, Russia, Slovakia, Slovenia, Spain, Sweden, Switzerland and Turkey. Additionally, Ocugen has licensed 10 patent applications from CU relating to OCU100 and OCU200 that cover the U.S., Brazil, Canada, China, Europe, India and Japan. Ocugen jointly owns three patents with UIC relating to OCU300 and OCU310 which cover the U.S. and Russia, and has 10 joint patent applications with UIC relating to OCU300 and OCU310 which cover the U.S., Australia, Brazil, Canada, China, Europe, India, Japan, Korea and Mexico. Ocugen has licensed one U.S. patent and one U.S. patent application from SERI and has one joint U.S. patent application with SERI, in each case related to OCU400. Ocugen also wholly owns four U.S. and two foreign patent applications. Ocugen's intellectual property consists of issued patents and pending patent applications for compositions of matter and methods of use, as well as for product candidates and other proprietary technology, including its OcuNanoETM technology.

### *Trade Secrets*

In addition to patents, Ocugen may rely, in some circumstances, on trade secrets to protect its technology. However, trade secrets can be difficult to protect. Ocugen seeks to protect its proprietary technology and processes, and obtain and maintain ownership of certain technologies, in part, by confidentiality and invention assignment agreements with its employees, consultants, scientific advisors and contractors. Ocugen also seeks to preserve the integrity and confidentiality of its data and trade secrets by maintaining physical security of its premises and physical and electronic security of its information technology systems.

## **GOVERNMENT REGULATION AND PRODUCT APPROVAL**

Government authorities in the United States, at the federal, state, and local level, and in other countries, extensively regulate, among other things, the research, development, testing, approval, manufacture, packaging, storage, recordkeeping, labeling, advertising, promotion, distribution, marketing, import, and export of biopharmaceutical and drug products such as those Ocugen is developing. In addition, labelers of biopharmaceutical and drug products (the entity owning the National Drug Code listed for a product) participating in Medicaid and Medicare are required to comply with mandatory price reporting, discount, and rebate requirements. The processes for obtaining regulatory approvals in the United States and in foreign countries, along with compliance with applicable statutes and regulations, require the expenditure of substantial time and financial resources.

### ***FDA Regulation***

In the United States, the FDA regulates drug products under the Federal Food, Drug, and Cosmetic Act (“FDCA”) and its implementing regulations. In addition to the FDCA and its implementing regulations, biologic products are regulated under the Public Health Services Act (“PHSA”) and its implementing regulations. The process required by the FDA before product candidates may be marketed in the United States generally involves the following:

- completion of preclinical laboratory tests, animal studies, and formulation studies in compliance with the FDA’s Good Laboratory Practice (“GLP”) regulations;
- submission to the FDA of an Investigational New Drug Application (“IND”), which must become effective before human clinical trials may begin at United States clinical trial sites;
- approval by an Institutional Review Board (“IRB”) for each clinical site, or centrally, before each trial may be initiated;
- adequate and well-controlled human clinical trials to establish the safety and efficacy, in the case of a drug product candidate, or safety, purity, and potency, in the case of a biologic product candidate for its intended use, performed in accordance with Good Clinical Practices (“GCPs”);
- development of manufacturing processes to ensure the product candidate’s identity, strength, quality, purity, and potency;
- submission to the FDA of a NDA, in the case of a drug product candidate, or Biologic License Application (“BLA”), in the case of a biologic product candidate;
- satisfactory completion of an FDA advisory committee review, if applicable;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the products are produced to assess compliance with current Good Manufacturing Practices (“cGMPs”), and to assure that the facilities, methods, and controls are adequate to preserve the therapeutics’ identity, strength, quality, purity, and potency as well as satisfactory completion of an FDA inspection of selected clinical sites and selected clinical investigators to determine GCP compliance; and
- FDA review and approval of the NDA or BLA to permit commercial marketing for particular indications for use.

### ***Preclinical Studies and IND Submission***

The testing and approval process of product candidates requires substantial time, effort, and financial resources. Satisfaction of FDA pre-market approval requirements typically takes many years and the actual time required may vary substantially based upon the type, complexity, and novelty of the product or disease. Preclinical studies include laboratory evaluation of chemistry, pharmacology, toxicity, and product formulation, as well as animal studies to assess potential safety and efficacy. Such studies must generally be conducted in accordance with the

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FDA's GLPs. Prior to commencing the first clinical trial at a United States investigational site with a product candidate, an IND sponsor must submit the results of the preclinical tests and preclinical literature, together with manufacturing information, analytical data, any available clinical data or literature, and proposed clinical study protocols among other things, to the FDA as part of an IND. In the case of drug product candidates for which the sponsor will seek marketing approval via a 505(b)(2) NDA application, some of the above information may be abbreviated or omitted.

An IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, notifies the applicant of safety concerns or questions related to one or more proposed clinical trials and places the trial on a clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. As a result, submission of an IND may not result in FDA authorization to commence a clinical trial. A separate submission to an existing IND must also be made for each successive clinical trial conducted during product development.

### *Clinical Trials*

Clinical trials involve the administration of the investigational product to human subjects under the supervision of qualified investigators in accordance with federal regulations and GCP requirements, which include the requirements that all research subjects provide their informed consent in writing for their participation in any clinical trial, as well as review and approval of the study by an IRB. Investigators must also provide certain information to the clinical trial sponsors to allow the sponsors to make certain financial disclosures to the FDA. Clinical trials are conducted under protocols detailing, among other things, the objectives of the trial, the trial procedures, the parameters to be used in monitoring safety, the effectiveness criteria to be evaluated, and a statistical analysis plan. A protocol for each clinical trial, and any subsequent protocol amendments, must be submitted to the FDA as part of the IND. If a product candidate is being investigated for multiple intended indications, separate INDs may also be required. In addition, an IRB at each study site participating in the clinical trial and/or a central IRB must review and approve the plan for any clinical trial, informed consent forms, and communications to study subjects before a study commences at that site. An IRB considers, among other things, whether the risks to individuals participating in the trials are minimized and are reasonable in relation to anticipated benefits, and whether the planned human subject protections are adequate. The IRB must continue to oversee the clinical trial while it is being conducted. Progress reports detailing the results of the clinical trials must also be submitted at least annually to the FDA and the IRB and more frequently if serious adverse events or other significant safety information is found.

The FDA may order the temporary, or permanent, discontinuation of a clinical trial at any time, or impose other sanctions, if it believes that the clinical trial either is not being conducted in accordance with FDA requirements or presents an unacceptable risk to the clinical trial patients. An IRB may also require the clinical trial at the site to be halted, either temporarily or permanently, for failure to comply with the IRB's requirements or if the trial poses an unexpected serious harm to subjects. The FDA or an IRB may also impose conditions on the conduct of a clinical trial. Clinical trial sponsors may also choose to discontinue clinical trials as a result of risks to subjects, a lack of favorable results, or changing business priorities.

Information about certain clinical trials, including a description of the study and study results, must be submitted within specific timeframes to the National Institutes of Health ("NIH") for public dissemination on their *clinicaltrials.gov* website. Sponsors or distributors of investigational products for the diagnosis, monitoring, or treatment of one or more serious diseases or conditions must also have a publicly available policy on evaluating and responding to requests for expanded access requests.

The manufacture of investigational drugs and biologics for the conduct of human clinical trials is subject to cGMP requirements. Investigational drugs and biologics and active ingredients and therapeutic substances imported into the United States are also subject to regulation by the FDA. Further, the export of investigational products outside of the United States is subject to regulatory requirements of the receiving country, as well as U.S. export requirements under the FDCA.

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In general, for purposes of NDA and BLA approval, human clinical trials are typically conducted in three sequential phases, which may overlap or be combined.

- *Phase 1*—Studies are initially conducted in healthy human volunteers or subjects with the target disease or condition to test the product candidate for safety, dosage tolerance, structure-activity relationships, mechanism of action, absorption, metabolism, distribution, and excretion. If possible, Phase 1 trials may also be used to gain an initial indication of product effectiveness.
- *Phase 2*—Controlled studies are conducted in limited subject populations with a specified disease or condition to evaluate preliminary efficacy, identify optimal dosages, dosage tolerance and schedule, possible adverse effects and safety risks, and expanded evidence of safety.
- *Phase 3*—These adequate and well-controlled clinical trials are undertaken in expanded subject populations, generally at geographically dispersed clinical trial sites, to generate enough data to provide statistically significant evidence of clinical efficacy and safety of the product candidate for approval, to establish the overall risk-benefit profile of the product candidate, and to provide adequate information for the labeling of the product candidate. Typically, two Phase 3 trials are required by the FDA for product approval. Under some limited circumstances, however, the FDA may approve an NDA or BLA based upon a single Phase 3 clinical study.

Moreover, in the case of 505(b)(2) NDAs, the above studies may be abbreviated. Additional kinds of data may also help to support a BLA or NDA, such as patient experience data and real world evidence. Real world evidence may also be used to assist in clinical trial design or to support an NDA for already approved products. For genetically targeted products and variant protein targeted products intended to address an unmet medical need in one or more patient subgroups with a serious or life threatening rare disease or condition, the FDA may allow a sponsor to rely upon data and information previously developed by the sponsor or for which the sponsor has a right of reference, that was previously submitted to support an approved application for a product that incorporates or utilizes the same or similar genetically targeted technology or a product that is the same or utilizes the same variant protein targeted drug as the product that is the subject of the application.

The FDA may also require, or companies may conduct, additional clinical trials for the same indication after a product is approved. These so-called Phase 4 studies may be made a condition to be satisfied after approval. The results of Phase 4 studies can confirm or refute the effectiveness of a product candidate, and can provide important safety information.

Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the product candidate as well as finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, manufacturers must develop methods for testing the identity, strength, quality, potency, and purity of the final product. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

### *Marketing Application Submission, Review by the FDA, and Marketing Approval*

Assuming successful completion of the required clinical and preclinical testing, the results of product development, including chemistry, manufacture, and controls, non-clinical studies, and clinical trial results, including negative or ambiguous results, as well as positive findings, are all submitted to the FDA, along with the proposed labeling, as part of an NDA, in the case of a drug, or BLA, in the case of a biologic, requesting approval to market the product for one or more indications. In most cases, the submission of a marketing application is subject to a substantial application user fee. These user fees must be paid at the time of the first submission of the application, even if the application is being submitted on a rolling basis. Fee waivers or



reductions are available in certain circumstances. One basis for a waiver of the application user fee is if the applicant employs fewer than 500 employees, including employees of affiliates, the applicant does not have an approved marketing application for a product that has been introduced or delivered for introduction into interstate commerce, and the applicant, including its affiliates, is submitting its first marketing application. Product candidates that are designated as orphan products, which are further described below, are also not subject to application user fees unless the application includes an indication other than the orphan indication.

In addition, under the Pediatric Research Equity Act, or PREA, a BLA or NDA or supplement to a BLA or NDA for a new active ingredient, indication, dosage form, dosage regimen, or route of administration, must contain data that are adequate to assess the safety and effectiveness of the product for the claimed indications in all relevant pediatric subpopulations, and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDA may, on its own initiative or at the request of the applicant, grant deferrals for submission of some or all pediatric data until after approval of the product for use in adults, or full or partial waivers from the pediatric data requirements. Orphan products are also exempt from the PREA requirements.

The FDA also may require submission of a risk evaluation and mitigation strategy (“REMS”) to ensure that the benefits of the product candidate outweigh the risks. The REMS plan could include medication guides, physician communication plans, and elements to assure safe use, such as restricted distribution methods, patient registries, or other risk minimization tools. An assessment of the REMS must also be conducted at set intervals. Following product approval, a REMS may also be required by the FDA if new safety information is discovered and the FDA determines that a REMS is necessary to ensure that the benefits of the product outweigh the risks.

Once the FDA receives an application, it has 60 days to review the NDA or BLA to determine if it is substantially complete to permit a substantive review, before it accepts the application for filing. The FDA may request additional information. In this event, the application must be resubmitted with the additional information. The resubmitted application is also subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review.

Under the goals and policies agreed to by the FDA under the Prescription Drug User Fee Act (“PDUFA”), the FDA has set the review goal of completing its review of 90% of all applications for new molecular entities within ten months of the 60-day filing date. The FDA also has the review goal of completing its review of 90% of non-new molecular entity marketing applications within ten months of the agency’s receipt of the application. These review goals are referred to as the PDUFA date. The PDUFA date is only a goal, thus, the FDA does not always meet its PDUFA dates. The review process and the PDUFA date may also be extended if the FDA requests or the sponsor otherwise provides substantial additional information or clarification regarding the submission.

The FDA may also refer certain applications to an advisory committee. Before approving a product candidate for which no active ingredient (including any ester or salt of an active ingredients) has previously been approved by the FDA, the FDA must either refer that product candidate to an external advisory committee or provide in an action letter, a summary of the reasons why the FDA did not refer the product candidate to an advisory committee. The FDA may also refer other product candidates to an advisory committee if FDA believes that the advisory committee’s expertise would be beneficial. An advisory committee is typically a panel that includes clinicians and other experts, which review, evaluate, and make a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

The FDA reviews applications to determine, among other things, whether a product candidate meets the agency’s approval standards and whether the manufacturing methods and controls are adequate to assure and preserve the product’s identity, strength, quality, potency, and purity. Before approving a marketing application, the FDA typically will inspect the facility or facilities where the product is manufactured, referred to as a Pre-Approval

Inspection. The FDA will not approve an application unless it determines that the manufacturing processes and facilities, including contract manufacturers and subcontractors, are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving a marketing application the FDA will inspect one or more clinical trial sites to assure compliance with GCPs.

After evaluating the marketing application and all related information, including the advisory committee recommendation, if any, and inspection reports regarding the manufacturing facilities and clinical trial sites, the FDA may issue an approval letter, or, in some cases, a Complete Response Letter (“CRL”). A CRL indicates that the review cycle for the application is complete and the application is not ready for approval. It also describes all of the specific deficiencies that the FDA identified. A CRL generally contains a statement of specific conditions that must be met in order to secure final approval of the marketing application, and may require additional clinical or preclinical testing in order for the FDA to reconsider the application. The deficiencies identified may be minor, for example, requiring labeling changes; or major, for example, requiring additional clinical trials. If a CRL is issued, the applicant may either: resubmit the marketing application, addressing all of the deficiencies identified in the letter; withdraw the application; or request an opportunity for a hearing. The FDA has the goal of reviewing 90% of application resubmissions following a CRL in either two or six months of the resubmission date, depending on the kind of resubmission. Even with submission of this additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval. If and when those conditions have been met to the FDA’s satisfaction, the FDA may issue an approval letter. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications.

Even if the FDA approves a product, it may limit the approved indications or populations for use of the product, require that contraindications, warnings, or precautions be included in the product labeling, including a boxed warning, require that post-approval studies, including Phase 4 clinical trials, be conducted to further assess a product’s safety and efficacy after approval, require testing and surveillance programs to monitor the product after commercialization, or impose other conditions, including distribution restrictions or other risk management mechanisms under a REMS which can materially affect the potential market and profitability of the product. The FDA may also not approve label statements that are necessary for successful commercialization and marketing.

After approval, some types of changes to the approved product, such as adding new indications, manufacturing changes, and additional labeling claims, are subject to further testing requirements and FDA review and approval. The FDA may also withdraw the product approval if compliance with the pre- and post-marketing regulatory standards are not maintained or if problems occur after the product reaches the marketplace. Further, should new safety information arise, additional testing, product labeling changes, or FDA notification may be required.

#### *505(b)(2) New Drug Applications and the Hatch-Waxman Act*

Section 505 of the FDCA describes three types of marketing applications that may be submitted to the FDA to request marketing authorization for a new drug. A Section 505(b)(1) NDA is an application that contains full reports of investigations of safety and efficacy. A 505(b)(2) NDA is an application that contains full reports of investigations of safety and efficacy but where at least some of the information required for approval comes from investigations that were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use. This regulatory pathway enables the applicant to rely, in part, on the FDA’s prior findings of safety and efficacy for an existing product, or published literature, in support of its application. Section 505(j) establishes an abbreviated approval process for a generic version of approved drug products through the submission of an Abbreviated New Drug Application (“ANDA”). An ANDA provides for marketing of a generic drug product that has the same active ingredients, dosage form, strength, route of administration, labeling, performance characteristics and intended use to a previously approved product. ANDAs are termed “abbreviated” because they are generally not required to include preclinical (animal) and clinical (human) data to establish safety and efficacy. Instead, generic applicants must scientifically demonstrate that their product is

bioequivalent to, or performs in the same manner as, the innovator drug through in vitro, in vivo, or other testing. The generic version must deliver the same amount of active ingredients to the site of action in the same amount of time as the innovator drug and can often be substituted by pharmacists under prescriptions written for the reference listed drug.

In seeking approval for a drug through an NDA, applicants are required to list with the FDA each patent with claims that cover the applicant's drug or a method of using the drug, as reflected in the NDA. Upon approval of a drug, each of the patents listed in the application for the drug is published in the FDA's list of Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book. Drugs listed in the Orange Book can, in turn, be cited by potential competitors in support of approval of an ANDA or 505(b)(2) NDA.

Upon submission of an ANDA or a 505(b)(2) NDA, an applicant must certify to the FDA that (1) no patent information has been submitted to the FDA; (2) such patent has expired; (3) the date on which such patent expires; or (4) such patent is invalid or will not be infringed upon by the manufacture, use or sale of the drug product for which the application is submitted. Generally, the ANDA or 505(b)(2) NDA cannot be approved until all listed patents have expired, except where the ANDA or 505(b)(2) NDA applicant challenges a listed patent through the last type of certification, also known as a paragraph IV certification. If the applicant does not challenge the listed patents or does not indicate that it is not seeking approval of a patented method of use, the ANDA or 505(b)(2) NDA application approval will not be made effective until all of the listed patents claiming the referenced product have expired.

If the ANDA or 505(b)(2) NDA applicant has provided a paragraph IV certification to the FDA, the applicant must send notice of the certification to the NDA and patent holders. The NDA and patent holders may then initiate a patent infringement lawsuit in response to the notice of the paragraph IV certification, in which case the FDA may not make an approval effective until the earlier of 30 months from the patent or application owner's receipt of the notice of the paragraph IV certification, the expiration of the patent, when the infringement case concerning each such patent is favorably decided in the applicant's favor or settled, or such shorter or longer period as may be ordered by a court. This prohibition is generally referred to as the 30-month stay. In instances where an ANDA or 505(b)(2) NDA applicant files a paragraph IV certification, the NDA holder or patent owner(s) regularly take action to trigger the 30-month stay. Thus, approval of an ANDA or 505(b)(2) NDA could be delayed for a significant period of time depending on the patent certification the applicant makes and the reference drug sponsor's decision to initiate patent litigation.

The Hatch-Waxman Act establishes periods of regulatory exclusivity for certain approved drug products, during which the FDA cannot accept an ANDA or 505(b)(2) application that relies on the branded reference drug or make an approval of such a product effective. For example, the holder of an NDA, including a 505(b)(2) NDA, may obtain five years of exclusivity upon approval of a new drug containing new chemical entities, or NCEs, that have not been previously approved by the FDA. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion, excluding appended portions that cause the drug to be an ester, salt, or other noncovalent derivative, responsible for the therapeutic activity of the drug substance. During the exclusivity period, the FDA may not accept for review an ANDA or a 505(b)(2) NDA submitted by another company that contains the previously approved active moiety. However, an ANDA or 505(b)(2) NDA may be submitted after four years if it contains a certification of patent invalidity or non-infringement.

The Hatch-Waxman Act also provides three years of marketing exclusivity to the holder of an NDA (including a 505(b)(2) NDA) for a particular condition of approval, or change to a marketed product, such as a new indication or formulation for a previously approved product, if one or more new clinical studies (other than bioavailability or bioequivalence studies) was essential to the approval of the application and was conducted/sponsored by the applicant. This three-year exclusivity period protects against the FDA making an ANDA and 505(b)(2) NDA approval effective for the condition of the new drug's approval. As a general matter, the three-year exclusivity

does not prohibit the FDA from approving ANDAs or 505(b)(2) NDAs for generic or modified versions of the original, unmodified drug product. Five-year and three-year exclusivity will not delay the submission or approval of a full NDA; however, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to all of the preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and efficacy.

### *Biosimilars and Exclusivity*

The Biologics Price Competition and Innovation Act of 2009 (“BPCIA”) creates an abbreviated approval pathway for biological products shown to be highly similar to or interchangeable with an FDA-licensed reference biological product. Biosimilarity sufficient to reference a prior FDA-approved product requires a high similarity to the reference product notwithstanding minor differences in clinically inactive components, and no clinically meaningful differences between the biological product and the reference product in terms of safety, purity, and potency. Biosimilarity must be shown through analytical studies, animal studies, and at least one clinical trial, absent a waiver by the FDA. There must be no difference between the reference product and a biosimilar in mechanism of action, conditions of use, route of administration, dosage form, and strength. A biosimilar product may be deemed interchangeable with a prior approved product if it meets the higher hurdle of demonstrating that it can be expected to produce the same clinical results as the reference product and, for products administered multiple times, the biologic and the reference biologic may be switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic.

A reference biologic is granted 12 years of exclusivity from the time of first licensure, and no application for a biosimilar can be submitted for four years from the date of licensure. However, certain changes and supplements to an approved BLA, and subsequent applications filed by the same sponsor, manufacturer, licensor, predecessor in interest, or other related entity do not qualify for the twelve-year exclusivity period. The PHSA also includes provisions to protect reference products that have patent protection. The biosimilar product sponsor and reference product sponsor may exchange certain patent and product information for the purpose of determining whether there should be a legal patent challenge. Based on the outcome of negotiations surrounding the exchanged information, the reference product sponsor may bring a patent infringement suit and injunction proceedings against the biosimilar product sponsor. The biosimilar applicant may also be able to bring an action for declaratory judgment concerning the patent.

### *Pediatric Exclusivity*

Pediatric exclusivity is another type of non-patent marketing exclusivity in the United States and, if granted, provides for the attachment of an additional six months of marketing protection to the term of any existing regulatory exclusivity for both drugs and biologics, and also Orange Book listed patents in the case of drugs. This six-month exclusivity may be granted if a sponsor submits pediatric data that fairly respond to a written request from the FDA for such data. The data do not need to show the product to be effective in the pediatric population studied; rather, if the clinical trial is deemed to fairly respond to the FDA’s request, the additional protection is granted.

### *Orphan Products*

The Orphan Drug Act provides incentives for the development of products for rare diseases or conditions. Specifically, sponsors may apply for and receive Orphan Drug Designation (“ODD”) if a product candidate is intended to treat rare diseases or conditions, which generally are diseases or conditions affecting less than 200,000 individuals in the United States, or affecting more than 200,000 in the United States and for which there is no reasonable expectation that the cost of developing and making the product available in the United States will be recovered from United States sales. Additionally, sponsors must present a plausible hypothesis for clinical superiority to obtain ODD if there is a product already approved by the FDA that that is considered by

the FDA to be the same as the already approved product and is intended for the same indication. This hypothesis must be demonstrated to obtain orphan exclusivity. If granted, prior to product approval, ODD entitles a party to financial incentives such as opportunities for grant funding towards clinical study costs, tax advantages, and certain user-fee waivers. The tax advantages, however, were limited in the 2017 Tax Cuts and Jobs Act. In addition, if a product candidate receives FDA approval for the indication for which it has ODD, the product is generally entitled to orphan exclusivity, which means the FDA may not approve any other application to market the same product for the same indication for a period of seven years, except in limited circumstances, such as a showing of clinical superiority over the product with orphan exclusivity.

#### *Patent Term Restoration*

If approved, drug and biologic products may also be eligible for periods of U.S. patent term restoration. If granted, patent term restoration extends the patent life of a single unexpired patent, that has not previously been extended, for a maximum of five years. The total patent life of the product with the extension also cannot exceed fourteen years from the product' approval date. Subject to the prior limitations, the period of the extension is calculated by adding half of the time from the effective date of an IND to the initial submission of a marketing application, and all of the time between the submission of the marketing application and its approval. This period may also be reduced by any time that the applicant did not act with due diligence.

#### *Special FDA Expedited Review and Approval Programs*

The FDA has various programs that are intended to expedite or simplify the process for the development and FDA review of certain products that are intended for the treatment of serious or life threatening diseases or conditions, and demonstrate the potential to address unmet medical needs or present a significant improvement over existing therapy. The purpose of these programs is to provide important new therapeutics to patients earlier than under standard FDA review procedures.

To be eligible for a Fast Track designation, the FDA must determine, based on the request of a sponsor, that a product candidate is intended to treat a serious or life threatening disease or condition and demonstrates the potential to address an unmet medical need. If Fast Track designation is obtained, sponsors may be eligible for more frequent development meetings and correspondence with the FDA. In addition, the FDA may initiate review of sections of an application before the application is complete. This "rolling review" is available if the applicant provides and the FDA approves a schedule for the remaining information. Whether FDA is able to commence its review of portions of an application, however, before receipt of the complete submission, depends on a number of factors. In some cases, a Fast Track product may be eligible for accelerated approval or priority review.

The FDA may give a priority review designation to product candidates that are intended to treat serious conditions and, if approved, would provide significant improvements in the safety or effectiveness of the treatment, diagnosis, or prevention of the serious condition. A priority review means that the goal for the FDA is to review an application within six months, rather than the standard review of ten months under current PDUFA guidelines.

Drug or biological products studied for their safety and effectiveness in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit over existing treatments may receive accelerated approval, which means the FDA may approve the product based upon a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. A drug or biologic candidate approved on this basis is subject to rigorous post-marketing compliance requirements, including the completion of Phase 4 or post-approval clinical trials to confirm the effect of the product. Failure to conduct required post-approval studies, or confirm a clinical benefit during

post-marketing studies, will allow the FDA to withdraw the drug or biologic from the market on an expedited basis. All promotional materials for drug or biologic candidates approved under accelerated regulations are subject to prior review by the FDA.

Under the provisions of the Food and Drug Administration Safety and Innovation Act (“FDASIA”), enacted in 2012, a sponsor can request designation of a product candidate as a “breakthrough therapy.” A breakthrough therapy is defined as a product that is intended, alone or in combination with one or more other products, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. Products designated as breakthrough therapies are eligible for intensive guidance on an efficient development program beginning as early as Phase 1 trials, a commitment from the FDA to involve senior managers and experienced review staff in a proactive collaborative and cross-disciplinary review, rolling review, and the facilitation of cross-disciplinary review.

Even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

### *Post-approval Requirements*

Any products manufactured or distributed pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements related to manufacturing, recordkeeping, and reporting, including adverse experience reporting, deviation reporting, shortage reporting, and periodic reporting, product sampling and distribution, advertising, marketing, promotion, certain electronic records and signatures, and post-approval obligations imposed as a condition of approval, such as Phase 4 clinical trials, REMS, and surveillance to assess safety and effectiveness after commercialization.

After approval, most changes to the approved product, such as adding new indications or other labeling claims are subject to prior FDA review and approval. There also are continuing annual program user fee requirements for approved products, excluding orphan products. In addition, manufacturers and other entities involved in the manufacture and distribution of approved therapeutics are required to register their establishments with the FDA and certain state agencies, list their products, and are subject to periodic announced and unannounced inspections by the FDA and these state agencies for compliance with cGMP and other requirements. Manufacturers must continue to expend time, money, and effort in the areas of production and quality-control to maintain compliance with cGMPs. Regulatory authorities may undertake regulatory enforcement action, withdraw product approvals, require label modifications, or request product recalls, among other actions, if a company fails to comply with regulatory standards, if it encounters problems following initial marketing, or if previously unrecognized problems are subsequently discovered.

Changes to the manufacturing process are strictly regulated and often require prior FDA approval or notification before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and specifications, and impose reporting and documentation requirements upon the sponsor and any third-party manufacturers that the sponsor may decide to use. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance.

The FDA also strictly regulates marketing, labeling, advertising, and promotion of products that are placed on the market. A company can make only those claims relating to a product that are approved by the FDA. Physicians, in their independent professional medical judgment, may prescribe legally available products for unapproved indications that are not described in the product’s labeling and that differ from those tested and approved by the FDA. Biopharmaceutical companies, however, are required to promote their products only for the approved indications and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have

improperly promoted off-label uses may be subject to significant liability, including, but not limited to, criminal and civil penalties under the FDCA and False Claims Act, exclusion from participation in federal healthcare programs, mandatory compliance programs under corporate integrity agreements, suspension and debarment from government contracts, and refusal of orders under existing government contracts.

In addition, the distribution of prescription biopharmaceutical samples is subject to the Prescription Drug Marketing Act, (“PDMA”), which regulates the distribution of samples at the federal level. Both the PDMA and state laws limit the distribution of prescription biopharmaceutical product samples and impose requirements to ensure accountability in distribution. Free trial or starter prescriptions provided through pharmacies are also subject to regulations under the Medicaid Drug Rebate Program and potential liability under anti-kickback and false claims laws.

Moreover, the enacted Drug Quality and Security Act (“DQSA”) imposes obligations on sponsors of biopharmaceutical products related to product tracking and tracing. Among the requirements of this legislation, sponsors are required to provide certain information regarding the products to individuals and entities to which product ownership is transferred, are required to label products with a product identifier, and are required to keep certain records regarding the product. The transfer of information to subsequent product owners by sponsors is also required to be done electronically. Sponsors must also verify that purchasers of the sponsors’ products are appropriately licensed. Further, under this legislation, manufactures have product investigation, quarantine, disposition, and notification responsibilities related to counterfeit, diverted, stolen, and intentionally adulterated products that would result in serious adverse health consequences or death to humans, as well as products that are the subject of fraudulent transactions or which are otherwise unfit for distribution such that they would be reasonably likely to result in serious health consequences or death. Similar requirements additionally are and will be imposed through this legislation on other companies within the biopharmaceutical product supply chain, such as distributors and dispensers, as well as certain sponsor licensees and affiliates.

Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in significant regulatory actions. Such actions may include refusal to approve pending applications, license or approval suspension or revocation, imposition of a clinical hold or termination of clinical trials, warning letters, untitled letters, cyber letters, modification of promotional materials or labeling, provision of corrective information, imposition of post-market requirements including the need for additional testing, imposition of distribution or other restrictions under a REMS, product recalls, product seizures or detentions, refusal to allow imports or exports, total or partial suspension of production or distribution, FDA debarment, injunctions, fines, consent decrees, corporate integrity agreements, suspension and debarment from government contracts, and refusal of orders under existing government contracts, exclusion from participation in federal and state healthcare programs, restitution, disgorgement, or civil or criminal penalties, including fines and imprisonment, and adverse publicity, among other adverse consequences.

#### *Additional controls for biologics*

To help reduce the increased risk of the introduction of adventitious agents, the PHSA emphasizes the importance of manufacturing controls for products whose attributes cannot be precisely defined. The PHSA also provides authority to the FDA to immediately suspend licenses in situations where there exists a danger to public health, to prepare or procure products in the event of shortages and critical public health needs, and to authorize the creation and enforcement of regulations to prevent the introduction or spread of communicable diseases in the United States and between states.

After a BLA is approved, the product may also be subject to official lot release as a condition of approval. As part of the manufacturing process, the manufacturer is required to perform certain tests on each lot of the product before it is released for distribution. If the product is subject to official release by the FDA, the manufacturer submits samples of each lot of product to the FDA together with a release protocol showing the results of all of

the manufacturer's tests performed on the lot. The FDA may also perform certain confirmatory tests on lots of some products before releasing the lots for distribution by the manufacturer.

In addition, the FDA conducts laboratory research related to the regulatory standards on the safety, purity, potency, and effectiveness of biological products.

Gene therapy products are also subject to the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules ("NIH Guidelines"), which require, among other things, that trials involving recombinant or synthetic nucleic acid molecules be reviewed by an institutional biosafety committee ("IBC"). The IBC reviews, approves, and supervise research involving recombinant or synthetic nucleic acid molecules.

In addition to the regulations discussed above, there are a number of additional standards that apply to clinical trials involving the use of gene therapy. The FDA has issued various guidance documents regarding gene therapies, which outline additional factors that the FDA will consider during product development. By example, the FDA recommends that sponsors observe subjects for potential gene therapy-related delayed adverse events for a prolonged period of time.

#### *Fraud and Abuse, Data Privacy and Security, and Transparency Laws and Regulations*

Ocugen's business activities, including but not limited to, research, sales, promotion, distribution, medical education, and other activities following product approval will be subject to regulation by numerous federal and state regulatory and law enforcement authorities in the United States in addition to the FDA, including potentially the Department of Justice, the Department of Health and Human Services and its various divisions, including the Centers for Medicare and Medicaid Services ("CMS") and the Health Resources and Services Administration, the Department of Veterans Affairs, the Department of Defense, and state and local governments. Its business activities must comply with numerous healthcare laws, including but not limited to, anti-kickback and false claims laws and regulations as well as data privacy and security laws and regulations, which are described below, as well as state and federal consumer protection and unfair competition laws. Moreover, to the extent that Ocugen licenses the right to sell its product candidates, if approved, to another entity under that entity's labeler code, the licensee would have regulatory responsibilities, including healthcare, reimbursement, pricing, and reporting regulatory responsibilities.

The federal Anti-Kickback Statute, which regulates, among other things, marketing practices, educational programs, pricing policies, and relationships with healthcare providers or other entities, prohibits, among other things, any person or entity, from knowingly and willfully offering, paying, soliciting, or receiving any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or in return for purchasing, leasing, ordering, or arranging for or recommending the purchase, lease, or order, or the referral to another for the furnishing or arranging for the furnishing of any item or service reimbursable under Medicare, Medicaid, or other federal healthcare programs, in whole or in part. The term "remuneration" has been interpreted broadly to include anything of value. The Anti-Kickback Statute has been interpreted to apply to arrangements between biopharmaceutical industry members on one hand and prescribers, purchasers, formulary managers, and beneficiaries on the other. There are certain statutory exceptions and regulatory safe harbors protecting some common activities from prosecution. The exceptions and safe harbors are drawn narrowly, and practices that involve remuneration that may be alleged to be intended to induce prescribing, purchases, or recommendations may be subject to scrutiny if they do not qualify for an exception or safe harbor. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the Anti-Kickback Statute. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all of its facts and circumstances. Several courts have interpreted the statute's intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of federal healthcare covered business, including purchases of products paid by federal healthcare programs, the statute has been violated. The Patient Protection and Affordable Care Act of 2010, as amended ("ACA"), modified the intent requirement under the Anti-Kickback Statute to a stricter



standard, such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. In addition, the ACA also provided that a violation of the federal Anti-Kickback Statute is grounds for the government or a whistleblower to assert that a claim for payment of items or services resulting from such violation constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act.

The federal civil False Claims Act (“FCA”) prohibits, among other things, any person or entity from knowingly presenting, or causing to be presented, a false or fraudulent claim for payment to, or approval by, the federal government, knowingly making, using, or causing to be made or used a false record or statement material to a false or fraudulent claim to the federal government, or avoiding, decreasing, or concealing an obligation to pay money to the federal government. A claim includes “any request or demand” for money or property presented to the U.S. government. The civil False Claims Act has been used to assert liability on the basis of kickbacks and other improper referrals, improperly reported government pricing metrics such as Best Price or Average Manufacturer Price, improper use of Medicare provider or supplier numbers when detailing a provider of services, improper promotion of off-label uses not expressly approved by the FDA in a product’s label, and allegations as to misrepresentations with respect to products, contract requirements, and services rendered. In addition, private payers have been filing follow-on lawsuits alleging fraudulent misrepresentation, although establishing liability and damages in these cases is more difficult than under the FCA. Intent to deceive is not required to establish liability under the civil False Claims Act. Civil False Claims Act actions may be brought by the government or may be brought by private individuals on behalf of the government, called “qui tam” actions. If the government decides to intervene in a qui tam action and prevails in the lawsuit, the individual will share in the proceeds from any fines or settlement funds. If the government declines to intervene, the individual may pursue the case alone. The civil FCA provides for treble damages and a civil penalty for each false claim, such as an invoice or pharmacy claim for reimbursement, which can aggregate into millions of dollars. For these reasons, since 2004, False Claims Act lawsuits against biopharmaceutical companies have increased significantly in volume and breadth, leading to several substantial civil and criminal settlements, as much as \$3.0 billion, regarding certain sales practices and promoting off label uses. Civil False Claims act liability may further be imposed for known Medicare or Medicaid overpayments, for example, overpayments caused by understated rebate amounts, that are not refunded within 60 days of discovering the overpayment, even if the overpayment was not caused by a false or fraudulent act. In addition, conviction or civil judgment for violating the FCA may result in exclusion from federal health care programs, and suspension and debarment from government contracts, and refusal of orders under existing government contracts.

The government may further prosecute conduct constituting a false claim under the criminal False Claims Act. The criminal False Claims Act prohibits the making or presenting of a claim to the government knowing such claim to be false, fictitious, or fraudulent and, unlike the civil False Claims Act, requires proof of intent to submit a false claim.

The civil monetary penalties statute is another potential statute under which biopharmaceutical companies may be subject to enforcement. Among other things, the civil monetary penalties statute imposes fines against any person who is determined to have knowingly presented, or caused to be presented, claims to a federal healthcare program that the person knows, or should know, is for an item or service that was not provided as claimed or is false or fraudulent.

Payment or reimbursement of prescription therapeutics by Medicaid or Medicare requires the product’s labeler to submit certified pricing information to CMS. The Medicaid Drug Rebate statute requires labelers, as a condition of payment by Medicaid, to calculate and report price points, which are used to determine Medicaid rebate payments shared between the states and the federal government and Medicaid payment rates for certain therapeutics, to pay quarterly rebates on prescriptions paid by Medicaid, and to provide a discount based on the Medicaid rebate percentage to certain hospitals and clinics under the 340B program. For most therapeutics paid under Medicare Part B, labelers must also calculate and report their Average Sales Price, which is used to determine the Medicare Part B payment rate. In addition, therapeutics covered by Medicaid are subject to an

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additional inflation penalty which can substantially increase rebate payments. For products approved under a BLA (including biosimilars) or an NDA, the Veterans Health Care Act (“VHCA”) requires labelers, as a condition of payment by Medicaid, to calculate and report to the Veterans Administration (“VA”) a different price called the Non-Federal Average Manufacturing Price, which is used to determine the maximum price that can be charged to certain federal agencies, referred to as the Federal Ceiling Price, or FCP. Like the Medicaid rebate amount, the FCP includes an inflation penalty. A Department of Defense statute and regulation requires labelers to provide this discount on therapeutics dispensed by retail pharmacies when paid by the TRICARE Program. All of these price reporting requirements create risk of submitting false information to the government, and potential FCA liability.

The VHCA also requires labelers of covered therapeutics participating in the Medicaid program to enter into Federal Supply Schedule contracts with the VA through which their covered therapeutics must be sold to certain federal agencies at FCP. This necessitates compliance with applicable federal procurement laws and regulations, including submission of commercial sales and pricing information, and subjects Ocugen to contractual remedies as well as administrative, civil, and criminal sanctions. In addition, the VHCA requires labelers participating in Medicaid to agree to provide different mandatory discounts to certain Public Health Service grantees and other safety net hospitals and clinics under the 340B program based on the labelers’s reported Medicaid pricing information. The 340B program has its own regulatory authority to impose sanctions for non-compliance and adjudicate overcharge claims against labelers by the purchasing entities.

The federal Health Insurance Portability and Accountability Act of 1996 (“HIPAA”) also created federal criminal statutes that prohibit, among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud or to obtain, by means of false or fraudulent pretenses, representations or promises, any of the money or property owned by, or under the custody or control of, a healthcare benefit program, regardless of whether the payor is public or private, in connection with the delivery or payment for health care benefits, knowingly and willfully embezzling or stealing from a health care benefit program, willfully obstructing a criminal investigation of a health care offense and knowingly and willfully falsifying, concealing, or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items, or services relating to healthcare matters. Additionally, the ACA amended the intent requirement of certain of these criminal statutes under HIPAA so that a person or entity no longer needs to have actual knowledge of the statute, or the specific intent to violate it, to have committed a violation.

The ACA further created new federal requirements for reporting, by applicable drug manufacturers of covered therapeutics, payments and other transfers of value to physicians and teaching hospitals, and ownership and investment interests held by physicians and other healthcare providers and their immediate family members.

Further, Ocugen may be subject to data privacy and security regulation by both the federal government and the states in which Ocugen conducts its business. HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act (“HITECH”) and its respective implementing regulations imposes certain requirements on covered entities relating to the privacy, security, and transmission of certain individually identifiable health information, known as protected health information. Among other things, HITECH, through its implementing regulations, makes HIPAA’s security standards and certain privacy standards directly applicable to business associates, defined as a person or organization, other than a member of a covered entity’s workforce, that creates, receives, maintains, or transmits protected health information on behalf of a covered entity for a function or activity regulated by HIPAA. HITECH also strengthened the civil and criminal penalties that may be imposed against covered entities, business associates, and individuals, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys’ fees and costs associated with pursuing federal civil actions. In addition, other federal and state laws may govern the privacy and security of health and other information in certain circumstances, many of which differ from each other in significant ways and may not be preempted by HIPAA, thus complicating compliance efforts.

Many states have also adopted laws similar to each of the above federal laws, which may be broader in scope and apply to items or services reimbursed by any third-party payor, including commercial insurers. Certain state laws

also regulate sponsors' use of prescriber-identifiable data. Certain states also require implementation of commercial compliance programs and compliance with the pharmaceutical industry's voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government, or otherwise restrict payments or the provision of other items of value that may be made to healthcare providers and other potential referral sources; impose restrictions on marketing practices; or require drug companies to track and report information related to payments, gifts, and other items of value to physicians and other healthcare providers. Recently, states have enacted or are considering legislation intended to make drug prices more transparent and deter significant price increases, typically as consumer protection laws. These laws may affect its future sales, marketing, and other promotional activities by imposing administrative and compliance burdens.

If Ocugen's operations are found to be in violation of any of the laws or regulations described above or any other applicable laws, Ocugen may be subject to penalties or other enforcement actions, including criminal and significant civil monetary penalties, damages, fines, disgorgement, imprisonment, exclusion from participation in government healthcare programs, corporate integrity agreements, suspension and debarment from government contracts, and refusal of orders under existing government contracts, reputational harm, diminished profits and future earnings, and the curtailment or restructuring of its operations, any of which could adversely affect its ability to operate its business and its results of operations. Enforcement actions can be brought by federal or state governments, or as "qui tam" actions brought by individual whistleblowers in the name of the government under the civil False Claims Act if the violations are alleged to have caused the government to pay a false or fraudulent claim.

To the extent that any of its products are sold in a foreign country, Ocugen may be subject to similar foreign laws and regulations, which may include, for instance, applicable post-marketing requirements, including safety surveillance, anti-fraud and abuse laws, and implementation of corporate compliance programs and reporting of payments or transfers of value to healthcare professionals.

### ***Coverage and Reimbursement Generally***

The commercial success of its product candidates and its ability to commercialize any approved product candidates successfully will depend in part on the extent to which governmental payor programs at the federal and state levels, including Medicare and Medicaid, private health insurers, and other third-party payors provide coverage for and establish adequate reimbursement levels for its product candidates. Government authorities, private health insurers, and other organizations generally decide which therapeutics they will pay for and establish reimbursement levels for healthcare. Medicare is a federally funded program managed by CMS through local fiscal intermediaries and carriers that administer coverage and reimbursement for certain healthcare items and services furnished to the elderly and disabled. Medicaid is an insurance program for certain categories of patients whose income and assets fall below state defined levels and who are otherwise uninsured that is both federally and state funded and managed by each state. The federal government sets general guidelines for Medicaid and each state creates specific regulations that govern its individual program, including supplemental rebate programs that restrict coverage to therapeutics on the state Preferred Drug List. Similarly, government laws and regulations establish the parameters for coverage of prescription therapeutics by health plans participating in state exchanges and Tricare, the health care program for military personnel, retirees, and related beneficiaries. Some states have also created pharmacy assistance programs for individuals who do not qualify for federal programs. In the United States, private health insurers and other third-party payors often provide reimbursement for products and services based on the level at which the government provides reimbursement through the Medicare or Medicaid programs for such products and services.

In the United States, the European Union, and other potentially significant markets for its product candidates, government authorities and third-party payors are increasingly attempting to limit or regulate the price of medical products and services, particularly for new and innovative products and therapies, which often has resulted in average selling prices lower than they would otherwise be and sometimes at or below the provider's acquisition cost. In the United States, it is also common for government and private health plans to use coverage

determinations to leverage rebates from labelers in order to reduce the plans' net costs. These restrictions and limitations influence the purchase of healthcare services and products and lower the realization on labelers' sales of prescription therapeutics. Third-party payors are developing increasingly sophisticated methods of controlling healthcare costs. Third-party payors may limit coverage to specific therapeutic products on an approved list, or formulary, which might not include all of the FDA-approved products for a particular indication or might impose high copayment amounts to influence patient choice. Third-party payors also control costs by requiring prior authorization or imposing other dispensing restrictions before covering certain products and by broadening therapeutic classes to increase competition. Third-party payors are increasingly challenging the price and examining the medical necessity and cost-effectiveness of medical products and services, in addition to their safety and efficacy. Absent clinical differentiators, third-party payors may treat products as therapeutically equivalent and base formulary decisions on net cost. To lower the prescription cost, labelers frequently rebate a portion of the prescription price to the third-party payors. Recently, purchasers and third-party payors have begun to focus on value of new therapeutics and sought agreements in which price is based on achievement of performance metrics.

Federal programs also impose price controls through mandatory ceiling prices on purchases by federal agencies and federally funded hospitals and clinics and mandatory rebates on retail pharmacy prescriptions paid by Medicaid and Tricare. These restrictions and limitations influence the purchase of healthcare services and products. Legislative proposals to reform healthcare or reduce costs under government programs may result in lower reimbursement for its product candidates or exclusion of its product candidates from coverage. In addition, government programs like Medicaid include substantial penalties for increasing commercial prices over the rate of inflation which can affect realization and return on investment.

Private payors often rely on the lead of the governmental payors in rendering coverage and reimbursement determinations. Therefore, achieving favorable CMS coverage and reimbursement is usually a significant gating issue for successful introduction of a new product. In addition, many government programs as a condition of participation mandate fixed discounts or rebates from labelers regardless of formulary position or utilization, and then rely on competition in the market to attain further price reductions, which can greatly reduce realization on the sale.

Further, the increased emphasis on managed healthcare in the United States and on country and regional pricing and reimbursement controls in the European Union will put additional pressure on product pricing, reimbursement, and utilization, which may adversely affect its future product sales and results of operations. These pressures can arise from rules and practices of managed care groups, competition within therapeutic classes, judicial decisions and governmental laws and regulations related to Medicare, Medicaid, and healthcare reform, biopharmaceutical coverage and reimbursement policies, and pricing in general. Patients who are prescribed treatments for their conditions and providers performing the prescribed services generally rely on third-party payors to reimburse all or part of the associated healthcare costs. Sales of its product candidates will therefore depend substantially, both domestically and abroad, on the extent to which the costs of its products will be paid by health maintenance, managed care, pharmacy benefit and similar healthcare management organizations, or reimbursed by government health administration authorities, such as Medicare and Medicaid, private health insurers, and other third-party payors.

As a result of the above, Ocugen may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of its products, in addition to the costs required to obtain the FDA approvals. Its product candidates may not be considered medically necessary or cost-effective, or the rebate percentages required to secure coverage may not yield an adequate margin over cost. Additionally, companies are increasingly finding it necessary to establish bridge programs to assist patients access new therapies during protracted initial coverage determination periods.

Moreover, a payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved or that significant price concessions will not be required to avoid restrictive conditions.

High health plan co-payment requirements may result in patients refusing prescriptions or seeking alternative therapies. Additionally, where a new indication has been approved for a drug previously approved under a different NDA, health plans may cover off-label use of the original drug, even if it cannot be marketed for the new indication. Adequate third-party reimbursement may not be available to enable Ocugen to maintain price levels sufficient to realize an appropriate return on its investment in therapeutic development. Legislative proposals to reform healthcare or reduce costs under government insurance programs may result in lower reimbursement for its products and product candidates or exclusion of its products and product candidates from coverage. The cost containment measures that healthcare payors and providers are instituting and any healthcare reform could significantly reduce its revenues from the sale of any approved product candidates. Ocugen cannot provide any assurances that Ocugen will be able to obtain and maintain third-party coverage or adequate reimbursement for its product candidates in whole or in part.

### ***Healthcare Reform Measures***

The United States and some foreign jurisdictions are considering or have enacted a number of legislative and regulatory proposals designed to change the healthcare system in ways that could affect its ability to sell its products profitably. Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality, and expanding access. In the United States, the biopharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives.

For example, the ACA created hybrid payment methodology for biosimilars under Medicare Part B, which covers products administered by physicians in an outpatient setting, intended to neutralize the incentive to purchase higher priced biologics reimbursed at Average Sales Price (“ASP”) plus 6% of ASP by paying providers ASP of a biosimilar but adding the margin based on ASP of the reference biologic. More recently, the Bipartisan Budget Act extended labeler responsibility for prescription costs in the Medicare Part D coverage gap to biosimilars, which had previously been exempt.

Similarly, the American Recovery and Reinvestment Act of 2009 established funding for the federal government to compare the effectiveness of different treatments for the same illness. The Agency for Healthcare Research and Quality among other things, conducts patient-centered outcome research, develops evidence-based tools and resources on medication therapies, maintains databases of health care related data and standards, and issues periodic reports on specific studies. Although the results of the comparative effectiveness studies are not intended to mandate coverage policies for public or private payors, it is not clear what effect, if any, the organization’s research has had or will have on the sales of any product, if any such product or the condition that it is intended to treat is the subject of a study. It is also possible that comparative effectiveness research demonstrating benefits in a competitor’s product could adversely affect the sales of its product candidates. If third-party payors do not consider its product candidates to be cost-effective compared to other available therapies, they may not cover its product candidates or may severely restrict access, once approved, as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow Ocugen to sell its products on a profitable basis.

Moreover, the ACA broadened access to health insurance, attempts to reduce or constrain the growth of healthcare spending, enhanced remedies against fraud and abuse, added new transparency requirements for healthcare and health insurance industries, imposed new taxes and fees on the health care industry, and imposed additional health policy reforms. The law expanded the eligibility criteria and mandatory eligibility categories for Medicaid programs, thereby potentially increasing both the volume of sales and labelers’ Medicaid rebate liability. The law also expanded the 340B discount program that mandates discounts to certain hospitals, community centers, and other qualifying providers, by expanding the categories of entities eligible to purchase under the program, although, with the exception of children’s hospitals, these newly eligible entities are ineligible to receive discounted 340B pricing on orphan therapeutics used to treat an orphan disease or condition. The ACA revised the definition of “average manufacturer price (AMP)” for reporting purposes, which generally increased the amount of Medicaid rebates to states and created a separate AMP for certain categories of

therapeutics provided in non-retail outpatient settings. The law additionally extended labeler's Medicaid rebate liability to covered therapeutics dispensed to patients enrolled in Medicaid managed care organizations and increased the statutory minimum rebates a labeler must pay under the Medicaid Drug Rebate program. The revisions to the AMP definition and Medicaid rebate formula can have the further effect of increasing the required 340B discounts. Further, the ACA requires labelers of therapeutics, to pay 50% of the pharmacy charge to Medicare Part D patients while they are in the coverage gap, and this percentage was increased to 70% by the Bipartisan Budget Act of 2018. Finally, the ACA imposes a significant annual fee on companies that manufacture or import branded prescription therapeutic products. Substantial new provisions affecting compliance have also been enacted through the ACA and otherwise, including the reporting of therapeutic sample distribution, which may require Ocugen to modify its business practices with healthcare practitioners. Although the ACA was recently amended to repeal the individual insurance mandate, and efforts to repeal and replace portions of the law may continue, it is likely that pressure on biopharmaceutical pricing, especially under the Medicare program, will continue, and may also increase its regulatory burdens and operating costs. Moreover, in the coming years, additional changes could be made to governmental healthcare programs that could significantly impact the success of its product candidates.

The cost of biopharmaceuticals continues to generate substantial governmental and third-party payor interest. Ocugen expects that the biopharmaceutical industry will experience pricing pressures due to the trend toward managed healthcare, the increasing influence of managed care organizations and additional legislative proposals. Its results of operations could be adversely affected by current and future healthcare reforms.

Some third-party payors also require pre-approval of coverage for new or innovative devices or therapies before they will reimburse healthcare providers that use such therapies. While Ocugen cannot predict whether any proposed cost-containment measures will be adopted or otherwise implemented in the future, the announcement or adoption of these proposals could have a material adverse effect on its ability to obtain adequate prices for its product candidates and operate profitably.

In addition, other legislative and regulatory changes have been proposed and adopted since the ACA was enacted. The Budget Control Act of 2011, as amended, created the Joint Select Committee on Deficit Reduction to recommend proposals in spending reductions to Congress. The Joint Select Committee on Deficit Reduction did not achieve its targeted deficit reduction of at least \$1.2 trillion for the years 2013 through 2021, triggering the legislation's automatic reductions to several government programs. These reductions include aggregate reductions to Medicare payments to providers of up to 2% per fiscal year. The Bipartisan Budget Act of 2018 retained the federal budget "sequestration" Medicare payment reductions of 2%, and extended it through 2027 unless congressional action is taken, and also increased labeler responsibility for prescription costs in the Medicare Part D coverage gap. The American Taxpayer Relief Act of 2012, further reduced Medicare payments to several categories of healthcare providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These and other healthcare reform initiatives may result in additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on its financial operations. Ocugen expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could further limit the prices Ocugen is able to charge, or the amounts of reimbursement available, for its product candidates once they are approved.

In 2016, CMS issued a final rule regarding the Medicaid drug rebate program. The final rule, effective April 1, 2016, among other things, extended labeler rebate obligations to U.S. territories, revised the manner in which the "average manufacturer price" is calculated by labelers participating in the program, and implements certain amendments to the Medicaid rebate statute created under the ACA. At the state level, legislatures are increasingly passing legislation and implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. The full impact of these laws, as well as other new laws and reform

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measures that may be proposed and adopted in the future remains uncertain, but may result in additional reductions in Medicare and other health care funding, or higher production costs which could have a material adverse effect on its customers and, accordingly, its financial operations.

There have been several recent U.S. Congressional inquiries and proposed and adopted federal and state legislation designed to, among other things, bring more transparency to drug pricing and deter price increases, review the relationship between pricing and sponsor patient programs, and reform government program reimbursement methodologies for drugs. Further, the current U.S. Presidential administration's budget proposal for fiscal year 2019 contained proposed policy changes and further drug price control measures that could be enacted in future legislation, including, for example, imposition of an inflation penalty on drugs paid by Medicare, basing Medicare Part B payment on an index of foreign prices, and measures to permit Medicare Part D plans to limit the number of drugs in therapeutic classes and negotiate the price of certain drugs under Medicare Part B, to allow some states to negotiate drug prices under Medicaid, and to eliminate cost sharing for generic drugs for low-income patients. Currently under review is a proposal concerning the Anti-Kickback Statute safe harbor for rebates paid to pharmacy benefit managers. While any proposed measures will require authorization through additional legislation to become effective, Congress and the current U.S. Presidential administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs.

### ***The Foreign Corrupt Practices Act***

The Foreign Corrupt Practices Act ("FCPA") prohibits any U.S. individual or business from paying, offering, or authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party, or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations. Activities that violate the FCPA, even if they occur wholly outside the United States, can result in criminal and civil fines, imprisonment, disgorgement, oversight, and suspension and debarment from government contracts, and refusal of orders under existing government contracts.

### **EMPLOYEES**

Ocugen has 13 full-time employees as of July 12, 2019. None of its employees are represented by any collective bargaining unit, and Ocugen believes that it maintains good relations with its employees.

### **FACILITIES**

Ocugen's headquarters are located in Malvern, Pennsylvania, and consist of an aggregate of approximately 8,038 square feet of leased office space under one lease that expires on February 28, 2022. Ocugen currently subleases laboratory space from another company in Malvern, Pennsylvania pursuant to an agreement that expires on June 30, 2020.

### **LEGAL PROCEEDINGS**

Ocugen currently is not subject to any material legal proceedings.

## HISTOGENICS MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

*The following discussion and analysis should be read in conjunction with Histogenics' audited annual consolidated financial statements and the related notes that appear elsewhere in this proxy statement/prospectus/information statement. This discussion contains forward-looking statements reflecting Histogenics' current expectations that involve risks and uncertainties. Actual results may differ materially from those discussed in these forward-looking statements due to a number of factors, including those set forth in the section entitled "Risk Factors" and elsewhere in this proxy statement/prospectus/information statement. For further information regarding forward-looking statements, please refer to the "Special Note Regarding Forward-Looking Statements" in this proxy statement/prospectus/information statement.*

### Overview

Histogenics historically focused on the development of restorative cell therapies ("RCTs"). Histogenics uses the term RCT to refer to a new class of products that are designed to offer patients rapid-onset pain relief and restored function through the repair of damaged or worn tissue. Histogenics' product, NeoCart®, is an innovative cell therapy that utilizes various aspects of Histogenics' RCT platform to treat tissue injury in the field of orthopedics, specifically cartilage damage in the knee.

NeoCart is based on Histogenics' RCT platform, which Histogenics believes has the potential to be used for a broad range of additional therapeutic indications and combines expertise in the following areas:

- Cell therapy and processing: the handling of tissue biopsies and the extraction, isolation and expansion of the cells;
- Biomaterials and Scaffold: three-dimensional biomaterials structures that enable the proper delivery, distribution and organization of cells in their natural environment to support tissue formation;
- Tissue engineering: the use of a combination of cells, engineering and biomaterials to improve or restore biological functions; and
- Bioadhesives: natural, biocompatible materials that act as adhesives for biological tissue and allow for natural cell and tissue infiltration and integration with native cells.

In the third quarter of 2018, Histogenics announced that its Phase 3 clinical trial of NeoCart did not meet the primary endpoint of a statistically significant improvement in pain and function in a dual threshold responder analysis one year after treatment as compared to microfracture. In the modified Intent to Treat ("mITT") population (which excludes those patients who were randomized but not treated with NeoCart), 74.2% of the NeoCart patients exhibited clinically meaningful improvements in pain and function compared to 62.0% of microfracture patients at one year ( $p=0.071$ ). However, in this mITT population, patients treated with NeoCart achieved a statistically significant improvement in pain and function ( $p=0.018$ ) six months after treatment as compared to patients treated with microfracture. In addition, NeoCart achieved a statistically significant improvement in pain and function at one year in certain patient populations including patients with lesion sizes greater than 2.2 cm<sup>2</sup> and those with a Body Mass Index, or BMI, of greater than 28. Both NeoCart and microfracture were well tolerated and exhibited strong safety profiles.

Based on the totality of the data, Histogenics initiated a dialogue with the United States Food and Drug Administration (the "FDA") in the third quarter of 2018 to discuss the regulatory path forward for NeoCart. Histogenics' primary objective in these discussions was to determine whether the FDA would accept a submission of a Biologics License Application ("BLA") for NeoCart without data from an additional clinical trial. Histogenics had a constructive dialogue with the FDA, which included requests for and review of additional statistical analyses, different subgroup analyses, and secondary endpoints. These additional analyses, while compelling, did not change the conclusion that the NeoCart Phase 3 trial failed to meet its primary and secondary



endpoints. In December 2018, Histogenics received final feedback from the FDA indicating that while the NeoCart Phase 3 clinical trial resulted in certain compelling data, particularly the early response in pain and function and the data in certain lesion sizes, an additional Phase 3 clinical trial would need to be completed before the FDA would accept the submission of a BLA for NeoCart. The FDA indicated receptivity to novel clinical trial methodologies and regenerative medicine advanced therapy designations in order to support additional data for a future potential submission. However, considering the time and funding required to conduct such a trial, Histogenics discontinued the development of NeoCart and is not planning to submit a BLA.

As a result of the FDA feedback, Histogenics initiated a process to evaluate strategic alternatives to maximize value for all of Histogenics' stakeholders. The process is being conducted with the assistance of financial and legal advisors and is evaluating the full range of potential strategic alternatives, including but not limited to, acquisitions, business combinations, joint ventures, public and private capital raises and recapitalization and sale transaction options, including a sale of assets or intellectual property. Since these efforts may not be successful and given Histogenics' limited cash reserves, Histogenics is also considering other possible alternatives, including a wind-down of operations, or Chapter 11 bankruptcy protection to complete or execute a restructuring transaction or liquidation. There is no guarantee that any cash (or other securities representing any value) will be returned to stockholders and there is the possibility that Histogenics common stock will be worthless in a bankruptcy, wind-down or other liquidation scenario. In January 2019 and March 2019, Histogenics implemented restructuring plans that were approved by Histogenics' Board involving reductions in headcount to reduce operating costs. The positions eliminated together represented all but one employee, and included Histogenics' Chief Executive Officer, Chief Operating Officer, Chief Medical Officer and Chief Business Officer. Histogenics intends to engage, Mr. Adam Gridley, Histogenics' Chief Executive Officer, Mr. Stephen Kennedy, Histogenics' Chief Operating Officer, along with up to four additional employees as consultants to assist with Histogenics' continuing evaluation of strategic alternatives.

Histogenics has devoted substantially all of its resources to the development of its RCT platform, the preclinical and clinical advancement of its product candidates, the creation and protection of related intellectual property and the provision of general and administrative support for these operations. Histogenics has funded its operations primarily through the private placement of preferred stock and convertible promissory notes, commercial bank debt, sales of common stock and its collaboration with MEDINET.

On May 8, 2019, Histogenics entered into an asset purchase agreement with Medavate Corp., a Colorado corporation, pursuant to which Histogenics has agreed to sell substantially all of its assets relating to its NeoCart program, including, without limitation, intellectual property, business and license agreements and clinical trial data (the "Assets") in return for a cash payment of \$6.5 million. The closing of the sale of the Assets is subject to and conditioned upon the consummation of the merger.

Histogenics has never been profitable and incurred net losses in each year since inception. Histogenics' accumulated deficit was \$226.2 million as of March 31, 2019. Substantially all of Histogenics' net losses resulted from costs incurred in connection with its research and development programs and from general and administrative costs associated with its operations. Histogenics' net losses may fluctuate significantly from quarter to quarter and year to year.

Histogenics does not expect to generate any future revenue from product sales until it successfully completes development and obtains regulatory approval for NeoCart. If Histogenics seeks and obtains regulatory approval for NeoCart, it expects to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution. Accordingly, Histogenics will seek to fund its operations through public or private equity or debt financings or other sources. However, Histogenics may be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all. Histogenics' failure to raise capital or enter into such other arrangements when needed would have a negative impact on its financial condition.

## Financial Operations Overview

Histogenics conducts operations in two geographic regions: Histogenics Corporation, a Delaware corporation, at its facilities in Waltham and Lexington, Massachusetts, and ProChon Biotech Ltd. (“ProChon”) in Tel Aviv, Israel. Histogenics owns 100% of the voting shares of ProChon. As the nature of the products, customers and methods to distribute products are the same and the nature of the regulatory environment, the production processes and historical and estimated future margins are similar, the two operations have been aggregated into one reporting segment.

In September 2016, Histogenics completed a private placement (the “Private Placement”) where it issued 2,596,059 shares of Histogenics common stock at a per share price of \$2.25 and 24,158.8693 shares of its newly-created Series A Convertible Preferred Stock, which shares of preferred stock are convertible into approximately 10,737,275 shares of common stock. The Series A Convertible Preferred Stock became convertible into shares of Histogenics common stock following approval of the private placement by its stockholders in the fourth quarter of 2016. As of December 31, 2018, 400.4910 shares of Series A Convertible Preferred Stock that are convertible into 177,996 shares of common stock were outstanding. The net proceeds after deduction of placement agent fees and other transaction-related expenses were \$27.6 million. As part of the Private Placement, the investors received warrants to purchase up to 13,333,334 shares of Histogenics common stock at an exercise price of \$2.25 per share (such warrants, along with warrants to purchase up to 133,333 shares of Histogenics common stock issued to the placement agent for the transaction, the “2016 Warrants”). The 2016 Warrants include a cashless-exercise feature that may be exercised solely in the event there is no effective registration statement registering, or no current prospectus available for, the resale of the shares of common stock underlying the warrants as of the six-month anniversary of the closing of the Private Placement. The 2016 Warrants became exercisable following approval of the Private Placement by Histogenics’ stockholders in the fourth quarter of 2016 and expire five years after the date of such stockholder approval.

In January 2018, Histogenics completed an underwritten registered direct offering of 2,691,494 shares of common stock at a price of \$2.35 per share. The total net proceeds of the offering were \$5.7 million after deducting underwriter’s discounts and commissions, and expenses related to the offering.

In March 2018, Histogenics entered into an equity distribution agreement (the “Equity Distribution Agreement”) with Canaccord Genuity, pursuant to which Histogenics may, from time to time, sell shares of Histogenics common stock (the “Shares”), having an aggregate offering price of up to \$10 million through Canaccord Genuity, as its sales agent. The Shares will be offered and sold by Histogenics pursuant to its previously filed and currently effective Registration Statement on Form S-3 (Reg. No. 333-216741) (the “Registration Statement”). The Shares may only be offered and sold by means of a prospectus, including a prospectus supplement, forming part of the effective Registration Statement. Sales of the common stock, if any, will be made at market prices by methods deemed to be an “at the market offering” as defined in Rule 415 promulgated under the Securities Act of 1933, as amended (the “Securities Act”), including sales made directly on The Nasdaq Capital Market, on any other existing trading market for the common stock, or to or through a market maker other than on an exchange. During the year ended December 31, 2018, Histogenics sold an aggregate of 6,633,903 shares of common stock and received \$4.5 million after deducting commissions.

On October 10, 2018, Histogenics closed an underwritten public offering of 26,155,000 shares of its common stock and warrants to purchase up to 19,616,250 shares of common stock (the “2018 Warrants”), at a combined purchase price of \$0.65 per share of common stock and accompanying warrant. The gross proceeds from this offering were \$17.0 million, before deducting underwriting discounts and commissions, and offering expenses payable by Histogenics. The 2018 Warrants were exercisable immediately upon issuance at a price of \$0.70 per share of common stock and have a term of five years commencing on the date of issuance.

In the first quarter of 2019, Histogenics and certain holders of the 2016 Warrants (the “Participating 2016 Holders”) entered into a Warrant Amendment and Exercise Agreement (the “2016 Exercise Agreement”)

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pursuant to which Histogenics agreed to reduce the exercise price of the 2016 Warrants held by such Participating 2016 Holders from \$2.25 to \$0.01 per share (the “2016 Reduced Exercise Price”) in consideration for the exercise of the 2016 Warrants held by such Participating 2016 Holders in full at the 2016 Reduced Exercise Price for cash. In connection with the exercise of the 2016 Warrants by the Participating 2016 Holders, Histogenics received aggregate gross proceeds of approximately \$0.1 million. After the exercise of the 2016 Warrants held by the Participating 2016 Holders, 2016 Warrants to purchase approximately 508,714 shares of Histogenics common stock remain outstanding.

Also in the first quarter of 2019, Histogenics reduced the exercise price of the 2018 Warrants from \$0.70 to \$0.01 per share (the “2018 Reduced Exercise Price”) and all of the holders of the 2018 Warrants (the “Participating 2018 Holders”) entered into a Warrant Exercise Agreement (the “2018 Exercise Agreement”) pursuant to which in consideration for the 2018 Reduced Exercise Price, the Participating 2018 Holders agreed to exercise the 2018 Warrants held by such Participating 2018 Holders in full at the 2018 Reduced Exercise Price for cash. In connection with the exercise of the 2018 Warrants by the Participating 2018 Holders, Histogenics received aggregate gross proceeds of approximately \$0.2 million.

The consolidated financial statements and the following information include the accounts of Histogenics, ProChon and Histogenics Securities Corporation. All intercompany accounts and transactions have been eliminated in consolidation.

### **Revenue**

Histogenics did not generate any revenue in 2018 or 2017 and does not expect to generate any revenue from product sales in the future unless it successfully complete the development of NeoCart and receive approval from the FDA to market NeoCart. As of December 31, 2018, Histogenics has recorded \$10 million in deferred revenue relating to the upfront payment from MEDINET.

### **Research and Development Expenses**

Research and development expenses consist of development costs associated with Histogenics’ RCT platform and development programs. These costs are expensed as incurred and include:

- compensation and employee-related costs including stock-based compensation;
- costs incurred under clinical trial agreements with investigative sites;
- costs to acquire, develop and manufacture preclinical study and clinical trial materials;
- costs associated with conducting its preclinical, clinical and regulatory activities, including fees paid to third-party professional consultants and service providers;
- costs for laboratory supplies and laboratory equipment;
- charges associated with the achievement of certain preclinical and financial milestones pursuant to Histogenics’ licenses for its bioadhesive, and its tissue engineering processor; and
- facilities, depreciation and other expenses including allocated expenses for rent and maintenance of facilities.

Histogenics expects its research and development expenses to decline in the future due to its decision to suspend the development of NeoCart and the restructuring plans it implemented in January 2019 and March 2019.

Histogenics cannot determine with certainty the timing and costs of initiation, the duration and the completion of current or future preclinical studies and clinical trials of its product candidates. Clinical and preclinical development timelines, the probability of success and related development costs can differ materially from expectations. In addition, Histogenics cannot forecast when future collaboration arrangements will be secured, if at all, and to what degree such arrangements would affect its development plans and capital requirements.

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Histogenics does not track research and development expenses by product. Histogenics does not allocate general equipment and supply costs, facilities, depreciation and other miscellaneous expenses to specific projects.

### ***General and Administrative Expenses***

General and administrative expenses consist primarily of salaries and employee-related costs, including stock-based compensation and travel expenses for Histogenics' employees in the executive, finance, sales and marketing, and human resource functions. Other general and administrative expenses include facility-related costs, professional fees for accounting, legal services and directors, consulting expenses and expenses associated with obtaining and maintaining patents.

### ***Total Other Income (Expense), Net***

Total other income (expense), net consists primarily of changes in liabilities that are held at fair value; interest income earned on cash, cash equivalents and marketable securities; interest expense on Histogenics' equipment loan that matured and was fully repaid in the second quarter of 2018; and the extinguishment of liability related to Intrexon Corporation.

### **Critical Accounting Policies and Significant Judgments and Estimates**

This management's discussion and analysis of Histogenics' consolidated financial condition and results of operations is based on Histogenics' consolidated financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles. The preparation of these consolidated financial statements requires Histogenics to make estimates and judgments that affect the reported amounts of assets, liabilities, revenue and expenses and the disclosure of contingent assets and liabilities in Histogenics' consolidated financial statements. On an ongoing basis, Histogenics evaluates its estimates and judgments, including those related to accrued expenses and stock-based compensation and the fair value of the warrants issued in connection with the Private Placement and 2018 underwritten public offering. Histogenics bases its estimates on historical experience, known trends and events, and various other factors that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

While Histogenics' significant accounting policies are described in more detail in the notes to its consolidated financial statements appearing elsewhere in this prospectus, Histogenics believes the following accounting policies to be most critical to the significant judgments and estimates used in the preparation of its consolidated financial statements.

### ***Revenue Recognition***

In May 2014, the Financial Accounting Standards Board (the "FASB") issued a new standard related to revenue recognition, Accounting Standards Updated ("ASU") No. 2014-09, Revenue from Contracts with Customers. This new accounting standard replaced most current U.S. GAAP guidance on this topic and eliminated most industry-specific guidance. It provides a unified model to determine when and how revenue is recognized. The core principle is that an entity should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration for which the entity expects to be entitled in exchange for those goods or services. Entities may adopt the new standard either retrospectively to all periods presented in the financial statements (the full retrospective method) or as a cumulative-effect adjustment as of the date of adoption (modified retrospective method) in the year of adoption without applying to comparative years' financial statements. Further, in August 2015, the FASB issued ASU No. 2015-14, Revenue from Contracts with Customers: Deferral of the Effective Date, to defer the effective adoption date by one year to December 15, 2017 for annual reporting periods beginning after that date and permitted early adoption of the standard, but not before fiscal years beginning after the original effective date of December 15, 2016. Histogenics elected to early adopt the guidance in 2017 using the modified retrospective method.

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Revenue is recognized when, or as, performance obligations are satisfied, which occurs when control of the promised products or services is transferred to customers. Revenue is measured as the amount of consideration Histogenics expects to receive in exchange for transferring products or services to a customer (transaction price). To the extent that the transaction price includes variable consideration, Histogenics estimates the amount of variable consideration that should be included in the transaction price utilizing the most likely amount method. Variable consideration is included in the transaction price if, in Histogenics' judgment, it is probable that a significant future reversal of cumulative revenue under the contract will not occur. Estimates of variable consideration and determination of whether to include estimated amounts in the transaction price are based largely on an assessment of Histogenics' anticipated performance and all information (historical, current and forecasted) that is reasonably available.

If the contract contains a single performance obligation, the entire transaction price is allocated to the single performance obligation. Contracts that contain multiple performance obligations require an allocation of the transaction price to each performance obligation based on a relative standalone selling price basis unless the transaction price is variable and meets the criteria to be allocated entirely to a performance obligation or to a distinct service that forms part of a single performance obligation. Histogenics' revenues are generated primarily through collaborative research, development and commercialization agreements. The terms of these agreements may contain multiple promises which may include: (i) licenses to Histogenics' technology; (ii) services related to the transfer and update of know-how; and (iii) manufacturing supply services. Payments under these arrangements typically include one or more of the following: non-refundable upfront license fees; milestone payments; royalties on future product sale; and fees for manufacturing supply services. None of Histogenics' contracts as of December 31, 2018 contained a significant financing component.

Histogenics assesses the promises to determine if they are distinct performance obligations. Once the performance obligations are determined, the transaction price is allocated based on a relative standalone selling price basis. Milestone payments and royalties are typically considered variable consideration at the outset of the contract and are recognized in the transaction price either upon occurrence or when the constraint of a probable reversal is no longer applicable.

### *Collaboration Revenue*

No revenue has been recognized as of December 31, 2018. The collaboration and license agreements are within the scope of Accounting Standards Codification ("ASC") 606 Revenue from Contracts with Customers.

In determining the appropriate amount of revenue to be recognized as Histogenics fulfills its obligations under the agreements, Histogenics performs the following steps: (i) identification of the promised goods or services in the contract; (ii) determination of whether the promised goods or services are performance obligations including whether they are distinct in the context of the contract; (iii) measurement of the transaction price, including the constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations; and (v) recognition of revenue when (or as) it satisfies each performance obligation. As part of the accounting for the arrangement, Histogenics must develop assumptions that require judgment to determine the stand-alone selling price for each performance obligation identified in the contract. Histogenics uses key assumptions to determine the stand-alone selling price, which may include market conditions, reimbursement rates for personnel costs, development timelines and probabilities of regulatory success.

*Licenses of intellectual property:* If the license to Histogenics' intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, Histogenics recognizes revenues from non-refundable, up-front fees allocated to the license when the license is transferred to the customer and the customer is able to use and benefit from the license. For licenses that are bundled with other promises, Histogenics utilizes judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue from non-refundable, up-front fees.

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Histogenics evaluates the measure of progress each reporting period and, if necessary, adjust the measure of performance and related revenue recognition.

*Manufacturing Supply Services:* If the promise to supply products for clinical and/or commercial development are determined to be distinct from the other performance obligations identified in the arrangement, Histogenics recognizes revenues from the fees allocated to the supply when or as the supply is transferred to the customer, generally upon delivery to the customer. If the promise to supply products for clinical and/or commercial development is not determined to be distinct from the other performance obligations identified in the arrangement, Histogenics utilizes judgement to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue, including amounts from non-refundable, up-front fees. Histogenics evaluates the measure of progress each reporting period and, if necessary, adjust the measure of performance and related revenue recognition.

*Milestone Payments:* At the inception of each arrangement that includes developmental and regulatory milestone payments, Histogenics evaluates whether the achievement of each milestone specifically relates to its effort to satisfy a performance obligation or transfer a distinct good or service within a performance obligation. If the achievement of a milestone is considered a direct result of Histogenics' efforts to satisfy a performance obligation or transfer a distinct good or service and the receipt of the payment is based upon the achievement of the milestone, the associated milestone value is allocated to that distinct good or service and revenue is recognized in the period in which the milestone is achieved. If the milestone payment is not specifically related to Histogenics' effort to satisfy a performance obligation or transfer a distinct good or service, Histogenics evaluates the milestone to determine whether the milestone is considered probable of being reached and estimate the amount to be included in the transaction price using either the most likely amount or the expected value method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price to be allocated. At the end of each subsequent reporting period, Histogenics re-evaluates the probability of achievement of such development milestones and any related constraint, and if necessary, adjusts its estimate of the overall allocation. Any such adjustments are recorded on a cumulative catch-up basis, which would affect license, collaboration and other revenues and earnings in the period of adjustment.

*Royalties:* For arrangements that include sales-based or usage-based royalties, including milestone payments based on the level of sales, and the license is deemed to be the predominant item to which the royalties relate, Histogenics will recognize revenue at the later of: (i) when the related sales occur; or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied).

### ***Income Taxes***

Histogenics utilizes the asset and liability method of accounting for income taxes. Under this method, deferred tax assets and liabilities are determined based on the difference between the financial statement carrying amounts and tax basis of assets and liabilities using enacted tax rates in effect for years in which temporary differences are expected to reverse. Histogenics provides a valuation allowance when it is more likely than not that deferred tax assets will not be realized. Histogenics recognizes the benefit of an uncertain tax position that has been taken or it expects to take on income tax returns if such tax position is more likely than not to be sustained.

Histogenics follows the authoritative guidance regarding accounting for uncertainty in income taxes, which prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. These unrecognized tax benefits relate primarily to issues related to the timing of certain income and deductions for federal income tax purposes. Histogenics applies a variety of methodologies in making these estimates which include advice and studies performed by independent subject matter experts, evaluation of public actions taken by the U.S. Internal Revenue Service and other taxing authorities, as well as Histogenics' own industry experience. Histogenics provides

estimates for unrecognized tax benefits which may be subject to material adjustments until matters are resolved with taxing authorities or statutes expire. If Histogenics' estimates are not representative of actual outcomes, its results of operations could be materially impacted.

Histogenics continues to maintain a valuation allowance against its deferred tax assets due to its assessment that their realization is not certain. Histogenics periodically evaluates the likelihood of the realization of deferred tax assets and reduce the carrying amounts of these deferred tax assets by a valuation allowance to the extent Histogenics believes a portion will not be realized. Histogenics considers many factors when assessing the likelihood of future realization of deferred tax assets, including its recent cumulative earnings experience by taxing jurisdiction, expectations of future taxable income, carryforward periods available to it for tax reporting purposes, various income tax strategies and other relevant factors. Significant judgment is required in making this assessment and, to the extent future expectations change, Histogenics would assess the recoverability of its deferred tax assets at that time. If Histogenics determines that the deferred tax assets become realizable in a future period, it would record material adjustments to income tax expense that period.

#### *Tax Reform*

On December 22, 2017, the Tax Cuts and Jobs Act (the "TCJA") was signed into United States law. The TCJA includes a number of changes to existing tax law, including, among other things, a permanent reduction in the federal corporate income tax rate from 34% to 21%, effective as of January 1, 2018, as well as limitation of the deduction for net operating losses to 80% of annual taxable income and elimination of net operating loss carrybacks, in each case, for losses arising in taxable years beginning after December 31, 2017 (though any such net operating losses may be carried forward indefinitely). The tax rate change resulted in (i) a reduction in the gross amount of Histogenics' deferred tax assets recorded as of December 31, 2017, without an impact on the net amount of its deferred tax assets, which are recorded with a full valuation allowance, and (ii) no income tax expense or benefit being recognized as of the enactment date of the TCJA.

The staff of the Securities and Exchange Commission issued Staff Accounting Bulletin No. 118 to address the application of U.S. GAAP in situations when a registrant does not have the necessary information available, prepared or analyzed (including computations) in reasonable detail to complete the accounting for certain income tax effects of the TCJA. In connection with the initial analysis of the impact of the TCJA, Histogenics remeasured its deferred tax assets and liabilities based on the rates at which they are expected to reverse in the future, which is generally 21%. The remeasurement of Histogenics' deferred tax assets and liabilities was offset by a corresponding change in the valuation allowance for the year ended December 31, 2017. As a result, there was no impact to Histogenics' consolidated statements of operations and comprehensive loss as a result of the reduction in tax rates. The other provisions of the TCJA did not have a material impact on Histogenics' consolidated financial statements. Histogenics' final determination of the TCJA impact and the remeasurement of its deferred assets and liabilities was completed prior to the deadline of one year from the enactment of the TCJA. For the year ended December 31, 2018, there were no material changes to the analysis originally performed as of December 31, 2017.

### ***Uncertain Income Tax Positions***

Histogenics records uncertain tax positions on the basis of a two-step process whereby (1) Histogenics determines whether it is more likely than not that the tax positions will be sustained on the basis of the technical merits of the positions and (2) for those tax positions that meet the more-likely-than-not recognition threshold, Histogenics recognizes the largest amount of tax benefit that is more than 50% likely to be realized upon ultimate settlement with the related tax authority. Histogenics recognizes interest and penalties related to unrecognized tax benefits within income tax expense. Any accrued interest and penalties are included within the related tax liability. A reconciliation of the beginning and ending pre-tax amounts of uncertain tax positions is as follows:

	<u>Tax Positions</u> <u>(in thousands)</u>
Balance at December 31, 2016	\$ (562)
Reductions based on tax positions related to the period	123
Federal rate revision	136
Balance at December 31, 2017	(303)
Reductions based on tax positions related to the period	—
Federal rate revision	—
Balance at December 31, 2018	<u>\$ (303)</u>

The uncertain tax positions giving rise to the unrecognized tax benefits of \$0.3 million at December 31, 2018 relate to the timing of certain income and deductions for federal income tax purposes. The reversal of unrecognized tax benefits would not have any impact on the effective tax rate in future periods and are not expected to create cash tax liability upon settlement due to Histogenics' ability to utilize both pre-change and post-change NOLs to offset their impact.

### ***Accrued Expenses***

As part of the process of preparing its consolidated financial statements, Histogenics is required to estimate its accrued expenses. This process involves reviewing open contracts and purchase orders, communicating with Histogenics' personnel to identify services that have been performed on its behalf and estimating the level of service performed and the associated cost incurred for the service when Histogenics has not yet been invoiced or otherwise notified of the actual cost. The majority of Histogenics' service providers invoice Histogenics monthly in arrears for services performed or when contractual milestones are met. Histogenics makes estimates of its accrued expenses as of each balance sheet date in its consolidated financial statements based on facts and circumstances known to it at that time. Histogenics periodically confirms the accuracy of its estimates with the service providers and makes adjustments if necessary. Examples of estimated accrued research and development expenses include fees payable to:

- clinical research organizations and investigative sites in connection with clinical trials;
- vendors in connection with preclinical development activities;
- vendors related to product manufacturing, development, and distribution of clinical materials; and
- professional service fees for consulting and related services.

Histogenics bases its expense accruals related to clinical trials on its estimates of the services received and efforts expended pursuant to its contract arrangements. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows and expense recognition. Payments under some of these contracts depend on factors such as the successful enrollment of patients and the completion of clinical trial milestones. In accruing service fees, Histogenics estimates the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from Histogenics' estimate, Histogenics adjusts the accrual



or prepaid accordingly. Histogenics' understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in its reporting changes in estimates in any particular period.

Although Histogenics does not expect its estimates to be materially different from amounts actually incurred, if Histogenics' estimates of the status and timing of services performed differs from the actual status and timing of services performed, it may report amounts that are too high or too low in any particular period. To date, there have been no material differences from Histogenics' estimates to the amount actually incurred.

#### ***Impairment of Long-Lived Assets***

Long-lived assets consist primarily of property and equipment. Histogenics tests long-lived assets for impairment at year end or whenever events or circumstances present an indication of impairment. If the sum of expected future cash flows (undiscounted and without interest charges) of the long-lived assets is less than the carrying amount of such assets, the assets would be written down to their estimated fair value based on the present value of expected future cash flows and an impairment loss would be recognized in earnings. Based on the triggering event that occurred in December 2018, Histogenics deemed the value of its fixed assets to be impaired and wrote-off \$4.3 million in net book value of such assets.

#### ***Impairment of Intangible Assets***

Histogenics tests intangible assets for impairment at year end or whenever events or circumstances present an indication of impairment. If the sum of expected future cash flows (undiscounted and without interest charges) of the intangible assets is less than the carrying amount of such assets, an impairment loss would be recognized in earnings in "impairment of goodwill and intangible assets." The intangible assets would be written down to the estimated fair value, calculated based on the present value of expected future cash flows. Histogenics' intangible assets consisted of in-process research and development (IPR&D) obtained through the acquisition of ProChon and the AT Grade license and are fully impaired.

#### ***Financial Instruments Indexed to and Potentially Settled in the Histogenics Common Stock***

Histogenics evaluates all financial instruments issued in connection with its equity offerings when determining the proper accounting treatment for such instruments in its financial statements. Histogenics considers a number of generally accepted accounting principles under U.S. GAAP to determine such treatment and evaluates the features of the instrument to determine the appropriate accounting treatment. Histogenics utilizes the Probability Weighted Expected Return Method (PWERM), Option Pricing Model (OM) or other appropriate methods to determine the fair value of its derivative financial instruments such as the warrant liability. For financial instruments indexed to and potentially settled in Histogenics common stock that are determined to be classified as liabilities on the consolidated balance sheet, changes in fair value are recorded as a gain or loss in Histogenics' consolidated statement of operations with the corresponding amount recorded as an adjustment to the liability on its consolidated balance sheet.

#### ***Stock-Based Compensation***

Histogenics accounts for grants of stock options and restricted stock based on their grant date fair value and recognize compensation expense over their vesting period. Histogenics estimates the fair value of stock options as of the date of grant using the Black-Scholes option pricing model and, if issued, restricted stock based on the fair value of the underlying common stock as determined by management or the value of the services provided, whichever is more readily determinable.

Stock-based compensation expense represents the cost of the grant date fair value of employee stock option grants recognized over the requisite service period of the awards (usually the vesting period) on a straight-line

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basis, net of estimated forfeitures. The expense is adjusted for actual forfeitures at year end. Stock-based compensation expense recognized in the financial statements is based on awards that are ultimately expected to vest.

The Black-Scholes option pricing model requires Histogenics to make certain assumptions and estimates concerning its stock price volatility, the rate of return of risk-free investments, the expected term of the awards, and Histogenics' anticipated dividends. Histogenics utilizes the volatility from an analysis of peer group companies used in the Black-Scholes model, as it does not believe it has sufficient historical data to support the assumption of utilizing only Histogenics' stock price volatility.

Histogenics accounts for stock options and restricted stock awards to non-employees using the fair value approach. Stock options and restricted stock awards granted to non-employees are subject to periodic revaluation over their vesting terms.

On October 1, 2018, the Compensation Committee of the Histogenics Board approved a repricing (the "Repricing") of 3,807,779 stock options (the "Options") granted prior to September 1, 2018 pursuant to Histogenics' 2013 Equity Incentive Plan and Histogenics' 2012 Equity Incentive Plan to executive officers, employees and consultants of Histogenics. The Options had exercise prices between \$0.75628 and \$9.97 per share, which were reduced to \$0.568 per share (the closing price of Histogenics common stock on The Nasdaq Capital Market on October 1, 2018). The number of shares, vesting schedules and expiration period of the Options were not altered. Options to purchase Histogenics common stock held by non-employee members of the Histogenics Board were not subject to the Repricing and remain unchanged. The impact to Histogenics' financial statements in 2018 was immaterial.

### **Other Histogenics Information**

#### ***JOBS Act***

On April 5, 2012, the Jumpstart Our Business Startups Act ("JOBS Act") was enacted. Section 107 of the JOBS Act permits an "emerging growth company" to delay the adoption of new or revised accounting standards until those standards would otherwise apply to private companies. Histogenics plans to avail itself of this exemption from new or revised accounting standards and, therefore, it may not be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

For so long as Histogenics is an "emerging growth company," it intends to rely on exemptions relating to: (1) providing an auditor's attestation report on its system of internal control over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act and (2) complying with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements, known as the auditor discussion and analysis. Histogenics will remain an emerging growth company until the earliest of (a) the last day of the fiscal year in which it has total annual gross revenue of \$1.07 billion or more, (b) December 31, 2019, the last day of Histogenics' fiscal year following the fifth anniversary of the date of the completion of its initial public offering, (c) the date on which Histogenics has issued more than \$1.0 billion in non-convertible debt during the previous three years and (d) the date on which Histogenics is deemed to be a large accelerated filer under the rules of the SEC.

#### ***Net Operating Loss Carryforwards***

Utilization of the net operating loss (NOL) and research and development credit carryforwards may be subject to a substantial annual limitation due to ownership change limitations that have occurred or that could occur in the future, as required by Section 382 and 383 of the Internal Revenue Code (Code), as well as similar state and foreign provisions. These ownership changes may limit the amount of NOL and research and development credit

carryforwards that can be utilized annually to offset future taxable income and tax, respectively. In general, an “ownership change” as defined by Section 382 of the Code results from a transaction or series of transactions over a three-year period resulting in an ownership change of more than 50% of the outstanding stock of a company by certain stockholders. Histogenics has completed a study to assess whether an ownership change has occurred or whether there have been multiple ownership changes since its formation. The results of this study indicated Histogenics experienced ownership changes, as defined by Section 382 of the Code, in each of 2006, 2011, 2012, 2013, and 2016. Histogenics has not recorded \$52.9 million of NOLs that as a result of the 2017 ownership change will expire unused.

As of December 31, 2018, and 2017, Histogenics had U.S. federal NOL carryforwards of \$67 million and \$44 million respectively, which may be available to offset future income tax liabilities and expire at various dates through 2037. As of December 31, 2018, and 2017, Histogenics also had U.S. state NOL carryforwards of \$67 million and \$43.6 million, respectively, which may be available to offset future income tax liabilities and expire at various dates through 2037. At December 31, 2018 and 2017, Histogenics also had \$26.4 million and \$26.3 million, respectively, of foreign NOL carryforwards which may be available to offset future income tax liabilities, which carryforwards do not expire.

As of March 31, 2019, Histogenics has provided a full valuation allowance for net deferred tax assets.

### **Recent Accounting Pronouncements**

In November 2018, the FASB issued ASU No. 2018-18, Collaborative Arrangements (Topic 808): Clarifying the Interaction between Topic 808 and Topic 606. The amendments in this update provide guidance on whether certain transactions between collaborative arrangement participants should be accounted for with revenue under Topic 606. The guidance also provides more comparability in the presentation of revenue for certain transactions between collaborative arrangement participants. For public business entities, the amendments in this update are effective for fiscal years and interim periods within those fiscal years, beginning after December 15, 2019. Early adoption is permitted, including adoption in any interim period, for public business entities for periods for which financial statements have not yet been issued. Histogenics is currently evaluating the impact that the adoption of this guidance will have on Histogenics’ consolidated financial statements and related disclosures.

In August 2018, the FASB issued ASU No. 2018-13, Fair Value Measurement (Topic 820): Changes to the Disclosure Requirements for Fair Value Measurement. The amendments in this update modify the disclosure requirements on fair value measurements based on the concepts in the Concepts Statement, including the consideration of costs and benefits. The amendments in this update are effective for all entities for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2019 with early adoption permitted upon issuance of this Update. Histogenics is currently evaluating the impact that the adoption of this guidance will have on Histogenics’ consolidated financial statements and related disclosures.

In August 2018, the SEC adopted the final rule under SEC Release No. 33-10532, Disclosure Update and Simplification. This final rule amends certain disclosure requirements that are redundant, duplicative, overlapping, outdated or superseded. In addition, the amendments expand the disclosure requirements on the analysis of stockholders’ equity for interim financial statements. Under the amendments, an analysis of changes in each caption of stockholders’ equity presented in the balance sheet must be provided in a note or separate statement. The analysis should present a reconciliation of the beginning balance to the ending balance of each period for which a statement of comprehensive income is required to be filed. This final rule is effective for Histogenics for all filings made on or after November 5, 2018. The SEC staff clarified that the first presentation of the changes in shareholders’ equity may be included in the first Form 10-Q for the quarter that begins after the effective date of the amendments. The adoption of the final rule did not have a material impact on Histogenics’ consolidated financial statements.

In June 2018, the FASB issued ASU No. 2018-07, Compensation-Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting. This update is to simplify the aspects of

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accounting for nonemployee shared based payment transactions for acquiring goods or services from nonemployees. The amendments in this update are effective for fiscal years beginning after December 15, 2018, including interim periods within that year. Histogenics has concluded that this guidance has no impact on Histogenics' consolidated financial statements and related disclosures.

In July 2017, the FASB issued ASU No. 2017-11, Earnings Per Share (Topic 260): Distinguishing Liabilities from Equity (Topic 480); Derivatives and Hedging (Topic 815): (PART I) Accounting for certain financial instruments with down round features. This update addresses the complexity of accounting for certain financial instruments with down round features. The guidance is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2018. Histogenics has concluded that this guidance has no material impact on the presentation of its results of operations, financial position and disclosures.

In May 2017, the FASB issued ASU No. 2017-09, Compensation-Stock Compensation (Topic 718): Scope of Modification Accounting. This standard provides guidance on changes to the terms or conditions of a share-based payment award that requires an entity to apply modification accounting. The guidance is effective prospectively for annual periods beginning after December 15, 2017, and for interim periods and annual periods thereafter. Histogenics has concluded that this guidance has no material impact on the presentation of its results of operations, financial position and disclosures. In November 2016, the FASB issued ASU 2016-18, Statement of Cash Flows: Restricted Cash (ASU 2016-18). The amendments in this update require that amounts generally described as restricted cash and restricted cash equivalents be included within cash and cash equivalents when reconciling the beginning-of-period and end-of-period total amounts shown on the statement of cash flows. ASU 2016-18 was effective January 1, 2018. As a result of adopting ASU 2016-18, Histogenics includes its restricted cash balance in the cash and cash equivalents reconciliation of operating, investing and financing activities. The following table provides a reconciliation of cash, cash equivalents, and restricted cash within the statement of financial position that sum to the total of the same such amounts shown in the statement of cash flows.

	As of December 31,	
	2018	2017
	(in thousands)	
Cash and cash equivalents	\$15,542	\$7,081
Restricted cash	137	137
Total cash, cash equivalents, and restricted cash shown in the statement of cash flows	<u>\$15,679</u>	<u>\$7,218</u>

In February 2016, the FASB issued ASU No. 2016-02- Leases (Topic 842). This standard requires companies to recognize on the balance sheet the assets and liabilities for the rights and obligations created by leased assets. ASU 2016-02 will be effective for Histogenics in the first quarter of 2019, with early adoption permitted. Histogenics estimates that it will recognize approximately \$8 million to \$10 million of right-of-use assets and corresponding lease liabilities on the balance sheet upon adoption. However, the population of contracts subject to balance sheet recognition and their initial measurement remains under evaluation; and the final impact on the balance sheet will depend on the lease portfolio at the time of adoption. Histogenics does not expect that adoption will have a material impact on its results of operations or statement of cash flows.

In May 2014, the FASB issued ASU No. 2014-09, Revenue from Contracts with Customers (Topic 606), which requires an entity to recognize the amount of revenue to which it expects to be entitled for the transfer of promised goods or services to customers. In the fourth quarter of 2017, Histogenics early adopted ASC 606 and this standard applies to all contracts with customers, except for contracts that are within the scope of other standards, such as leases, insurance, collaboration arrangements and financial instruments. Histogenics had only one revenue arrangement as of the adoption date. Topic 606 requires an entity to recognize the amount of revenue to which it expects to be entitled for the transfer of promised goods or services to customers. Topic 606 provides a five-step model for determining revenue recognition for arrangements that are within the scope of the

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standard: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation. Histogenics only applies the five-step model to contracts when it is probable that the entity will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer. At contract inception, once the contract is determined to be within the scope of Topic 606, Histogenics assesses the goods or services promised within each contract and determines those that are performance obligations, and assesses whether each promised good or service is distinct. Histogenics then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied. For a complete discussion of accounting for revenues, see Note 2, Revenue Recognition.

### Results of Operations

#### Three Month Periods Ended March 31, 2019 and 2018

The following table summarizes the results of operations for the three-month period ended March 31, 2019 and 2018:

	Three Months Ended March 31,		Change	
	2019	2018	\$	%
	(in thousands)			
Research and development expenses	\$ 1,583	\$ 3,286	\$(1,703)	(52)%
General and administrative expenses	2,929	2,807	122	4
Restructuring	2,789	—	—	—
Loss due to asset impairment	750	—	—	—
Other income (expense), net	(1,364)	(8,740)	(7,376)	(84)

**Research and Development Expenses.** Research and development expenses were \$1.6 million for the three months ended March 31, 2019 as compared to \$3.3 million for the three months ended March 31, 2018. The decrease of \$1.7 million was primarily due to suspending the development of NeoCart and Histogenics' related restructuring plans that it implemented in January 2019 and March 2019. Histogenics expects its research and development expenses will be minimal until the anticipated closing of the merger.

**General and Administrative Expenses.** General and administrative expenses were \$2.9 million for the three months ended March 31, 2019 substantially unchanged compared to \$2.8 million for the three months ended March 31, 2018. Histogenics expects its general and administrative expenses to be minimal until the anticipated closing of the merger.

**Restructuring.** During the three months ended March 31, 2019, Histogenics implemented two restructurings that resulted in the termination of substantially all of its employees. In connection with the employee terminations, Histogenics incurred approximately \$2.8 million in severance-related expenses. Substantially all of the severance activity was incurred and paid by March 31, 2019.

**Loss due to asset impairment.** Histogenics incurred cost of \$0.9 million in 2018 related to the License Agreement with MEDINET, of which \$0.8 million was recorded as an asset that was to be expensed proportionally over the performance service period. However, given the decision to discontinue the development of NeoCart and terminate manufacturing operations, Histogenics concluded that the asset was fully impaired and therefore the full asset value was written off in the first quarter of 2019.

**Other Income (Expense), Net.** Net other expense was (\$1.4) million for the three months ended March 31, 2019 as compared to (\$8.7) million for the three months ended March 31, 2018. In both periods, the charges were primarily due to changes in warrant liability caused by a decrease in Histogenics' stock price during the respective periods.

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### **Years Ended December 31, 2018 and 2017**

The following table summarizes the results of Histogenics' operations for the years ended December 31, 2018 and 2017:

	<b>December 31,</b>		<b>Change</b>	
	<b>2018</b>	<b>2017</b>	<b>\$</b>	<b>%</b>
	<b>(in thousands)</b>			
Research and development expenses	\$15,634	\$15,566	\$ 68	0%
General and administrative expenses	10,204	9,384	820	9
Loss due to asset impairment	4,270	—	4,270	100
Other income (expense), net	21,465	(1,464)	22,929	(1,566)

**Revenue.** Histogenics did not record any revenue for the years ended December 31, 2018 and 2017. Histogenics does not expect to generate any product sales revenue in the future unless it successfully completes the development of NeoCart and receives approval from the FDA to market NeoCart. As of December 31, 2018, Histogenics has recorded \$10 million in deferred revenue relating to the upfront payment from MEDINET.

**Research and Development Expenses.** Research and development expenses were \$15.6 million for the year ended December 31, 2018 as compared to \$15.5 million for the year ended December 31, 2017. The increase in research and development expenses of \$0.1 million was primarily due to an increase in consulting expense of \$1.6 million, an increase in materials costs of \$0.9 million and an increase in repairs and maintenance expense of \$0.3 million which were partially offset by a \$1.8 million decline in clinical trial costs, a \$0.6 million decline in depreciation expense and a \$0.5 million decline in salaries and benefits. Histogenics expects its research and development expenses to decline in 2019 in connection with its decision to suspend the development of NeoCart and its related restructuring plans that it implemented in January 2019 and March 2019.

**General and Administrative Expenses.** General and administrative expenses were \$10.2 million for the year ended December 31, 2018 as compared to \$9.4 million for the year ended December 31, 2017. The increase in expense of \$0.8 million was primarily due to an increase in professional fees of \$0.6 million, an increase in facility-related expenses of \$0.6 million and an increase in public relations expense of \$0.1 million which were partially offset by a decrease in depreciation expense of \$0.5 million. Histogenics expects its general and administrative expenses to decline in 2019 due to the restructuring plans that it implemented in January 2019 and March 2019.

**Loss due to Asset Impairment.** The loss due to asset impairment of \$4.3 million for the year ended December 31, 2018 was in connection with the impairment of long-term assets.

**Other Income (Expense), Net.** Other income (expense), net was \$21.5 million for the year ended December 31, 2018 as compared to (\$1.5) million for the year ended December 31, 2017. The \$22.9 million increase was primarily due to the reduction of the fair value of warrant liability of \$20.6 million and a \$1.5 million gain on extinguishment of liability which were partially offset by warrant expense of \$0.8 million related to Histogenics' underwritten equity offering in October 2018.

### Cash Flow Summary for the Three Months Ended March 31, 2019

The following table sets forth a summary of the net cash flow activity for each of the periods indicated:

	<u>Three Months Ended March 31,</u>		<u>Change</u>	
	<u>2019</u>	<u>2018</u>	<u>\$</u>	<u>%</u>
	(in thousands)			
Net cash provided by (used in) operating activities	\$ (8,492)	\$ 3,286	\$(11,778)	(358)%
Net cash used in investing activities	—	(355)	355	100
Net cash provided by financing activities	326	5,495	(5,169)	(94)
Net increase (decrease) in cash and cash equivalents	\$ (8,166)	\$ 8,426	\$(16,592)	(197)%

#### Operating Activities

Cash from operating activities decreased from a source of \$3.3 million to a use of \$8.5 million for the three months ended March 31, 2018 compared to the three months ended March 31, 2019. During the three months ended March 31, 2019, net cash used in operating activities was driven primarily by Histogenics' net loss of \$9.4 million and a combined reduction in accounts payable and accrued expenses of \$1.4 million, partially offset by non-cash charges for the change in the fair value of warrant liability of \$1.4 million and loss on asset impairment of \$0.8 million. During the three months ended March 31, 2018, Histogenics' net cash provided by operations was favorably impacted by the receipt of \$10 million of deferred revenue associated with the MEDINET License Agreement.

#### Investing Activities

Histogenics had no cash flows from investing activities for the three months ended March 31, 2019 compared to a net use of \$0.3 million for the same three-month period of 2018.

#### Financing Activities

Cash provided by financing activities decreased \$5.2 million for the three months ended March 31, 2019 compared to the same period of 2018. The net cash provided in 2018 was primarily due to the issuance of Histogenics common stock. The net cash provided in 2019 was due to proceeds from the exercise of warrants to purchase common stock.

The following table sets forth a summary of the net cash flow activity for each of the periods indicated:

	<u>December 31,</u>		<u>Change</u>	
	<u>2018</u>	<u>2017</u>	<u>\$</u>	<u>%</u>
	(in thousands)			
Net cash used in operating activities	\$(15,777)	\$(23,020)	\$ 7,243	(31)%
Net cash used in investing activities	(1,113)	(1,230)	117	(10)
Net cash provided by (used in) financing activities	25,351	(577)	25,928	(4,494)
Net increase (decrease) in cash and cash equivalents	\$ 8,461	\$(24,827)	\$33,288	(134)%

#### Operating Activities

Cash used in operating activities decreased \$7.2 million to \$15.8 million for the year ended December 31, 2018 from \$23.0 million for the year ended December 31, 2017. During the year ended December 31, 2018, the net cash used in operating activities of \$15.8 million consisted primarily of Histogenics' net loss of \$8.6 million adjusted for non-cash items, including a decrease in fair value of warrants of \$20.6 million, an increase in

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deferred revenue of \$10.0 million, a decrease in operating assets and liabilities of \$2.8 million, a \$4.3 million loss from the impairment of long term assets, a \$1.5 million gain on extinguishment of liability, \$1.6 million in stock-based compensation expense, a \$0.7 million decrease in deferred rent and lease incentive, \$0.7 million in warrant expense and \$0.5 million in depreciation expense. During the year ended December 31, 2017, the net cash used for operating activities of \$23.0 million consisted primarily of Histogenics' net loss of \$26.4 million adjusted for non-cash items, including the increase in fair value of warrants of \$1.5 million, \$1.5 million in depreciation expense, \$1.6 million in stock-based compensation expense, a \$0.7 million decrease in operating assets and liabilities and a \$0.5 million decrease in deferred rent and lease incentive.

### ***Investing Activities***

Cash used in investing activities decreased \$0.1 million to \$1.1 million for the year ended December 31, 2018 from \$1.2 million for the year ended December 31, 2017. The difference was primarily related to purchases of property and equipment of \$2.0 million partially offset by maturities of marketable securities of \$0.9 million.

### ***Financing Activities***

Cash provided by financing activities increased \$26.0 million to \$25.4 million for the year ended December 31, 2018 due to the issuance of common stock of \$25.5 million.

### **Loan and Security Agreements**

#### ***Equipment Loan***

In July 2014, Histogenics entered into a loan and security agreement with Silicon Valley Bank, which provides for a line of credit to finance certain equipment purchases up to an aggregate of \$1.75 million through March 31, 2015. The line has been fully drawn and is payable in 36 monthly installments of principal and interest commencing six months following the date of the draw with an annual interest rate of 2.75% plus the greater of 3.25% and the prime rate in effect at the time of each draw, as published in the Wall Street Journal. The outstanding balance was fully paid as of May 2018.

In accordance with the terms of the equipment line of credit, Histogenics issued a warrant to Silicon Valley Bank in July 2014 to purchase 6,566 shares of its common stock at an exercise price per share of \$7.99.

### **Off-Balance Sheet Arrangements**

As of March 31, 2019 and March 31, 2019, Histogenics did not have any off-balance sheet arrangements, as defined in the rules and regulations of the SEC.

### **Liquidity and Capital Resources**

As of March 31, 2019, Histogenics had an accumulated deficit of \$226.2 million. Histogenics has historically funded its consolidated operations primarily through the proceeds from the sale of common stock, the private placement of preferred stock and convertible notes and commercial bank debt. As of March 31, 2019, Histogenics had cash, cash equivalents and marketable securities of \$7.4 million. Histogenics believes its existing cash and cash equivalents will be sufficient to fund its projected cash needs through the expected closing of the merger in the third quarter of 2019 and enable it to complete the merger with Ocugen. However, if there is a delay in completing the merger, Histogenics will require additional capital to sustain its operations through such completion or Histogenics will need to pursue an immediate dissolution. If Histogenics needs additional capital, it would need to raise such capital through debt or equity financings, asset sales or other strategic transactions. However, there can be no assurances that Histogenics will be able to complete any such transaction on acceptable terms or otherwise. The failure to obtain sufficient funds on commercially acceptable terms when



needed could have a material adverse effect on Histogenics' business, results of operations and financial condition and may prevent it from completing the merger. Accordingly, these factors, among others, raise substantial doubt about Histogenics' ability to continue as a going concern.

### ***Operating Capital Requirements***

Histogenics anticipates that it will continue to incur losses for the next several quarters and may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect its business. Histogenics may also need additional funding in the future in connection with its continuing operations if the merger is delayed.

If Histogenics raises additional funds through the issuance of additional debt or equity securities, it could result in dilution to its existing stockholders, increased fixed payment obligations and the existence of securities with rights that may be senior to those of Histogenics' common stock. If Histogenics incurs indebtedness, it could become subject to covenants that would restrict Histogenics' operations and potentially impair its competitiveness, such as limitations on its ability to incur additional debt, limitations on its ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact Histogenics' ability to conduct its business. Any of these events could significantly harm Histogenics' business, financial condition and prospects.

Histogenics' forecast of the period of time through which its financial resources will be adequate to support its operations is a forward-looking statement and involves risks and uncertainties, and actual results could vary as a result of a number of factors. Histogenics has based this estimate on assumptions that may prove to be wrong, and it could utilize its available capital resources sooner than Histogenics currently expects. The amount and timing of future funding requirements, both near- and long-term, will depend on many factors, including:

- the accuracy of Histogenics' estimates regarding expenses and any capital requirements;
- the cost of retaining key personnel and consultants;
- the cost of establishing and maintaining development and commercialization partnerships and or licensing transactions Histogenics may pursue;
- the extent to which Histogenics is required to pay milestone or other payments under its in-license agreements and the timing of such payments;
- the timely completion of the merger with Ocugen;
- the timing, completion and funds received from any asset sales Histogenics makes in connection with the merger;
- any unexpected expenses and liabilities that related to the wind-down of Histogenics' operations and preparation for the merger
- the cost of defending any litigation or other claims; and
- the cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights.

If Histogenics cannot capitalize on its business opportunities because it lacks sufficient capital, Histogenics' business, financial condition and results of operations could be materially adversely affected.

As previously announced, on October 17, 2018, Nasdaq notified Histogenics that it did not meet Nasdaq's \$1.00 per share minimum bid price requirement under Nasdaq Listing Rule 5550(a)(2) for continued listing on The Nasdaq Capital Market, and Histogenics was given an initial grace period of 180 days, or until April 15, 2019, to regain compliance with this Rule. On April 16, 2019, Histogenics received the Letter from the Staff

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notifying Histogenics that, based upon the Histogenics' continuing non-compliance with Rule 5550(a)(2), the Staff had determined that the Histogenics' common stock would be delisted from Nasdaq unless Histogenics timely requests a hearing before a Panel. The Letter also noted that Histogenics was not eligible for a second 180 day grace period as it did not comply with the stockholders' equity initial listing requirement for The Nasdaq Capital Market.

Accordingly, Histogenics timely requested a hearing before the Panel, which took place in May 2019. On May 31, 2019, Histogenics received the Decision, indicating that the Panel had granted Histogenics' request to continue its listing on The Nasdaq Capital Market in order to complete the proposed merger with Ocugen. The Decision specifies that Histogenics shall complete the merger no later than September 30, 2019, and demonstrate to the satisfaction of the Staff and the Panel that the combined entity meets all of the applicable requirements for initial listing on The Nasdaq Capital Market. The Panel reserved the right to reconsider the terms of the extension based on any event, condition or circumstance that exists or develops that would, in the opinion of the Panel, make continued listing of the Histogenics' common stock on The Nasdaq Capital Market inadvisable or unwarranted. Histogenics' common stock will continue to trade on The Nasdaq Capital Market under the symbol "HSGX" through the earlier of the expiration of the extension period granted by the Panel or the closing of the proposed merger.

On June 19, 2019, Histogenics received a letter (the "June Letter") from the Staff notifying Histogenics that it had failed to regain compliance with the Rule 5550(b)(2) and that such compliance failure serves as an additional basis for delisting Histogenics' common stock from The Nasdaq Capital Market. The June Letter also noted that such letter served as formal notification that the Panel will consider the failure to regain compliance with the Rule 5550(b)(2) in its decision regarding Histogenics' continued listing on The Nasdaq Capital Market, and that Histogenics should present its views with respect to this additional compliance deficiency to the Panel in writing no later than June 26, 2019. Histogenics timely presented its views to the Panel on June 26, 2019.

A delisting would likely make it more difficult for Histogenics to obtain financing through the sale of its equity. Any such sale of equity would likely be more dilutive to Histogenics' current stockholders than would be the case if its shares were listed.

## OCUGEN MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

*You should read the following discussion and analysis of Ocugen's financial condition and results of operations together with Ocugen's consolidated financial statements and related notes appearing in this proxy statement/prospectus/information statement. Some of the information contained in this discussion and analysis is set forth elsewhere in this prospectus, including information with respect to Ocugen's plans and strategy for Ocugen's business and related financing, includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the "Risk factors" section of this proxy statement/prospectus/information statement, Ocugen's actual results could differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.*

### Overview

Ocugen is a clinical stage biopharmaceutical company focused on discovering, developing and commercializing a pipeline of innovative therapies, including gene therapies and biologicals, to address rare and underserved eye diseases.

Ocugen is developing a modifier gene therapy platform for unmet medical needs in the area of retinal diseases, including inherited retinal diseases ("IRDs"). Ocugen's modifier gene therapy platform is novel in that it targets nuclear hormone receptor ("NHR") genes that have the potential to restore homeostasis to the retina and may target multiple genes that are associated with a range of IRDs. Unlike single-gene replacement therapies, which only target one genetic mutation, Ocugen believes that its gene therapy platform, through its use of NHRs, may impact multiple genes that are associated with a range of genetically diverse diseases. Ocugen's first gene therapy candidate, OCU400 received Orphan Drug Designation ("ODD"), from the Food and Drug Administration (the "FDA"), for the treatment of *NR2E3* mutation-associated retinal degenerative disease. OCU400 uses an adeno-associated virus vector. Ocugen is planning to initiate a Phase 1/2a clinical trial for OCU400 in the next two years.

Ocugen has a late-stage, Phase 3 program, OCU300, that also has received ODD from the FDA. OCU300 is a small molecule therapeutic currently in Phase 3 clinical development for patients with ocular graft-versus-host disease ("oGVHD"). Ocugen is the first and only company to receive ODD for the treatment of oGVHD. Ocugen estimates the current prevalence of patients suffering from oGVHD in the United States to be approximately 50,000. The final manufacturing processes for OCU300 has been scaled up by Ocugen's existing contract manufacturer at a cGMP facility located in the United States to support potential commercialization, and chemistry, manufacturing and control ("CMC") development is ongoing.

OCU300 is formulated using Ocugen's proprietary nanoemulsion technology, OcuNanoE—Ocugen's ONE Platform™ ("OcuNanoE™"). Ocugen is the first and only company to use nanoemulsion technology in the ophthalmology space, and Ocugen believes that OcuNanoE™ provides additional protection to the ocular surface. Ocugen's technology delivers the active drug with the use of defined narrow-range globules with an average diameter of less than 100 nanometers. Ocugen believes this provides the potential for enhanced efficacy compared to traditional formulations.

Ocugen is developing OCU310 for patients with dry eye disease ("DED"), which is also formulated using OcuNanoE™. Ocugen has completed a Phase 3 clinical trial for OCU310 that was initiated in September 2018 with the first patient dosed in December 2018. Although the study showed that OCU310 is well-tolerated, as demonstrated by no adverse events regarded as "severe," it did not meet its co-primary endpoints for symptom and sign. However, a pre-specified exploratory efficacy endpoint of reduction in redness (sign) from the baseline visit, measured by a Validated Bulbar Redness score, was significantly better for OCU310 relative to placebo at both Day 14 and Day 28. Post-hoc analysis of the Phase 3 clinical trial is ongoing, subsequent to which a consultation with the FDA will be sought. Ocugen is evaluating its options and timing for the continued development of OCU310, including partnering for future clinical trials.

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Ocugen is developing OCU200, a novel fusion protein, that is currently in preclinical development for treating wet age-related macular degeneration (“wet AMD”). Ocugen expects to initiate a Phase 1/2 clinical trial for OCU200 within the next two years. In addition, Ocugen plans to expand the therapeutic applications of OCU200 beyond wet AMD to potentially include diabetic retinopathy (“DR”), diabetic macular edema (“DME”), macular edema following retinal vein occlusion (“RVO”), and myopic choroidal neovascularization (“mCNV”). Ocugen’s novel biologic, OCU100 for the treatment of retinitis pigmentosa (“RP”) has received ODD in the United States and the European Union.

To date, Ocugen has viewed its operations and manages its business as one operating segment. As of March 31, 2019, all of Ocugen’s assets were located in the United States. Its headquarters and operations are located in Malvern, Pennsylvania.

### **Development Stage Company**

Ocugen is a development stage company, and it has no products approved for sale. As a result, Ocugen has not generated any revenue to date and has primarily funded its operations to date through the sale of common stock, warrants to purchase common stock, the issuance of convertible notes, and debt. Specifically, since Ocugen’s inception and through March 31, 2019, it has raised an aggregate of \$23.3 million to fund its operations, of which \$13.3 million was from the sale of Ocugen common stock and warrants, \$8.8 million was from convertible notes, \$1.0 million was from borrowings under the U.S. Government’s Immigrant Investor Program, commonly known as the EB-5 program (the “EB-5 Program”) and \$0.2 million was from a research grant from the state of Colorado. As of March 31, 2019, Ocugen had a cash and cash equivalents balance of \$0.3 million.

Since Ocugen’s inception, it has devoted substantial resources to research and development and has incurred significant net losses and expects to continue to incur net losses for the foreseeable future. Ocugen incurred net losses of approximately \$6.3 million and \$5.0 million for the three months ended March 31, 2019 and 2018, respectively, and \$18.2 million and \$7.8 million for the years ended December 31, 2018 and 2017, respectively. As of March 31, 2019, Ocugen had an accumulated deficit of \$37.5 million.

Ocugen’s ability to generate revenue sufficient to achieve profitability will depend on the successful development and eventual commercialization of its product candidates, which is subject to significant uncertainty. Ocugen expects that over the next several years it will continue to incur losses from operations as it increases its expenditures in research and development in connection with clinical trials and other development activities. If adequate funds are not available to Ocugen on a timely basis, or at all, Ocugen may be required to terminate or delay certain development activities.

Ocugen believes that the net proceeds from the Pre-Merger Financing and the Asset Sale, together with the existing cash and cash equivalents of the combined company, will be sufficient to fund its operations into mid-2020, during which time Ocugen expects to continue its development efforts with respect to its product candidates. However, Ocugen will need to raise additional capital in the future to further the development and commercialization of its other product candidates. Until such time, if ever, as Ocugen generates product revenue, Ocugen expects to obtain additional financing through the issuance of its common stock, through other equity or debt financings or through collaborations or partnerships with other companies. Ocugen may not be able to raise additional capital on terms acceptable to it, or at all, and any failure to raise capital as and when needed could compromise its ability to execute on its business plan and cause it to delay or curtail its operations until such funding is received.

### **Financial Operations Overview**

#### **Revenue**

Ocugen has not generated revenue from the sale of any products, and it does not expect to generate revenue unless or until it obtains regulatory approval of and commercializes one or more of its product candidates.

### **Research and development expense**

Research and development costs are expensed as incurred. These costs consist of internal and external expenses. Internal expenses include the cost of salaries, benefits and other related costs, including stock-based compensation, for personnel serving in Ocugen's product development functions, as well as allocated rent and utilities expenses. External expenses include development, clinical trials, patent costs and regulatory compliance costs incurred with research organizations and other third-party vendors. License fees paid to acquire access to proprietary technology are expensed to research and development unless it is determined that the technology is expected to have an alternative future use. All patent related costs incurred in connection with filing and prosecuting patent applications are expensed as incurred to research and development expense due to the uncertainty about the recovery of the expenditure. Ocugen records costs for certain development activities, such as clinical trials, based on its evaluation of the progress to completion of specific tasks using data such as patient enrollment, clinical site activations, or information provided to Ocugen by Ocugen's vendors on their actual costs incurred. Payments for these activities are based on the terms of the individual arrangements, which may differ from the pattern of costs incurred, and are reflected in the consolidated financial statements as prepaid or accrued research and development expense, as the case may be.

(in thousands)	Year ended December 31,		Three months ended March 31, (unaudited)	
	2018	2017	2019	2018
Research and development	\$10,321	\$4,928	\$3,793	\$3,012

Ocugen plans to incur research and development expenses for the foreseeable future as it expects to seek to continue development and eventual commercialization of one or more of its product candidates. At this time, due to the inherently unpredictable nature of preclinical and clinical development, Ocugen is unable to estimate with any certainty the costs it will incur and the timelines it will require in its continued development efforts.

As a result of the uncertainties discussed above, successful development and completion of clinical trials is uncertain and may not result in approved products. Completion dates and completion costs can vary significantly for each future product candidate and are difficult to predict. Ocugen will continue to make determinations as to which product candidates to pursue and how much funding to direct to each product candidate on an ongoing basis in response to its ability to enter into collaborations with respect to each product candidate, the scientific and clinical success of each product candidate as well as ongoing assessments as to the commercial potential of product candidates. Ocugen may seek to obtain additional financing in the future through the issuance of its common stock, through other equity or debt financings or through collaborations or partnerships with other companies. Ocugen may not be able to raise additional capital on terms acceptable to it, or at all, and any failure to raise capital as and when needed could compromise Ocugen's ability to execute on its business plan and cause it to delay or curtail its operations until such funding is received.

### **General and administrative expense**

General and administrative expense consists primarily of personnel expenses, including salaries, benefits and stock-based compensation expense, for employees in executive, accounting and other administrative functions. General and administrative expense also includes corporate facility costs, including rent and utilities, as well as legal fees related to corporate matters and fees for accounting and other consulting services.

Ocugen anticipates that its general and administrative expense will increase as a result of an expanded infrastructure and an increased headcount. Ocugen anticipates higher corporate infrastructure costs including, but not limited to accounting, legal, human resources, consulting and investor relations fees, as well as increased director and officer insurance premiums, associated with becoming a public company. Additionally, if and when Ocugen believes a regulatory approval of a product candidate appears likely, it anticipates an increase in payroll and expense as a result of its preparation for commercial operations, especially as it relates to the sales and marketing of its product candidates.

***Change in fair value of derivative liabilities***

Change in fair value of derivative liabilities represents the change in fair value each reporting period of the embedded conversion features and embedded change in control features required to be bifurcated from certain of the outstanding convertible promissory notes.

***Other income (expense)***

Other income (expense) consists primarily of interest expense, the amortization of debt issuance costs related to Ocugen's debt and accretion of the discount created by the bifurcation of the embedded conversion features and embedded change in control features from certain of the convertible promissory notes, interest earned on Ocugen's cash and cash equivalents held with institutional banks, as well as foreign currency income (losses) due to exchange rate fluctuations on transactions denominated in a currency other than its functional currency.

**Critical Accounting Policies and Significant Judgments and Estimates**

Ocugen's consolidated financial statements are prepared in accordance with U.S. generally accepted accounting principles, or GAAP. The preparation of Ocugen's financial statements requires it to make estimates and judgments that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reported period. Ocugen bases its estimates on historical experience, known trends and events and various other factors that it believes to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Ocugen evaluates its estimates and assumptions on an ongoing basis. Ocugen's actual results may differ from these estimates under different assumptions and conditions.

While Ocugen's significant accounting policies are described in more detail in the notes to its consolidated financial statements appearing elsewhere in this proxy statement/prospectus/information statement, Ocugen believes that the following accounting policies and estimates are those most critical to the preparation of its consolidated financial statements.

***Research and development expenses***

Research and development costs are expensed as incurred and consist of internal and external expenses. Internal expenses include employee compensation, benefits and certain overhead such as rent and utilities. External expenses include development, clinical trials, patent costs and regulatory compliance costs incurred with research organizations and other third-party vendors.

Ocugen records costs for certain development activities, such as clinical trials, based on its evaluation of the progress to completion of specific tasks using data such as patient enrollment, clinical site activations, or information provided to Ocugen by its vendors on their actual costs incurred. Payments for these activities are based on the terms of the individual arrangements, which may differ from the pattern of costs incurred, and are reflected in the consolidated financial statements as prepaid or accrued research and development expense, as the case may be.

***Income taxes***

Ocugen records income taxes in accordance with Financial Accounting Standards Board ("FASB") Accounting Standards Codifications ("ASC") Topic 740, *Income Taxes* ("ASC 740"), which provides for deferred taxes using an asset and liability approach. Ocugen recognizes deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements or tax returns. Deferred tax assets and liabilities are determined based on the differences between the financial statement and tax bases of assets and

liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. Valuation allowances are provided if based upon the weight of available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized.

Ocugen accounts for uncertain tax positions in accordance with the provisions of ASC 740. When uncertain tax positions exist, Ocugen recognizes the tax benefit of tax positions to the extent that the benefit will more likely than not be realized. The determination as to whether the tax benefit will more likely than not be realized is based upon the technical merits of the tax position as well as consideration of the available facts and circumstances. As of March 31, 2019 and December 31, 2018, Ocugen did not have any uncertain tax positions.

Ocugen has incurred substantial losses during its history. Ocugen does not anticipate generating revenue from sales of products for the foreseeable future, if ever, and it may never achieve profitability. To the extent that Ocugen continues to generate tax losses, unused losses will carry forward to offset future taxable income, if any, until such unused losses expire. Under Section 382 of the Internal Revenue Code of 1986, as amended, if a corporation undergoes an “ownership change,” which is generally defined as a greater than 50% change, by value, in its equity ownership over a three-year period, the corporation’s ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes to offset its post-change income may be limited. Ocugen has not completed its analysis to determine what, if any, impact any prior ownership change has had on its ability to utilize its net operating loss carryforwards. In addition, Ocugen may experience ownership changes in the future as a result of subsequent shifts in its stock ownership, such as in connection with the merger or the Pre-Merger Financing. As of December 31, 2018, Ocugen had federal net operating loss carryforwards of approximately \$23.7 million that could be limited if Ocugen has experienced, or if in the future it experiences, an ownership change. As of March 31, 2019, Ocugen had recorded a full valuation allowance against these loss carryforwards.

### ***Stock-based compensation***

Ocugen accounts for its stock-based compensation awards in accordance with FASB ASC Topic 718, *Compensation-Stock Compensation* (“ASC 718”). ASC 718 requires all stock-based payments to employees, including grants of employee stock options and restricted stock units and modifications to existing agreements, to be recognized in the statements of operations based on their fair values. Ocugen uses the Black-Scholes option-pricing model to determine the fair value of options granted.

Ocugen’s stock-based awards are subject to either service or performance-based vesting conditions. Compensation expense related to awards to employees and directors with service-based vesting conditions is recognized on a straight-line basis based on the grant date fair value over the associated service period of the award, which is generally the vesting term. Compensation expense related to awards to employees with performance-based vesting conditions is recognized based on the grant date fair value over the requisite service period to the extent achievement of the performance condition is probable.

Estimating the fair value of options requires the input of subjective assumptions, including the estimated fair value of Ocugen common stock, the expected life of the option, stock price volatility, the risk-free interest rate and expected dividends. The assumptions used in Ocugen’s Black-Scholes option-pricing model represent management’s best estimates and involve a number of variables, uncertainties and assumptions and the application of management’s judgment, as they are inherently subjective. If any assumptions change, Ocugen’s stock-based compensation expense could be materially different in the future.

These assumptions used in Ocugen’s Black-Scholes option-pricing model are as follows:

*Expected Term.* Due to the lack of a public market for the trading of Ocugen common stock and the lack of sufficient company-specific historical data, the expected term of employee options is determined using the “simplified” method, as prescribed in SEC’s Staff Accounting Bulletin (“SAB No. 107”), whereby the expected life equals the arithmetic average of the vesting term and the original contractual term of the option. The expected term of non-employee options is equal to the contractual term.

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*Expected Volatility.* The expected volatility is based on historical volatilities of similar entities within Ocugen's industry which were commensurate with the expected term assumption as described in SAB No. 107.

*Risk-Free Interest Rate.* The risk-free interest rate is based on the interest rate payable on U.S. Treasury securities in effect at the time of grant for a period that is commensurate with the assumed expected term.

*Expected Dividends.* The expected dividend yield is 0% because Ocugen has not historically paid, and do not expect for the foreseeable future to pay, a dividend on its common stock.

The following table reflects the assumptions used to estimate the fair value of options granted during the periods presented.

	Three months ended March 31,		Year ended December 31,	
	2019	2018	2018	2017
Expected option term (years)	—	6.0 - 10.0	6.0 - 10.0	6.0 - 10.0
Weighted-average expected stock price volatility	—	118.65%	85%	99%
Risk-free interest rate	—	2.3% - 2.8%	2.3% - 3.0%	1.8% - 2.4%
Expected dividend yield	—	0%	0%	0%
Weighted-average common stock price	—	\$ 3.54	\$ 4.66	\$ 3.32

Stock-based compensation expense was \$0.4 million and \$0.3 million for the three months ended March 31, 2019 and 2018, respectively, and \$1.1 million and \$0.5 million for the years ended December 31, 2018 and 2017, respectively. At March 31, 2019, Ocugen had \$1.7 million of unamortized stock-based compensation expense related to unvested service-based stock options, which is expected to be recognized over a remaining weighted-average vesting period of 1.9 years. Ocugen expects the impact of its stock-based compensation expense for stock options granted to employees and non-employees to increase in future periods due to the potential increases in the value of its common stock and in headcount.

### **Valuation of common stock**

As there has been no public market for Ocugen common stock to date, the estimated fair value of its common stock has been determined by the Ocugen Board as of the date of each option grant and quarter end, with input from management, considering Ocugen's most recently available third-party valuations of common stock. These factors include, but are not limited to:

- Ocugen's most recently available valuations of its common stock by an unrelated third party;
- the price at which Ocugen sold shares of its common stock to outside investors in arms-length transactions;
- Ocugen's results of operations, financial position and capital resources;
- current business conditions and projections;
- the lack of marketability of Ocugen common stock;
- the hiring of key personnel and the experience of management;
- the risk inherent in the development of Ocugen's products;
- Ocugen's stage of development and material risks related to its business;
- the fact that the option grants involve illiquid securities in a private company; and
- the likelihood of achieving a liquidity event, such as an initial public offering or sale, in light of prevailing market conditions.



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Ocugen has periodically determined the estimated fair value of its common stock at various dates using contemporaneous valuations performed in accordance with the guidance outlined in the American Institute of Certified Public Accountants' Accounting and Valuation Guide, *Valuation of Privately-Held-Company Equity Securities Issued as Compensation*, or the Practice Aid. The Practice Aid identifies various available methods for allocating enterprise value across classes and series of capital stock to determine the estimated fair value of common stock at each valuation date. In accordance with the Practice Aid, the Ocugen Board considered the following methods:

- *Current Value Method.* Under the Current Value Method, or CVM, Ocugen's value is determined based on its balance sheet. This value is then first allocated based on the liquidation preference associated with preferred stock issued as of the valuation date, and then any residual value is assigned to the common stock.
- *Option-Pricing Method.* Under the option-pricing method, or OPM, shares are valued by creating a series of call options with exercise prices based on the liquidation preferences and conversion terms of each equity class. The estimated fair values of the preferred and common stock are inferred by analyzing these options.
- *Probability-Weighted Expected Return Method.* The probability-weighted expected return method, or PWERM, is a scenario-based analysis that estimates value per share based on the probability-weighted present value of expected future investment returns, considering each of the possible outcomes available to Ocugen, as well as the economic and control rights of each share class.

Based on Ocugen's early stage of development and other relevant factors, Ocugen determined that a PWERM was the most appropriate method for allocating its enterprise value to determine the estimated fair value of its common stock. Ocugen common stock valuation as of March 31, 2019 was prepared using the PWERM.

The Ocugen Board and management develop best estimates based on application of these approaches and the assumptions underlying these valuations, giving careful consideration to the advice from Ocugen's third-party valuation expert. Such estimates involve inherent uncertainties and the application of significant judgment. As a result, if factors or expected outcomes change and Ocugen uses significantly different assumptions or estimates, Ocugen's equity-based compensation could be materially different.

Following the closing of the merger, the Ocugen Board will determine the fair market value of Ocugen common stock based on its closing price as reported on the date of grant on the primary stock exchange on which Ocugen common stock is traded.

### **Warrants**

Ocugen accounts for its warrants, all issued prior to December 31, 2017, as equity instruments. Ocugen estimated their fair value in the same manner as Ocugen's stock options using the Black-Scholes model, and the valuation assumptions are similar to those used in estimating the fair value of Ocugen's stock options.

### **Derivative liabilities**

The derivative liabilities are embedded conversion features bifurcated from Ocugen's convertible promissory notes because the number of common shares to be issued upon conversion is variable and embedded change in control features because it represents a redemption feature not clearly and closely related to the debt host. Ocugen estimated the fair value of the embedded conversion and change in control features at each issuance of convertible promissory notes and at the end of each reporting period using an income approach model. Inputs into this model include the expected time until conversion or change in control and Ocugen's estimate of the probability of conversion or change in control occurring.

## Results of Operations

### Comparison of the Three Months Ended March 31, 2019 and March 31, 2018

The following table summarizes the results of Ocugen's operations for the three months ended March 31, 2019 and 2018:

(in thousands)	Three months ended		Changes
	2019	2018	
Operating expenses:			
Research and development	\$ 3,793	\$ 3,012	\$ 781
General and administrative	1,048	982	66
Total Operating Expenses	4,841	3,994	847
Loss from Operations	(4,841)	(3,994)	(847)
Other Income (expense):			
Change in fair value of derivative liability	(776)	(245)	(531)
Interest income	1	7	(6)
Interest expense	(696)	(799)	103
Other expense	(1)	(8)	7
Total other expense	(1,472)	(1,045)	(427)
Net Loss	<u><u>\$ (6,313)</u></u>	<u><u>\$ (5,039)</u></u>	<u><u>\$ (1,274)</u></u>

#### Research and development expense

Research and development expense increased by \$0.8 million for the three months ended March 31, 2019 when compared to the three months ended March 31, 2018 primarily as a result of a net increase of \$1.0 million in clinical trial activities and a decrease of \$0.2 million in other costs. Specifically, OCU310 and OCU300 clinical trials began in 2018 into early 2019 causing an increase of \$2.0 million and \$0.1 million, respectively. Also, the progression of the clinical trials resulted in a \$0.9 million decrease in pre-clinical, manufacturing and regulatory costs and OCU100 development activity costs decreased \$0.2 million. In addition, R&D headcount decreased to 12 full and part-time employees at March 31, 2019 from 14 at March 31, 2018, resulting in decreased bonus, travel and wage and salaries expenses totaling \$0.2 million.

#### General and administrative expense

General and administrative expenses increased by \$0.1 million for the three months ended March 31, 2019 when compared to the three months ended March 31, 2018. This increase was primarily due to an increase in stock compensation expense.

#### Change in fair value of derivative liability

The change in fair value of derivative liability increased the gain by \$0.5 million for the three months ended March 31, 2019 when compared to the three months ended March 31, 2018. This increase in the gain relates to the remeasurement of embedded features on the convertible notes which were issued in 2018 and 2019 as the fair value of the common stock decreased at March 31, 2019 when compared to March 31, 2018.

#### Interest income

Interest income was \$594 for the three months ended March 31, 2019 compared to \$7,431 for the three months ended March 31, 2018. This relates to interest earned on cash and cash equivalents and lower cash balances in 2019 when compared to 2018.

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### *Interest expense*

Interest expense was \$0.7 million for the three months ended March 31, 2019 compared to \$0.8 million for the three months ended March 31, 2018. The decreased expense is primarily due to full accretion of the debt discount attributable to the embedded conversion features and embedded change in control features on certain of the convertible promissory notes during 2018.

### *Other expense*

Other expense was \$416 for the three months ended March 31, 2019 compared to \$8,406 for the three months ended March 31, 2018. The first quarter of 2019 expense relates to a foreign exchange revaluation for Ocugen's Irish subsidiary, and the first quarter of 2018 expense relates to the forfeiture of a portion of a security deposit on lab space vacated in March 2018.

### **Comparison of the Years Ended December 31, 2018 and 2017**

The following table summarizes the results of Ocugen's operations for the years ended December 31, 2018 and December 31, 2017:

(in thousands)	Year ended December 31,		Change
	2018	2017	
Operating expenses:			
Research and development	\$ 10,321	\$ 4,927	\$ 5,394
General and administrative	5,819	2,862	2,957
Total Operating Expenses	16,140	7,789	8,351
Loss from Operations	(16,140)	(7,789)	(8,351)
Other Income (expense):			
Change in fair value of derivative liabilities	1,665	—	1,665
Interest income	19	31	(12)
Interest expense	(3,751)	(56)	(3,695)
Other expense	(12)	(1)	(11)
Total other expense	(2,079)	(26)	(2,053)
Net Loss	<u>\$(18,219)</u>	<u>\$(7,815)</u>	<u>\$(10,404)</u>

### *Research and development expense*

Research and development expense increased by \$5.4 million for the year ended December 31, 2018 when compared to the year ended December 31, 2017 primarily as a result of a net increase in program development and clinical trial activities of \$3.9 million and an increase of \$1.5 million in other costs. Specifically, OCU300 and OCU310 development and clinical trial activities increased in 2018 causing an increase of \$1.8 million and \$1.7 million, respectively, the OCU400 development activities began in late 2018 generating an increase of \$0.6 million, and OCU200 development activities were increased in 2018 generating an increase of \$0.1 million. OCU100 development activities decreased resulting in a \$0.3 million decrease in expenses. In addition, R&D headcount increased to 14 full and part-time employees at the end of 2018 from 12 at the end of 2017, resulting in increased employee costs of \$1.4 million, due to changes in compensation to improve market competitiveness, as well as employee benefits and payroll costs. Stock-based compensation expense increased by \$0.2 million for the year ended December 31, 2018 compared to the year ended December 31, 2017, due to additional grants made during 2018 at a higher stock price. Rent expenses related to Ocugen's lab lease, beginning in 2018, were \$0.2 million. License fees related to the University of Illinois milestone increased research and development expense by \$0.2 million during 2018. The other costs were offset by decreases of \$0.3 million due to unpaid bonuses and \$0.2 million due to the research and development tax credit recognized in 2018.

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### *General and administrative expense*

General and administrative expenses (“G&A”) increased by \$3.0 million for the year ended December 31, 2018 when compared to the year ended December 31, 2017 primarily as a result of preparation of registration statement costs of \$2.0 million that took place in the fourth quarter of 2018. In addition, G&A headcount increased to 7 full and part-time employees at the end of 2018 from 5 at the end of 2017, resulting in increased payroll and benefits of \$0.6 million. Stock-based compensation expense increased by \$0.3 million for the year ended December 31, 2018 compared to the year ended December 31, 2017, due to additional grants made during 2018 at a higher stock price. Severance payments of \$0.3 million were owed in 2018 to two executives who were terminated in 2018. Three additional consulting contracts were entered into in 2018 totaling to \$0.2 million. The remaining \$0.3 million increase is primarily related to expenses for the additional office space in Malvern, public relations and dues and subscription costs. The G&A expenses were offset by approximately \$0.7 million relating to unpaid bonuses and zero warrants granted in 2018.

### *Interest income*

Interest income was \$19,213 for the year ended December 31, 2018 and \$31,148 for the year ended December 31, 2017. This decrease relates to interest earned on cash and cash equivalents.

### *Interest expense*

Interest expense was \$3.8 million for the year end December 31, 2018 and \$55,827 for the year ended December 31, 2017. The higher expense in 2018 was related to debt issuance costs and amortization of the debt discount on the convertible notes which were issued in 2018.

### *Other expense*

Other expense was \$12,428 for the year ended December 31, 2018 and \$1,277 for the year ended December 31, 2017. This increase relates to forfeiture of a portion of a security deposit on lab space which was vacated in March 2018.

## **Liquidity and Capital Resources**

Ocugen has funded its operations primarily through the sale and issuance of common stock and warrants to purchase common stock, proceeds from convertible notes payable, and debt. Specifically, since its inception and through March 31, 2019, Ocugen has raised an aggregate of \$23.3 million to fund its operations, of which \$13.3 million was from the sale of Ocugen common stock and warrants, \$8.8 million was from convertible notes, \$1.0 million was from borrowings under the EB-5 Program, and \$0.2 million was a grant for research from the State of Colorado. As of March 31, 2019, Ocugen had \$0.3 million in cash and cash equivalents.

Since Ocugen’s inception, it has devoted substantial resources to research and development and has incurred significant net losses and expects to continue to incur net losses for the foreseeable future. Ocugen incurred net losses of approximately \$6.3 million and \$5.0 million for the three months ended March 31, 2019 and 2018, respectively, and \$18.2 million and \$7.8 million for the years ended December 31, 2018 and 2017, respectively. As of March 31, 2019, Ocugen had an accumulated deficit of \$37.5 million.

In September 2016, pursuant to the EB-5 Program, Ocugen entered into an arrangement to borrow up to \$10.0 million from EB5 Life Sciences, L.P. (the “Lender”) in \$0.5 million increments. Borrowing may be limited by the amount of funds raised by the Lender and are subject to certain job creation requirements by Ocugen. Borrowings are at a fixed interest rate of 4.0% and are to be utilized in the clinical development, manufacturing, and commercialization of the Ocugen’s products and for the general working capital needs of Ocugen. Outstanding borrowings pursuant to the EB-5 Program become due upon the seventh anniversary of the final disbursement. Amounts repaid cannot be re-borrowed. At March 31, 2019, there is \$1.0 million of principal outstanding under the EB-5 program.

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Although it is difficult to predict future liquidity requirements, Ocugen believes that the net proceeds from the Pre-Merger Financing and Asset Sale, together with the existing cash and cash equivalents of the combined company, will be sufficient to fund its operations into mid-2020, during which time, Ocugen expects to continue its development efforts with respect to its product candidates. However, Ocugen will need to raise additional capital in the future to further the development and commercialization of its other product candidates. Until such time, if ever, as Ocugen generates product revenue, Ocugen expects to obtain additional financing through the issuance of its common stock, through other equity or debt financings or through collaborations or partnerships with other companies. Ocugen may not be able to raise additional capital on terms acceptable to it, or at all, and any failure to raise capital as and when needed could compromise its ability to execute on its business plan and cause it to delay or curtail its operations until such funding is received.

The following table shows a summary of Ocugen's cash flows for the periods indicated (in thousands):

	Three months ended March 31,		Years ended December 31,	
	2019	2018	2018	2017
Net cash used in operating activities	\$(2,667)	\$(2,793)	\$(11,631)	\$(6,320)
Net cash used in investing activities	(11)	(54)	(77)	(170)
Net cash provided by financing activities	\$ 1,359	\$ 4,964	7,185	7,453
Effect on cash of changes in exchange rate	—	—	—	—
Net increase in cash, cash equivalents and restricted cash	<u>\$(1,319)</u>	<u>\$ 2,117</u>	<u>\$ (4,523)</u>	<u>\$ 963</u>

### *Operating activities*

Cash used in operating activities was \$2.7 million for the three months ended March 31, 2019 compared with \$2.8 million for the three months ended March 31, 2018. The \$0.1 million decrease in cash used in operating activities is primarily due to a \$1.1 million increase in net loss for the three months ended March 31, 2019 compared with the three months ended March 31, 2018, partially offset by a \$0.5 million increase in the change in fair value of derivative liabilities and a \$0.5 million increase in changes in operating assets and liabilities.

Cash used in operating activities was \$11.6 million for the year ended December 31, 2018 compared with \$6.3 million for the year ended December 31, 2017. The \$5.3 million increase in cash used in operating activities is primarily due to a \$10.4 million increase in net loss for the year ended December 31, 2018 compared with the year ended December 31, 2017, partially offset by a combined \$2.4 million increase in non-cash expense due to interest, stock-based compensation and the fair value change of the derivative liabilities on the convertible notes and an increase of \$2.7 million due to changes in operating assets and liabilities.

### *Investing activities*

Cash used in investing activities, related to equipment purchases and improvements, was relatively flat at less than \$0.1 million for the three months ended March 31, 2019 compared to the three months ended March 31, 2018.

Cash used in investing activities was \$0.1 million for the year ended December 31, 2018, related to equipment purchases and improvements, compared to \$0.2 million for the year ended December 31, 2017.

### *Financing activities*

Cash provided by financing activities was \$1.4 million for the three months ended March 31, 2019 compared to \$5.0 million for the three months ended March 31, 2018. This \$3.6 million decrease is primarily due to the increased level of the convertible note offerings in 2018 compared to 2019.

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Cash provided by financing activities was \$7.2 million for the year ended December 31, 2018 compared to \$7.5 million for the year ended December 31, 2017. This decrease of \$0.3 million is primarily due a total of \$7.3 million convertible debt issued in 2018 compared to \$7.5 million of common stock offerings and warrants in 2017.

### ***Funding requirements***

Ocugen expects to continue to incur significant expenses in connection with its ongoing activities, particularly as it continues research and development, including clinical development activities of its product candidates, increases its headcount and adds operational, financial and information systems to execute its business plan, maintains, expands and protects its patent portfolio, contracts to manufacture its product candidates, and operates as a public company.

Ocugen's future funding requirements, both near- and long-term, will depend on many factors, including, but not limited to:

- the initiation, progress, timing, costs and results of clinical trials for its product candidates;
- the outcome, timing and cost of the regulatory approval process for its product candidates by the FDA;
- future costs of manufacturing and commercialization;
- the cost of filing, prosecuting, defending and enforcing its patent claims and other intellectual property rights;
- the cost of defending intellectual property disputes, including patent infringement actions brought by third parties against it;
- the costs of expanding infrastructure and increasing headcount, as well as the higher corporate infrastructure costs associated with becoming a public company; and
- the extent to which it in-licenses or acquires other products, product candidates or technologies.

Ocugen believes that the net proceeds from the Pre-Merger Financing and the Asset Sale, together with the existing cash and cash equivalents of the combined company, will be sufficient to fund its operations into mid-2020, during which time Ocugen expects to continue its development efforts with respect to its product candidates. Ocugen has based this estimate on assumptions that may prove to be wrong, and Ocugen could utilize its available capital resources sooner than it expects. Ocugen expects that it will need to raise additional capital in the future to complete the clinical development of its product candidates. Additional funds may not be available on a timely basis, on favorable terms, or at all, and such funds, if raised, may not be sufficient to enable Ocugen to continue to implement its long-term business strategy. If Ocugen cannot expand its operations or otherwise capitalize on its business opportunities because it lacks sufficient capital, Ocugen's business, financial condition and results of operations could be materially adversely affected, and it may need to delay or curtail its operations until such funding is received.

**Contractual Obligations**

The following table summarizes Ocugen’s contractual obligations and commitments at March 31, 2019 (in thousands):

<u>Contractual Obligations</u>	<u>Payments due by period as of March 31, 2019</u>				
	<u>Total</u>	<u>Less than 1 year</u>	<u>1 - 3 years</u>	<u>4 - 5 years</u>	<u>More than 5 years</u>
Operating lease commitments (1)	\$ 546	\$ 289	\$ 257	\$ —	\$ —
Capital lease commitments (2)	54	24	30	—	—
Long-term debt obligations, including interest (3)	10,207	—	9,110	1,097	—
	<u>\$10,807</u>	<u>\$ 313</u>	<u>\$9,397</u>	<u>\$1,097</u>	<u>\$ —</u>

- (1) Reflects obligations pursuant to Ocugen’s office leases in Malvern, PA and Boulder, CO.  
(2) Reflects obligations pursuant to Ocugen’s specialized research equipment.  
(3) Reflects two loans for \$0.5 million each dated September 2016 and December 2016, as well as two convertible notes for \$2.5 million each dated January 2018, three convertible notes totaling \$1.0 million dated June 2018, eight convertible notes totaling \$1.2 million dated November 2018, one convertible note totaling \$0.2 million dated December 2018, two convertible notes totaling \$0.5 million dated January 2019 and five convertible notes totaling \$1.0 million dated February 2019.

This table does not include potential future milestone payments or royalty obligations to third parties under license and other agreements to the extent that the timing and likelihood of such milestone payments are not known, and, in the case of royalty obligations, if the amount of such obligations are not reasonably estimable, as discussed below.

**Milestone, Royalty-Based and Other Commitments****License Agreement with University of Colorado**

In March 2014, Ocugen entered into a license patent agreement with the University of Colorado (“CU”), which was amended in January 2017 and clarified by a letter of understanding in November 2017 (the exclusive license agreement, as amended and clarified, is referred to as the “CU Agreement”). The CU Agreement gives Ocugen an exclusive, worldwide, sublicensable license to patents for OCU100 and OCU200. The CU Agreement requires the payment of certain regulatory milestones, aggregating \$1.5 million, and low single digit percentage earned royalties on net sales.

In exchange for the licensed patents, Ocugen issued CU 180,000 shares of Ocugen common stock. The license agreement included an anti-dilution provision, requiring the issuance of additional shares to maintain a specified ownership interest until such time as Ocugen achieved a specified level of financing. Between the effective date of the agreement and December 31, 2016, Ocugen issued CU an additional 67,000 shares of Ocugen common stock. The anti-dilution provision was no longer effective per the terms of the agreement, as amended, after the closing in December 2016 of Ocugen’s common stock financing round designated as Series A. Ocugen also reimbursed CU for \$26,179 of fees and costs previously incurred by CU.

The agreement with CU calls for minimum annual royalty payments of \$20,000, starting on the third anniversary of the agreement and on each annual anniversary thereafter, and after sales commence, increasing to a percentage rate in the mid-twenties of the previous year’s royalty payment paid to CU, through the term of the agreement. Ocugen paid \$20,000 during 2018 and will pay \$20,000 in 2019 as the minimum royalty is due annually beginning in 2017 and recognized such amount as research and development expense. No additional royalties were paid or incurred during 2018 or the three months ended March 31, 2019 as Ocugen has not achieved any milestones, net sales or sublicensing for OCU100 or OCU200. Future annual royalties will be recognized in the

years they are earned, per the license agreement. Ocugen may cancel the license agreement at any time with 60 days' written notice.

#### **License Agreement with University of Illinois, Chicago**

In February 2016, Ocugen entered into a license agreement with the University of Illinois, Chicago ("UIC"). This agreement gives Ocugen an exclusive, worldwide, non-transferable, sublicensable license to patents and patent rights for OCU300 and OCU310. Commencing in 2019, Ocugen pays UIC an annual minimum payment and reimburses UIC for reasonable documented patent costs and expenses. The UIC agreement requires the payment of certain regulatory and commercial milestones, aggregating \$1.25 million.

Ocugen is required to pay royalties ranging from the low single digits to low teens to UIC based on net sales and sublicense revenues generated by OCU300 and OCU310. Ocugen is also required to pay minimum annual royalties to UIC, beginning with an annual payment of \$20,000 on the third anniversary of the effective date of the agreement, and increasing gradually to \$50,000 by the sixth anniversary and continuing through the term of the agreement. These minimum royalties will be recognized over the annual period to which they relate. Ocugen is also obligated to pay UIC up to \$1.25 million upon the achievement of certain development and regulatory milestones.

Ocugen recognized \$5,833 and \$3,333 of royalty expense related to this agreement during the three months ended March 31, 2019 and March 31, 2018, respectively. Additionally, during 2018, Ocugen incurred \$250,000 in milestone payments due to achieving a milestone associated with dosing the first patient in a Phase 3 clinical trial. The \$250,000 is in Accrued Expenses as of March 31, 2019 and December 31, 2018. Ocugen has not achieved any other milestones, net sales or sublicensing for OCU300 or OCU310. Ocugen may cancel the license agreement at any time with 90 days' written notice.

#### **License Arrangement with The Schepens Eye Research Institute**

In December 2017, Ocugen entered into a license agreement with The Schepens Eye Research Institute ("SERI"). The agreement gives Ocugen an exclusive, worldwide, sublicensable license to patent rights, biological materials and technical information for nuclear hormone receptor genes *NR1D1*, *NR2E3* (*OCU400*), *RORA*, *NUPR1* and *NR2C1*. Ocugen is required to pay an annual license maintenance fee, as well as payment of certain regulatory and commercial milestones, aggregating \$16.5 million, and low single-digit percentage royalties on annual net sales of products that fall under the licensed patent rights.

This agreement is accounted for as a Collaborative Arrangement. In connection with acquiring the license, Ocugen was required to pay a license fee of \$125,000, which was recognized in 2017.

Ocugen was also required to reimburse SERI for all patent costs incurred prior to the effective date of the agreement, totaling \$39,681, and will be required to reimburse SERI for all future patent costs related to this licensed technology. These license and patent fees were recognized as research and development expense in 2017. These license and patent fees were recognized as research and development expense in 2017.

Ocugen is obligated to pay SERI up to \$6.0 million upon the achievement of certain development and regulatory milestones. Ocugen is also obligated to pay SERI up to \$10.5 million upon the achievement of certain commercial milestones. Ocugen will also pay SERI royalties in the low single digits based on net sales, which will be credited against the annual license maintenance fees. The license agreement dictates that Ocugen will pay an annual license maintenance fee of \$25,000 for the first two years following expiration or termination of the Sponsored Research Agreement, and \$50,000 for each year thereafter. No license maintenance fees were paid during the three months ended March 31, 2019 or in 2018. No milestones or royalties were paid or incurred through March 31, 2019, as Ocugen has not achieved any milestones, net sales or sublicensing under this agreement. Ocugen may cancel the license agreement at any time with 180 days' written notice.



In December 2017, Ocugen also entered into a Sponsored Research Agreement with SERI which is effective for two years. Pursuant to the terms of the agreement, Ocugen expects to make payments of approximately \$1.1 million for research services for OCU400 over the period beginning December 2017 and ending December 2019. Ocugen recognized approximately \$159,250 and \$145,600 as research and development expense in the three months ended March 31, 2019 and March 31, 2018, respectively for work performed under this agreement.

### **Off-Balance Sheet Arrangements**

Ocugen did not have off-balance sheet arrangements during the periods presented, and it does not currently have any off-balance sheet arrangements as defined in the rules and regulations of the SEC.

### **Recently Adopted Accounting Pronouncements**

In May 2014, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) 2014-09, *Revenue from Contracts with Customers (Topic 606)*. This standard requires revenue recognition to depict the transfer of goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. ASU 2014-09 sets forth a new revenue recognition model that requires identifying the contract, identifying the performance obligations, determining the transaction price, allocating the transaction price to performance obligations, and recognizing the revenue upon satisfaction of performance obligations. In August 2015, the FASB modified the standard with ASU 2015-14, *Deferral of the Effective Date*. ASU 2014-09 is effective for annual reporting periods beginning after December 15, 2017, and interim periods within that reporting period. Nonpublic entities are required to apply the guidance in annual periods beginning after December 15, 2018 and in interim periods beginning after December 15, 2019. Ocugen adopted ASU 2014-09 in 2018, however, there was no impact as Ocugen does not generate revenue.

In February 2016, the FASB issued ASU No. 2016-02 Leases (ASC 842). In July 2018, the FASB issued ASU No. 2018-10, “Codification Improvements to Topic 842, Leases” (ASU 2018-10), which provides narrow amendments to clarify how to apply certain aspects of the new lease standard, and ASU No. 2018-11, “Leases (Topic 842)—Targeted Improvements” (ASU 2018-11), which addressed implementation issues related to the new lease standard. These and certain other lease-related ASUs have generally been codified in ASC 842. ASC 842 supersedes the lease accounting requirements in Accounting Standards Codification Topic 840, Leases (ASC 840). ASC 842 establishes a right-of-use model that requires a lessee to record a right-of-use (“ROU”) asset and a lease liability on the balance sheet for all leases. Under ASC 842, leases are classified as either finance or operating, with classification affecting the pattern of expense recognition in the income statement. The standard also requires disclosures to help investors and other financial statement users better understand the amount, timing and uncertainty of cash flows arising from leases. ASU 2016-02 is effective for annual reporting periods beginning after December 15, 2018 and interim periods within that reporting period. Nonpublic entities are required to apply the guidance in annual periods beginning after December 15, 2019 and in interim periods beginning after December 15, 2020. Ocugen adopted ASC 842 on January 1, 2019 using the effective date transition method. Prior period results continue to be presented under ASC 840 based on the accounting standards originally in effect for such periods.

Ocugen has elected certain practical expedients permitted under the transition guidance within ASC 842 to leases that commenced before January 1, 2019, including the package of practical expedients. The election of the package of practical expedients resulted in Ocugen not reassessing prior conclusions under ASC 840 related to lease identification, lease classification and initial direct costs for expired and existing leases prior to January 1, 2019. Ocugen did not elect the practical expedient to not record short-term leases on its consolidated balance sheet. The adoption of ASU 2016-02 did not have a significant impact on Ocugen’s consolidated results of operations or cash flows. Upon adoption, Ocugen recognized a ROU asset and lease liability of \$0.4 million and \$0.4 million, respectively.

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In August 2016, the FASB issued ASU 2016-15, *Statement of Cash Flows, Classification of Certain Cash Receipts and Cash Payments*, which reduces existing diversity in the classification of certain cash receipts and cash payments on the statements of cash flows. ASU 2016-15 is effective for fiscal years beginning after December 15, 2017, and interim periods within that reporting period. Early adoption is permitted. Nonpublic entities are required to apply the guidance in annual periods beginning after December 15, 2018 and in interim periods beginning after December 15, 2019. Ocugen adopted this standard on January 1, 2018 and it did not have an impact on its financial statements.

In November 2016, the FASB issued ASU 2016-18, *Restricted Cash*. The guidance is intended to address the diversity that currently exists in the classification and presentation of changes in restricted cash on the statement of cash flows. The new standard requires that entities show the changes in the total of cash and cash equivalents, restricted cash and restricted cash equivalents on the statement of cash flows and no longer present transfers between cash and cash equivalents, restricted cash and restricted cash equivalents on the statement of cash flows. ASU 2016-18 is effective for fiscal years beginning after December 15, 2017, and interim periods within that reporting period. Nonpublic entities are required to apply the guidance in annual periods beginning after December 15, 2018 and in interim periods beginning after December 15, 2019. Early adoption is permitted. Ocugen adopted this standard on January 1, 2018 and retrospectively to all periods presented.

In May 2017, the FASB issued ASU 2017-09, *Compensation—Stock Compensation (Topic 718): Scope of Modification Accounting*, to clarify when to account for a change to the terms or conditions of a share-based payment award as a modification. Under the new guidance, modification accounting is required only if the fair value, the vesting conditions, or the classification of the award (as equity or liability) changes as a result of the change in terms or conditions. The guidance is effective prospectively for annual periods and interim periods within those annual periods, beginning after December 15, 2017 for all entities. Ocugen adopted this standard as of January 1, 2018. It did not have an impact on its financial statements.

In June 2018, the FASB issued ASU 2018-07 intended to reduce cost and complexity and to improve financial reporting for nonemployee share-based payments. Currently, the accounting requirements for nonemployee and employee share-based payment transactions are significantly different. This ASU expands the scope of Topic 718, *Compensation-Stock Compensation* (which currently only includes share-based payments to employees) to include share-based payments issued to nonemployees for goods or services. Consequently, the accounting for share-based payments to nonemployees and employees will be substantially aligned. This ASU supersedes Subtopic 505-50, *Equity-Equity-Based Payments to Nonemployees*. The amendments in this ASU are effective for annual periods and interim periods within those annual periods beginning after December 15, 2018, with early adoption permitted. Nonpublic entities are required to apply the guidance in annual periods beginning after December 15, 2019 and in interim periods beginning after December 15, 2020. Upon transition, the entity is required to measure these nonemployee awards at fair value as of the adoption date through a cumulative-effect adjustment to retained earnings as of the beginning of the fiscal year of adoption. Ocugen adopted as of July 1, 2018 and there was no impact. Early adoption is permitted to the extent ASC 606 has been adopted, which occurred in 2018.

### **Internal Control Over Financial Reporting**

Assessing Ocugen's staffing and training procedures to improve its internal control over financial reporting is an ongoing process. Ocugen is not currently required to comply with Section 404 of the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, and are therefore not required to make an assessment of the effectiveness of its internal control over financial reporting. As a result, Ocugen's management did not perform an evaluation of Ocugen's internal control over financial reporting as of December 31, 2018 or March 31, 2019. Further, Ocugen's independent registered public accounting firm has not been engaged to express, nor have they expressed, an opinion on the effectiveness of Ocugen's internal control over financial reporting.

### **Quantitative and Qualitative Disclosures About Market Risks**

Ocugen is exposed to market risks in the ordinary course of its business. These market risks are principally limited to interest rate fluctuations.

As of March 31, 2019, Ocugen had cash and cash equivalents of \$0.3 million, consisting primarily of funds in cash and money market accounts. The primary objective of Ocugen's investment activities is to preserve principal and liquidity while maximizing income without significantly increasing risk. Ocugen does not enter into investments for trading or speculative purposes. Due to the short-term nature of Ocugen's investment portfolio, Ocugen does not believe an immediate 10% increase in interest rates would have a material effect on the fair market value of its portfolio, and accordingly Ocugen does not expect its operating results or cash flows to be materially affected by a sudden change in market interest rates.

### ***Proposed Merger with Histogenics***

On April 5, 2019, Ocugen and Histogenics entered into the Merger Agreement. Upon the terms and subject to the satisfaction of the conditions described in the Merger Agreement, including approval of the transaction by Ocugen's stockholders and Histogenics' stockholders, a wholly-owned subsidiary of the Histogenics will be merged with and into Ocugen, with Ocugen surviving the merger as a wholly-owned subsidiary of Histogenics. The proposed merger is structured as a stock-for-stock transaction whereby all of Ocugen's outstanding shares of common stock and securities convertible into or exercisable for shares of Ocugen common stock will be converted into the right to receive shares Histogenics common stock and securities convertible into or exercisable for Histogenics common stock. Based on the exchange ratio of 28.7650, the former Ocugen equity holders immediately before the merger are expected to own approximately 86.24% of the outstanding capital stock of Histogenics, and the stockholders and warrant holders of Histogenics immediately before the merger are expected to own approximately 13.76% of the outstanding capital stock of Histogenics, including the Initial Shares but excluding the Additional Shares issued in the Financing SPA (as such terms are defined in the section entitled "Agreements Related to the Merger—Securities Purchased Agreement" above). If the proposed merger is not completed and the Merger Agreement is terminated under certain circumstances, Histogenics or Ocugen may be required to pay the other party a termination fee of up to \$600,000 or \$700,000, respectively. Even if a termination fee is not payable in connection with a termination of the Merger Agreement, each of Histogenics and Ocugen will have incurred significant fees and expenses, which must be paid whether or not the merger is completed.

## QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISKS

Histogenics is a smaller reporting company, as defined by Rule 12b-2 of the Securities Exchange Act of 1934, as amended, and is not required to provide the information required under this item.

### MANAGEMENT PRIOR TO AND FOLLOWING THE MERGER

#### Executive Officers and Directors of Histogenics Prior to the Merger

##### *Directors of Histogenics Prior to the Merger*

**Joshua Baltzell** has served as chair of the Histogenics Board since February 2019 and as a member of the Histogenics Board since July 2012. Mr. Baltzell is a Venture Partner at Split Rock Partners, and also serves as a Venture Partner at SightLine Partners. He has been with Split Rock since 2004 and with SightLine since 2014. Mr. Baltzell has over 20 years of experience in the healthcare industry. Prior to his tenure in the venture capital industry, Mr. Baltzell held roles as an investment banker at Piper Jaffray Companies from 2000 to 2002, where he focused primarily on mergers and acquisitions in the medical device sector, as well as various marketing and business development positions with SCIMED and Boston Scientific. Mr. Baltzell currently serves on the boards of Magnolia Medical, ViewPoint Medical and Colorescience. Mr. Baltzell holds a B.A. in economics from St. Olaf College and an M.B.A. from the University of Minnesota's Carlson School of Management. Histogenics believes that Mr. Baltzell's qualifications to serve as a director of Histogenics include his extensive experience in the venture capital industry, his investment banking experience in the healthcare and medical device industries with both publicly and privately held companies and his significant prior board experience.

**David C. Hood** has served as a member of the Histogenics Board since July 2019. Mr. Hood currently serves on the board of directors of Fathom Realty where he has served since May 2019 and as a board member of Rise Against Hunger where he has served since January 2015. Previously, Mr. Hood was a partner at Ernst & Young, LLP, where he served as an audit partner from July 2005 to July 2015 and prior to that he was an audit senior manager from July 2000 to June 2005. Prior to joining Ernst & Young, LLP, Mr. Hood was the vice president of finance at QuintilesIMS (now IQVIA) from July 1993 to July 2000. Mr. Hood was a board member, audit committee chair, treasurer and served on the executive committee at Guilford College from October 2007 to October 2018. Mr. Hood received a B.S. in accounting from Guilford College and is licensed as a C.P.A. in the State of North Carolina. Histogenics believes that Mr. Hood's qualifications to serve as a director of Histogenics include his extensive experience as an auditor of both public and private biotechnology and technology companies and his experience as a director of numerous private companies, including as a member and/or chairman of such company's audit committees.

**Susan B. Washer** has served as a member of the Histogenics Board since April 2018. Ms. Washer is the President and Chief Executive Officer of Applied Genetic Technologies Corporation (AGTC), where she has served in such capacity since March 2002 and as a member of its board of directors since November 2003. Ms. Washer was also AGTC's chief operating officer from October 2001 to March 2002. From June 1994 to October 2001, Ms. Washer led two entrepreneurial firms including serving as president and chief executive officer of Scenic Productions and as the Founding Executive Director and then Business Advisor for the North Florida Technology Innovation Center, a public-private organization financing and providing services to entrepreneurial companies licensing STEM based technology from Florida universities. Ms. Washer currently serves on the board of directors of Biotechnology Innovation Organization (BIO) and the Alliance for Regenerative Medicine. Previously, Ms. Washer served as chairman of the BioFlorida board and the Southeast BIO board and continues her involvement with both organizations as a member of their respective boards. From October 1983 to June 1994, Ms. Washer served in various research and pharmaceutical management positions with Abbott Laboratories and Eli Lilly and Company. Ms. Washer received a B.S. in biochemistry from Michigan State University and an M.B.A. from the University of Florida. Histogenics believes that Ms. Washer's qualifications to serve as a director of Histogenics include her education and professional background in science

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and business management, her years of experience in the pharmaceutical and biotechnology industries and her service as a senior executive of early and late stage biotechnology companies.

### ***Executive Officers of Histogenics Prior to the Merger***

The following table sets forth the name, age and position of each of Histogenics' executive officers as of June 30, 2019. Information as of June 30, 2019 about the number of shares of common stock beneficially owned by each of the individuals designated as an executive officer as June 30, 2019, whether held directly or indirectly, appears below under the heading "*Principal Stockholders of Histogenics.*"

<u>Name</u>	<u>Age</u>	<u>Current Positions</u>
Adam Gridley	46	President, Secretary, Treasurer and Director (1)
Jonathan Lieber	49	Interim Chief Financial Officer

- (1) Pursuant to a reduction in force approved by the Histogenics Board in March 2019, Mr. Gridley's employment with Histogenics terminated effective March 22, 2019. Mr. Gridley has retained his statutory titles of president, treasurer and secretary of Histogenics while he continues to provide consulting services to Histogenics, and will remain a director of Histogenics. In connection with the execution of the separation entered into with Mr. Gridley in connection with his termination, Histogenics and Mr. Gridley also entered into a consulting agreement pursuant to which Mr. Gridley provides consulting services to Histogenics for an hourly fee of \$250.

### **Executive Officers and Directors Following the Merger**

#### ***Resignation of Current Executive Officers of Histogenics***

Pursuant to the Merger Agreement, all of the current executive officers of Histogenics will resign immediately prior to the completion of the merger.

#### ***Executive Officers and Directors of the Combined Organization Following the Merger***

The Histogenics Board is currently composed of four directors. Following the merger, the Histogenics Board will be increased to seven directors with such seven members designated by Ocugen. Pursuant to the Merger Agreement, all of the current directors of Histogenics shall resign from the Histogenics Board at or prior to the Effective Time. It is anticipated that, following the closing of the merger, the members of the Histogenics management team and the Histogenics Board will be constituted as follows:

<u>Name</u>	<u>Age</u>	<u>Position After the Merger</u>
<b><i>Executive Officers</i></b>		
Shankar Musunuri, Ph.D., MBA	55	Chief Executive Officer, Executive Chairman of the Board, Co-Founder
Daniel Jorgensen, M.D., M.P.H., MBA	59	Chief Medical Officer
Rasappa Arumugham, Ph.D.	67	Chief Scientific Officer
Vijay Tammara, Ph.D.	59	Vice President, Regulatory & Quality
Kelly Beck, MBA, SPHR, SHRM-SCP, PMP	42	Vice President, Investor Relations & Administration
<b><i>Non-Employee Directors</i></b>		
Uday Kompella, Ph.D.	52	Director
Ramesh Kumar, Ph.D.	63	Director
Frank Leo	63	Director
Manish Potti	33	Director
Suha Taspolatoglu, M.D.	57	Director
Junge Zhang	52	Director

### **Composition of the Board of Directors Prior to and Following the Merger**

The Histogenics Board is currently comprised of four directors divided into three staggered classes, each class serving three-year terms. The staggered structure of the Histogenics Board will remain in place following completion of the merger. At the most recent annual meeting of Histogenics' stockholders held in 2018, Class I directors were elected. As a result, the term of the Class I directors of the combined organization will expire upon the election and qualification of successor directors at the annual meeting of stockholders in 2021, with the terms of the Class II directors and Class III directors expiring upon the election and qualification of successor directors at the annual meetings of stockholders to be held in 2019 and 2020, respectively.

The director classes for Histogenics are currently as follows:

- Class I director: Joshua Baltzell
- Class II directors: Adam Gridley and Susan Washer
- Class III director: David C. Hood

Pursuant to the Merger Agreement, each of the directors and officers of Histogenics shall resign immediately prior to the Effective Time. In connection with the merger, the Histogenics Board will be expanded to include a total of seven directors. Pursuant to the Merger Agreement, all such directors shall be designated by Ocugen. It is anticipated that these directors will be appointed to the three staggered director classes of the combined organization's board of directors to be determined at the time of appointment.

The division of the Histogenics Board into three classes with staggered three-year terms may delay or prevent a change of management or a change of control of Histogenics, or, following the completion of the merger, the combined organization.

Histogenics' Nominating/Governance Committee is responsible for reviewing the board of directors, on an annual basis. In evaluating the suitability of individual candidates (both new candidates and current members), the Nominating and Corporate Governance Committee and the board of directors of the combined organization may take into account many factors, including the following:

- diversity of personal and professional background, perspective, experience, age, gender, ethnicity and country of citizenship;
- personal and professional integrity and ethical values;
- experience in one or more fields of business, professional, governmental, scientific or educational endeavors, and a general appreciation of major issues facing public companies similar in scope and size to Histogenics;
- experience relevant to Histogenics' industry or social policy concerns;
- relevant academic expertise or other proficiency in an area of Histogenics' operations;
- objective and mature business judgment and expertise; and
- any other relevant qualifications, attributes or skills.

There are no family relationships among any of Histogenics' current directors and executive officers, and there are no family relationships among any of the combined organization's proposed directors and executive officers.

### **Director Independence**

As required under the Nasdaq listing standards, a majority of the members of a listed company's board of directors must qualify as "independent," as affirmatively determined by the board of directors. The Ocugen Board has determined that after the completion of the merger, six of the combined company's seven directors are

expected to be independent members of the combined company’s board of directors within the meaning of the applicable Nasdaq listing standards: Dr. Musunuri is not expected to be “independent” within the meaning of the Nasdaq listing standards because he will have served as an executive officer of Ocugen immediately prior to the Effective Time and is expected to serve as Chief Executive Officer of the combined organization.

**Committees of the Board of Directors Prior to and Following the Merger**

The Histogenics Board currently has three standing committees: the Audit Committee, the Compensation Committee and the Nominating/Corporate Governance Committee. The charters for the committees are available on Histogenics’ website (<http://ir.histogenics.com>) under “Investors” at “Corporate Governance.” The current membership of each of the committees are shown below. Information about the duties and responsibilities of each of the committees are provided below. After the merger, each of these committees are expected to retain these duties and responsibilities.

After the merger, the Compensation Committee and the Nominating/Corporate Governance Committee of the combined company’s board of directors are expected to be comprised entirely of directors who are independent within the meaning of the Nasdaq listing standards, and the members of the Audit Committee are expected to be independent under applicable Nasdaq listing standards and SEC rules.

**Audit Committee**

*Number of Meetings held in 2018: Six*

<u>Current Members</u>	<u>Anticipated Members After Merger</u>	<u>Current and Anticipated Committee Functions</u>
David C. Hood (Chair)	Ramesh Kumar, Ph.D. (Chair)	<ul style="list-style-type: none"> <li>• Oversees financial and operational matters involving accounting, corporate finance, auditing, internal control over financial reporting, compliance, and business ethics.</li> <li>• Oversees other financial audit and compliance functions as assigned by the board of directors.</li> <li>• Oversees those functions which may pose material financial risk to Histogenics.</li> <li>• Has the sole authority to select, evaluate, replace and oversee Histogenics’ independent registered public accounting firm.</li> <li>• Has the sole authority to approve non-audit and audit services to be performed by the independent registered public accounting firm.</li> <li>• Monitors the independence and performance of the independent registered public accounting firm.</li> <li>• Provides an avenue of communications among the independent registered public accounting firm, management and the board of directors.</li> <li>• Reviews, approves and provides oversight of “related party transactions.”</li> <li>• Has the specific responsibilities and authority necessary to comply with the Nasdaq listing standards applicable to audit committees.</li> </ul>
Joshua Baltzell	Manish Potti	
Susan Washer	Suha Taspolatoglu, M.D.	

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<u>Current Members</u>	<u>Anticipated Members After Merger</u>	<u>Current and Anticipated Committee Functions</u>
		<ul style="list-style-type: none"><li>• Reviews, approves and provides oversight of “related party transactions.”</li><li>• Has the specific responsibilities and authority necessary to comply with the Nasdaq listing standards applicable to audit committees.</li></ul>

**Compensation Committee**

*Number of Meetings held in 2018: Seven*

<u>Current Members</u>	<u>Anticipated Members After Merger</u>	<u>Committee Functions</u>
Joshua Baltzell (Chair) Susan Washer	Frank Leo (Chair) Manish Potti Junge Zhang	<ul style="list-style-type: none"><li>• Reviews the performance of Histogenics officers and establishes overall executive compensation policies and programs.</li><li>• Reviews and approves compensation elements such as base salary, bonus awards, stock option grants and other forms of long-term incentives for Histogenics officers.</li><li>• Has the authority, in its sole discretion, to retain (or obtain the advice of) any compensation consultant, legal counsel or other adviser to assist it in the performance of its duties.</li><li>• Evaluates the independence of Histogenics’ compensation advisers.</li><li>• Has the direct responsibility for the appointment, compensation and oversight of the work of any advisers retained or engaged by the Compensation Committee.</li><li>• Reviews board of directors compensation.</li><li>• Has the specific responsibilities and authority necessary to comply with the Nasdaq listing standards applicable to compensation committees.</li></ul>



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### ***Nominating and Corporate Governance Committee***

*Number of Meetings held in 2018: Three*

<u>Current Members</u>	<u>Anticipated Members After Merger</u>	<u>Committee Functions</u>
Joshua Baltzell (Chair) Susan Washer	Junge Zhang (Chair) Ramesh Kumar, Ph.D. Uday Kompella, Ph.D.	<ul style="list-style-type: none"><li>• Evaluates governance standards for Histogenics to ensure that appropriate governance policies and procedures have been established and are being followed.</li><li>• Develops criteria to determine the qualifications and appropriate tenure of directors.</li><li>• Reviews such qualifications and makes recommendations to the board regarding the nomination of current directors for re-election to the board as well as new nominees to fill vacancies on the board.</li><li>• Considers any stockholder recommendations for board nominees, as described below.</li><li>• Recommends to the board the chairmanship and membership of each board committee.</li><li>• Reviews succession plans for Histogenics officers.</li></ul>

### ***Compensation Committee Membership, Interlocks and Insider Participation***

Following completion of the merger, each member of the Compensation Committee is expected to be a “non-employee” director within the meaning of Rule 16b-3 of the rules promulgated under the Exchange Act, and independent within the meaning of the independent director guidelines of Nasdaq and the SEC. None of the proposed executive officers of the combined organization serves as a member of the board of directors or compensation committee of any entity that has one or more executive officers who is proposed to serve on the combined organization’s board of directors or Compensation Committee following the merger.

### ***Audit Committee Matters***

The Audit Committee of the Histogenics Board oversees the quality and integrity of Histogenics’ financial statements and other financial information provided to Histogenics’ stockholders, the retention and performance of Histogenics’ independent accountants, the effectiveness of Histogenics’ internal controls and disclosure controls and Histogenics’ compliance with ethics policies and SEC and related regulatory requirements. Pursuant to the Audit Committee charter, the functions of the Audit Committee include, among other things: (1) appointing, approving the compensation of and assessing the independence of Histogenics’ registered public accounting firm; (2) overseeing the work of Histogenics’ registered public accounting firm, including through the receipt and consideration of reports from such firm; (3) reviewing and discussing with management and the registered public accounting firm Histogenics’ annual and quarterly financial statements and related disclosures; (4) monitoring Histogenics’ internal control over financial reporting and Histogenics’ disclosure controls and procedures; (5) meeting independently with Histogenics’ registered public accounting firm and management; (6) furnishing the audit committee report required by SEC rules; (7) reviewing and approving or ratifying any related person transactions; and (8) overseeing Histogenics’ risk assessment and risk management policies. Histogenics’ Audit Committee charter is available on the “Investors” section of Histogenics’ corporate website located at <http://ir.histogenics.com>. Three directors comprised the Audit Committee as of December 31, 2018:

Mr. Gill (the Chairman of the Audit Committee), Mr. Johnson and Mr. Rakin. Mr. Johnson, Mr. Rakin and Mr. Gill resigned from the Histogenics Board (and all committees thereof) effective February 27, 2019, June 20, 2019 and July 18, 2019, respectively. Ms. Washer, Mr. Baltzell and Mr. Hood were appointed to the Audit Committee effective February 27, 2019, June 20, 2019 and June 19, 2019, respectively. Mr. Hood was appointed as the chairman of the Audit Committee on July 19, 2019. The Audit Committee met six times during 2018. In addition, the members of the Audit Committee met informally in conjunction with each regularly scheduled quarterly Board meeting and at other times throughout the year to discuss a variety of matters.

All members of Histogenics' Audit Committee meet the requirements for financial literacy under the applicable rules and regulations of the SEC and Nasdaq. The Histogenics Board has determined that Messrs. Hood and Baltzell are "audit committee financial experts" as defined by applicable SEC rules and have the requisite financial sophistication as defined under the applicable Nasdaq rules and regulations.

The Histogenics Board annually reviews the Nasdaq listing standards definition of independence for Audit Committee members and has determined that all members of Histogenics' Audit Committee are independent (as independence is currently defined in applicable Nasdaq listing standards and Rule 10A-3 promulgated under the Exchange Act).

#### ***Nominating/Corporate Governance Committee Matters***

Histogenics' Nominating/Corporate Governance Committee identifies, evaluates and recommends nominees to the Histogenics Board and committees of the Histogenics Board, conducts searches for appropriate directors and evaluates the performance of the Histogenics Board and of individual directors. Pursuant to the Nominating/Corporate Governance Committee charter, the functions of the Nominating/Corporate Governance Committee include, among other things: (1) identifying, evaluating and making recommendations to the Histogenics Board and Histogenics' stockholders concerning nominees for election to the Histogenics Board, to each of the Histogenics Board's committees and as committee chairs; (2) annually reviewing the performance and effectiveness of the Histogenics Board and developing and overseeing a performance evaluation process; (3) annually evaluating the performance of management, the Histogenics Board and each Histogenics Board committee against their duties and responsibilities relating to corporate governance; (4) annually evaluating adequacy of Histogenics' corporate governance structure, policies and procedures; and (5) providing reports to the Histogenics Board regarding the Committee's nominations for election to the Histogenics Board and its committees. Histogenics' Nominating/Corporate Governance Committee charter is available on the "Investors" section of Histogenics' corporate website located at <http://ir.histogenics.com>. Three directors comprised the Nominating/Corporate Governance Committee as of December 31, 2018: Dr. Kong (the Chairman of the Nominating/Corporate Governance Committee), Mr. Baltzell and Mr. Lewis. Dr. Kong and Mr. Lewis resigned from the Histogenics Board (and all committees thereof) effective February 27, 2019 and June 20, 2019, respectively. Ms. Washer was appointed to the Nominating/Corporate Governance Committee effective June 20, 2019. Mr. Baltzell was appointed as the Chairman of the Nominating/Corporate Governance Committee effective February 22, 2019. The Nominating/Corporate Governance Committee met three times during 2018. In addition, the members of the Nominating/Corporate Governance Committee met informally in conjunction with each regularly scheduled quarterly Board meeting and at other times throughout the year to discuss a variety of matters.

The Nominating/Corporate Governance Committee believes that candidates for director should have certain minimum qualifications, including being able to read and understand basic financial statements and having a general understanding of Histogenics' industry and market. The Nominating/Corporate Governance Committee also considers other factors it deems appropriate, including, but not limited to:

- the candidate's relevant expertise and experience upon which to offer advice and guidance to management;
- the candidate having sufficient time to devote to the affairs of Histogenics;

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- the candidate having a proven track record in his or her field;
- the candidate's ability to exercise sound business judgment;
- the candidate's commitment to vigorously represent the long-term interests of Histogenics' stockholders;
- whether or not a conflict of interest exists between the candidate and Histogenics' business;
- whether the candidate would be considered independent under applicable Nasdaq and SEC standards;
- the current composition of the Histogenics Board; and
- the operating requirements of Histogenics.

In conducting this assessment, the Nominating/Corporate Governance Committee considers diversity, gender, age, skills and such other factors as it deems appropriate given the then-current needs of the Histogenics Board and Histogenics, to maintain a balance of knowledge, experience and capability. While diversity and variety of experiences and viewpoints represented on the Histogenics Board should always be considered, the Nominating/Corporate Governance Committee believes that a director nominee should not be chosen nor excluded solely or largely because of race, color, gender, national origin or sexual orientation or identity.

In the case of incumbent directors whose terms of office are set to expire, the Nominating/Corporate Governance Committee reviews such directors' overall service to Histogenics during their term, including the number of meetings attended, level of participation, quality of performance and any other relationships and transactions that might impair such directors' independence.

When there is a vacancy on the Histogenics Board, the Nominating/Corporate Governance Committee uses its network of contacts to compile a list of potential candidates, but may also engage, if it deems it appropriate, a professional search firm. The Nominating/Corporate Governance Committee conducts any appropriate and necessary inquiries into the backgrounds and qualifications of possible candidates after considering the function and needs of the Histogenics Board. The Nominating/Corporate Governance Committee meets to discuss and consider such candidates' qualifications and then selects a nominee for recommendation to the Histogenics Board by majority vote.

The Nominating/Corporate Governance Committee will consider director candidates recommended by stockholders and evaluate them using the same criteria as candidates identified by the Histogenics Board or the Nominating/Corporate Governance Committee for consideration. If a stockholder of Histogenics wishes to recommend a director candidate for consideration by the Nominating/Corporate Governance Committee, the stockholder recommendation should be delivered to the Corporate Secretary of Histogenics at the principal executive offices of Histogenics pursuant to the terms and conditions of the Bylaws. The stockholder recommendation must, among other things, set forth:

- for each person whom the stockholder proposes to nominate for election or reelection as a director, all information relating to such person as would be required to be disclosed in solicitations of proxies for the election of such nominees as directors pursuant to Regulation 14A promulgated under the Exchange Act and such person's written consent to serve as a director if elected;
- as to the stockholder giving the notice and the beneficial owner, if any, on whose behalf the nomination or proposal is made: (1) the name and address of such stockholder, as they appear on Histogenics' books, and of such beneficial owner; (2) the class and number of shares of Histogenics that are owned beneficially and of record by such stockholder and such beneficial owner and a representation that the stockholder will notify Histogenics in writing of the class and number of such shares owned beneficially and of record in accordance with Histogenics amended and restated bylaws; (3) whether either such stockholder or beneficial owner intends to deliver a proxy statement and form of proxy to holders of, in the case of a proposal, at least the percentage of Histogenics' voting shares required

under applicable law to carry the proposal or, in the case of a nomination or nominations, a sufficient number of holders of Histogenics' voting shares to elect such nominee or nominees; and (4) whether and the extent to which any derivative instrument, swap, option, warrant, short interest, hedge or profit interest or other transaction has been entered into by or on behalf of such stockholder with respect to stock of Histogenics and whether any other agreement, arrangement or understanding (including any short position or any borrowing or lending of shares of stock) has been made by or on behalf of such stockholder, the effect or intent of any of the foregoing being to mitigate loss to, or to manage risk of stock price changes for, such stockholder or to increase or decrease the voting power or pecuniary or economic interest of such stockholder with respect to stock of Histogenics;

- any option, warrant, convertible security, stock appreciation right, or similar right with an exercise or conversion privilege or a settlement payment or mechanism at a price related to any class or series of shares of Histogenics or with a value derived in whole or in part from the value of any class or series of shares of Histogenics, whether or not such instrument or right shall be subject to settlement in the underlying class or series of capital stock of Histogenics or otherwise (a "Derivative Instrument") directly or indirectly owned beneficially by such stockholder and any other direct or indirect opportunity to profit or share in any profit derived from any increase or decrease in the value of shares of Histogenics and a representation that the stockholder will notify Histogenics in writing of any such Derivative Instrument in accordance with Histogenics amended and restated bylaws;
- a description of any agreement, arrangement or understanding with respect to the proposal of business between or among such stockholder and the beneficial owner, if any, on whose behalf the proposal is made, any of their respective affiliates or associates, and any others acting in concert with any of the foregoing and a representation that the stockholder will notify Histogenics in writing of any such agreements, arrangements or understandings in effect pursuant to the terms and conditions of the Bylaws;
- a representation that the stockholder is a holder of record of stock of Histogenics entitled to vote at such meeting and intends to appear in person or by proxy at the meeting to propose such business; and
- any other information that is required to be provided by the stockholder pursuant to Section 14 of the Exchange Act and the rules and regulations promulgated thereunder in such stockholder's capacity as a proponent of a stockholder proposal.

In addition, Histogenics amended and restated bylaws require that the stockholder recommendation shall set forth as to each person whom the stockholder proposes to nominate for election or reelection as a director: (1) the name, age, business address and residence address of the person; (2) the principal occupation or employment of the person; (3) the class, series and number of shares of capital stock of Histogenics that are owned beneficially and of record by the person; (4) a statement as to the person's citizenship; (5) the completed and signed representation and agreement described above; (6) any other information relating to the person that is required to be disclosed in solicitations for proxies for election of directors pursuant to Section 14 of the Exchange Act; (7) such person's written consent to being named in the proxy statement as a nominee and to serving as a director if elected; and (8) whether and the extent to which any derivative instrument, swap, option, warrant, short interest, hedge or profit interest or other transaction has been entered into by or on behalf of such person with respect to stock of Histogenics and whether any other agreement, arrangement or understanding (including any short position or any borrowing or lending of shares of stock) has been made by or on behalf of such person, the effect or intent of any of the foregoing being to mitigate loss to, or to manage risk of stock price changes for, such person or to increase or decrease the voting power or pecuniary or economic interest of such person with respect to stock of Histogenics.

Histogenics believes that each of its directors and nominees brings a strong background and set of skills to the Histogenics Board, giving the Histogenics Board, as a whole, an appropriate balance of the knowledge, experience, attributes, skills and expertise. In addition, three of Histogenics' four directors are independent under Nasdaq standards (Mr. Gridley, Histogenics' President and former Chief Executive Officer, being the only

exception as he was a Company employee until March 2019 and continues to serve as a consultant to and as president of Histogenics) and Histogenics' Nominating/Corporate Governance Committee believes that all eight directors are independent of the influence of any particular stockholder or group of stockholders whose interests may diverge from the interests of Histogenics' stockholders as a whole. Histogenics believes that its directors have a broad range of personal characteristics including leadership, management, biotechnology, pharmaceutical, business, marketing and financial experience and abilities to act with integrity, with sound judgment and collegially, to consider strategic proposals, to assist with the development of Histogenics' strategic plan and oversee its implementation, to oversee Histogenics' risk management efforts and executive compensation and to provide leadership, to commit the requisite time for preparation and attendance at board and committee meetings and to provide required expertise on the Histogenics Board committees. As described above, the Nominating/Corporate Governance Committee has recommended the members of the Histogenics Board for their directorships. In evaluating such directors, Histogenics' Nominating/Corporate Governance Committee has reviewed the experience, qualifications, attributes and skills of Histogenics' directors and nominees, including those identified in the biographical information set forth above in the section entitled "Biographical Information – Directors." The Nominating/Corporate Governance Committee believes that the members of the Histogenics Board offer insightful and creative views and solutions with respect to issues facing Histogenics. In addition, the Nominating/Corporate Governance Committee also believes that the members of the Histogenics Board function well together as a group. The Nominating/Corporate Governance Committee believes that the above-mentioned attributes and qualifications, along with the leadership skills and other experiences of the members of the Histogenics Board described in further detail above under the section entitled "Biographical Information—Directors," provide Histogenics with the perspectives and judgment necessary to guide Histogenics' strategies and monitor their execution.

### ***Compensation Committee Matters***

The Compensation Committee of the Histogenics Board reviews and approves the design of, assesses the effectiveness of and administers compensation programs for officers and employees, including Histogenics' equity incentive plans. Pursuant to the Compensation Committee charter, the functions of the Compensation Committee include: (1) evaluating the performance of Histogenics' chief executive officer and determining the chief executive officer's salary and contingent compensation based on his or her performance and other relevant criteria; (2) identifying the corporate and individual objectives governing the chief executive officer's compensation; (3) approving the compensation of Histogenics' other executive officers; (4) making recommendations to the Histogenics Board with respect to director compensation; (5) reviewing and approving the terms of material agreements between Histogenics and its executive officers; (6) overseeing and administering Histogenics' equity incentive plans and employee benefit plans; (7) reviewing and approving policies and procedures relating to the perquisites and expense accounts of Histogenics' executive officers; (8) preparing the annual Compensation Committee report required by SEC rules; and (9) conducting a review of executive officer succession planning, as necessary, reporting its findings and recommendations to the Histogenics Board and working with the Histogenics Board in evaluating potential successors to executive officer positions. In accordance with Nasdaq listing standards and Histogenics' amended and restated Compensation Committee charter, the Histogenics Board has granted Histogenics' Compensation Committee the authority and responsibility to retain or obtain the advice of compensation consultants, legal counsel and other compensation advisers, the authority to fund such advisers, and the responsibility to consider the independence factors specified under applicable law and any additional factors the Compensation Committee deems relevant. Histogenics' Compensation Committee charter is available on the "Investors" section of Histogenics' corporate website located at <http://ir.histogenics.com>.

In addition, the Compensation Committee has adopted additional internal policies and procedures relating to administration of Histogenics' equity incentive plans, including the following:

- Members of the Compensation Committee receive initial and periodic training from an independent consultant with expertise in compensation management matters concerning Histogenics' operative

equity incentive plans and compensation procedures as well as general best practices for compensation committees.

- With the assistance of legal counsel, the Compensation Committee conducts reviews of the Compensation Committee's charter, Histogenics' equity incentive plans and the Compensation Committee's current practices, procedures and controls and has developed equity compensation compliance procedures and a checklist of key plan provisions to be reviewed prior to the issuance and delivery of equity awards. Among other things, the checklist addresses: (1) the expiration date of the applicable equity incentive plan or any portion thereof; (2) the overall shares available under the applicable plan; (3) any annual limitations on awards as set forth in the applicable equity incentive plan; (4) prior grants made to proposed recipients during any relevant period; and (5) the proper recording of the equity grants in accordance with the terms of the applicable equity incentive plan. The Compensation Committee has designated Histogenics' Interim Chief Financial Officer to monitor compliance with the foregoing compliance procedures and checklists (the Compliance Monitor).
- In advance of the Compensation Committee's first meeting each year, the Compliance Monitor provides the Compensation Committee information on the following: (1) the aggregate number of shares available for issuance under each equity incentive plan still in effect; (2) the expiration date for each such equity incentive plan; (3) the annual limit on equity grants to any one individual under each equity incentive plan; and (4) the number of shares covered by awards already granted to each of Histogenics' executive officers under Histogenics' equity incentive plans. The Compensation Committee reviews this information prior to making any equity compensation award to any executive officer.
- Prior to the dissemination of Histogenics' annual proxy statement released in conjunction with the annual meeting of stockholders, the Histogenics Board (or an appropriate committee thereof), with the assistance of legal counsel, verifies that all awards made under, amendments or proposed amendments of, and summaries or descriptions of, Histogenics' equity compensation plans have been disclosed accurately and properly in such proxy statement.
- With the assistance of legal counsel, the Compensation Committee formally reviews and approves all disclosures in Histogenics' SEC filings concerning executive officer and director compensation matters before the documents are publicly filed.
- In the event of a proposed or contemplated stock split, reverse stock split or any other change to Histogenics' capitalization, the Histogenics Board will receive guidance from outside legal counsel on the effect of such capitalization change on Histogenics' equity incentive plans, if any, including but not limited to the aggregate and annual limitations of those equity incentive plans.
- The Histogenics Board will seek stockholder approval of any amendment made to Histogenics' equity incentive plans in Histogenics' next annual meeting of stockholders following the amendment if such approval is required by the terms of such equity incentive plan, applicable Delaware law, SEC regulations or Nasdaq governance rules and listing standards.
- The Histogenics Board receives periodic reports on Histogenics' compliance with its procedures, policies and guidelines for issuing equity awards. These reports are prepared and made with the input of the Compliance Monitor, the Compensation Committee and outside legal counsel.

Four directors comprised the Compensation Committee of the Histogenics Board as of December 31, 2018: Mr. Johnson (the Chairman of the Compensation Committee), Mr. Baltzell, Mr. Rakin and Ms. Washer. Mr. Johnson and Mr. Rakin resigned from the Histogenics Board (and all committees thereof) effective February 27, 2019 and June 20, 2019, respectively. Mr. Baltzell was appointed as Chairman of the Compensation Committee effective February 27, 2019. Ms. Washer was appointed to the Compensation Committee effective June 20, 2019. The Compensation Committee met seven times during 2018 and acted twice by written consent. In addition, the members of the Compensation Committee met informally in conjunction with each regularly scheduled quarterly Board meeting and at other times throughout the year to discuss a variety of matters.

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The Histogenics Board has determined that all members of the Compensation Committee are independent (as independence is currently defined in the Nasdaq listing standards). In addition, each of Histogenics' directors serving on its Compensation Committee satisfies the heightened independence standards for members of a compensation committee under Nasdaq listing standards. Each member of this committee is also a non-employee director, as defined pursuant to Rule 16b-3 promulgated under the Exchange Act, and an outside director, as defined pursuant to Section 162(m) of the Internal Revenue Code of 1986, as amended (the "Code").

Histogenics' President and Histogenics' Interim Chief Financial Officer often participate in the Compensation Committee's meetings. Neither of them participates in the determination of their own respective compensation or the compensation of directors. However, Mr. Gridley does make recommendations to the Compensation Committee regarding the amount and form of the compensation of the other executive officers and key employees, and he often participates in the Compensation Committee's deliberations about their compensation. No other executive officers participate in the determination of the amount or form of the compensation of executive officers or directors.

The Compensation Committee has retained Radford, an independent compensation consulting firm, since January 2015. In February 2018, Radford presented a summary executive compensation report to the Compensation Committee. Radford previously provided the Compensation Committee with data about the compensation paid by Histogenics' peer group of companies and other employers who compete with Histogenics for executives, updated the Compensation Committee on new developments in areas that fall within the Compensation Committee's jurisdiction and was available to advise the Compensation Committee regarding all of its responsibilities. The consultant serves at the pleasure of the Compensation Committee, rather than Histogenics, and the consultant's fees are approved by the Compensation Committee. In February 2018, Histogenics' Compensation Committee assessed the independence of Radford pursuant to applicable SEC rules and Nasdaq listing standards and concluded that the work of Radford has not raised any conflict of interest.

### **Histogenics 2018 Summary Compensation Table**

The following table provides information concerning the compensation paid to Adam Gridley, Histogenics' President, and Histogenics' next two most highly compensated executive officers during the year ended December 31, 2018, who are Stephen Kennedy, Histogenics' former Executive Vice President and former Chief Operating Officer, and Donald Haut, Ph.D., Histogenics' former Chief Business Officer. Histogenics' refer to these individuals as its named executive officers.

<b>Name and Principal Position</b>	<b>Year</b>	<b>Salary (\$)</b>	<b>Bonus (\$)</b>	<b>Option Awards (\$ (4))</b>	<b>All Other Compensation (\$)</b>	<b>Total (\$)</b>
Adam Gridley (1)	2018	478,065	—	186,056	—	664,121
<i>Director and President</i>	2017	435,000	382,725	182,548	—	1,000,273
Stephen Kennedy (2)	2018	391,875	—	74,156	—	466,031
<i>Former Executive Vice President and Chief Operating Officer</i>	2017	352,914 (2)	240,438	138,729	—	732,081
Donald Haut, Ph.D. (3)	2018	377,415	—	40,436	—	417,851
<i>Former Chief Business Officer</i>	2017	213,546	94,343	184,974	—	492,863

- (1) Pursuant to a reduction in force approved by the Histogenics Board in March 2019, Mr. Gridley's employment with Histogenics terminated effective March 22, 2019. Mr. Gridley has retained his titles of president and treasurer of Histogenics while he continues to provide consulting services to Histogenics, and will remain a director of Histogenics. In connection with the execution of the separation entered into with Mr. Gridley in connection with his termination, Histogenics and Mr. Gridley also entered into a consulting agreement pursuant to which Mr. Gridley provides consulting services to Histogenics through at least June 30, 2019 for an hourly fee of \$250.

- (2) Pursuant to a reduction in force approved by the Histogenics Board in March 2019, Mr. Kennedy's employment with Histogenics terminated effective March 22, 2019. In connection with the execution of the separation entered into with Mr. Kennedy in connection with his termination, Histogenics and Mr. Kennedy also entered into a consulting agreement pursuant to which Mr. Kennedy provides consulting services to Histogenics through at least June 30, 2019 for an hourly fee of \$220.
- (3) Dr. Haut's service with Histogenics terminated on January 23, 2019 in connection with a reduction in force.
- (4) Represents the aggregate grant date fair value of option awards, computed in accordance with FASB ASC Topic 718. See Note 11 to Histogenics' consolidated financial statements included in Histogenics, Annual Report on Form 10-K for the year ended December 31, 2018 for a discussion of the assumptions made by Histogenics in determining the fair value of Histogenics' equity awards.

### **Narrative Explanation of Certain Aspects of Histogenics Summary Compensation Table**

The compensation paid to Histogenics' named executive officers consists of the following components:

- base salary;
- performance-based cash bonuses; and
- long-term incentive compensation in the form of stock options.

#### ***Base Salaries***

For the year ended December 31, 2018, the annual base salaries for Histogenics' named executive officers were as follows: Mr. Gridley—\$478,065; Mr. Kennedy—\$391,875; and Dr. Haut—\$377,415. In addition to actions taken with respect to hiring new, or promoting existing, executive officers, the Compensation Committee of the Histogenics Board approved the annual base salaries for Histogenics' named executive officers for the twelve-month period ended December 31, 2018, and approved option grants under Histogenics' 2013 Equity Incentive Plan to certain of Histogenics' named officers, as listed below in the section entitled "*Outstanding Equity Awards at 2018 Fiscal Year-End.*" Due to the discontinuation of the NeoCart program, the base salaries of Histogenics' named executive officers were not increased for the year ending December 31, 2019.

#### ***Performance-Based Bonuses***

Pursuant to employment agreements with Messrs. Gridley and Kennedy and Dr. Haut, each named executive officer is to earn an annual bonus equal to a specified percentage of his base salary (60% with respect to Mr. Gridley, 40% with respect to Mr. Kennedy and 35% with respect to Dr. Haut). The actual amount of bonus earned is determined by the Histogenics Board based on Histogenics' performance and the officer's achievement of objectives and goals determined by Histogenics' chief executive officer (or, with respect to Mr. Gridley, the Histogenics Board). Due to the discontinuation of the NeoCart program, no performance-based bonuses were awarded to Histogenics' named executive officers for the year ended December 31, 2018 and no changes were made to the specified percentage of base salary potentially available as a performance-based bonus for Histogenics' named executive officers for the year ending December 31, 2019.

#### ***Long-Term Incentive Compensation***

Histogenics historically offered stock options to its employees, including Histogenics' named executive officers, as the long-term incentive component of Histogenics' compensation program. Histogenics' stock options allow Histogenics' employees to purchase shares of Histogenics common stock at a price equal to the fair market value of Histogenics common stock on the date of grant. Histogenics' stock options granted to newly hired employees generally vest as to 25% of the total number of option shares on the first anniversary of the award and in equal monthly installments over the following 36 months.



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For information regarding the vesting acceleration provisions applicable to the options held by Histogenics' named executive officers, please see "Histogenics Severance Benefits" and "Histogenics Change in Control Benefits" below.

### Histogenics Outstanding Equity Awards at 2018 Fiscal Year-End

The following table sets forth information regarding each unexercised option held by each of Histogenics' named executive officers as of December 31, 2018.

Name	Option Awards			
	Number of Securities Underlying Unexercised Options Exercisable(#)	Number of Securities Underlying Unexercised Options Unexercisable(#)	Option Exercise Price (\$)	Option Expiration Date
Adam Gridley (8)	197,435	— (1)	7.99	April 29, 2024
	38,220	— (1)	8.97	July 16, 2024
	99,666	4,334 (2)	9.96	February 26, 2025
	123,958	51,042 (3)	1.58	December 15, 2026
	80,208	94,792 (2)	1.72	February 13, 2027
	—	300,000 (2)	2.63	February 15, 2028
Stephen Kennedy (9)	27,767	— (4)	7.13	December 10, 2023
	47,054	2,046 (2)	9.96	February 26, 2025
	42,708	7,292 (5)	6.11	July 29, 2025
	17,708	7,292 (2)	2.56	February 25, 2026
	34,375	40,625 (2)	1.72	February 13, 2027
	14,583	35,417 (6)	2.12	October 9, 2027
Donald Haut, Ph.D. (10)	—	115,000 (2)	2.63	February 15, 2028
	73,125	121,875 (7)	6.37	July 1, 2025
	—	105,000 (2)	2.63	February 15, 2028

- (1) Option vests over four years of service following May 12, 2014, with 25% vesting upon completion of twelve months of service and in 36 equal monthly installments thereafter.
- (2) Option vests over four years of service commencing on the date of grant, with 25% vesting upon completion of twelve months of service and in 36 equal monthly installments thereafter.
- (3) Option vests over four years of service following February 26, 2016, with 25% vesting upon completion of twelve months of service and in 36 equal monthly installments thereafter.
- (4) Option vests over four years of service following August 19, 2013, with 25% vesting upon completion of twelve months of service and in 36 equal monthly installments thereafter.
- (5) Option vests over four years of service following July 29, 2015, with 25% vesting upon completion of twelve months of service and in 36 equal monthly installments thereafter.
- (6) Option vests over four years of service following October 10, 2017, with 25% vesting upon completion of twelve months of service and in 36 equal monthly installments thereafter.
- (7) Option vests over four years of service following June 5, 2017, with 25% vesting upon completion of twelve months of service and in 36 equal monthly installments thereafter.
- (8) Pursuant to a reduction in force approved by the Histogenics Board in March 2019, Mr. Gridley's employment with Histogenics terminated effective March 22, 2019. Mr. Gridley has retained his statutory titles of president, treasurer and secretary of Histogenics while he continues to provide consulting services to Histogenics, and will remain a director of Histogenics. In connection with the execution of the separation entered into with Mr. Gridley in connection with his termination, Histogenics and Mr. Gridley also entered into a consulting agreement pursuant to which Mr. Gridley provides consulting services to Histogenics through at least June 30, 2019.

- (9) Pursuant to a reduction in force approved by the Histogenics Board in March 2019, Mr. Kennedy's employment with Histogenics terminated effective March 22, 2019. In connection with the execution of the separation entered into with Mr. Kennedy in connection with his termination, Histogenics and Mr. Kennedy also entered into a consulting agreement pursuant to which Mr. Kennedy provides consulting services to Histogenics through at least June 30, 2019.
- (10) Dr. Haut's service with Histogenics terminated on January 23, 2019 in connection with a reduction in force.

For information regarding the vesting acceleration provisions applicable to the options held by Histogenics' named executive officers, please see "*Change in Control Benefits*" below.

Due to the suspension of the NeoCart program, no equity awards were made to Histogenics' named executive officers for the year ended December 31, 2018.

### **Histogenics Employment Agreements**

#### ***Adam Gridley***

In April 2014, Histogenics entered into a letter agreement with Adam Gridley, under which Mr. Gridley agreed to become Histogenics' president and chief executive officer, effective as of May 12, 2014. Under this agreement, Mr. Gridley's base salary for 2018 was \$478,065 per year. Mr. Gridley was eligible to receive an annual cash bonus with a target equal to 60% of his base salary, subject to satisfaction of objective or subjective criteria established by the Histogenics Board. Pursuant to a reduction in force approved by the Histogenics Board in March 2019, Mr. Gridley's employment with Histogenics terminated effective March 22, 2019. Mr. Gridley has retained his statutory titles of president, treasurer and secretary of Histogenics while he continues to provide consulting services to Histogenics, and remains a director of Histogenics. In connection with the execution of the separation entered into with Mr. Gridley in connection with his termination, Histogenics and Mr. Gridley also entered into a consulting agreement pursuant to which Mr. Gridley provides consulting services to Histogenics through at least June 30, 2019 for an hourly fee of \$250. For a period of twelve months after the termination of his employment, Mr. Gridley will be subject to certain restrictions on competing with Histogenics and prohibiting the solicitation of Histogenics' employees and customers. Mr. Gridley had an at-will employment relationship with Histogenics.

Pursuant to his letter agreement, Mr. Gridley received an option to purchase up to 197,435 shares of Histogenics common stock. In addition, upon the final closing for the sale of shares of Histogenics' Series A-1 Preferred Stock in May 2014, Mr. Gridley was granted an additional option to purchase up to 38,220 shares such that, together with the original option, Mr. Gridley's options represented 4% of Histogenics common stock, including shares issuable upon conversion of option and warrants, outstanding on the date of such final closing. The shares subject to such options vest 25% after the first twelve months of Mr. Gridley's continuous service, with the remainder vesting in equal monthly installments over the next three years of his continuous service. In addition, for information regarding the vesting acceleration provisions applicable to Mr. Gridley's options, please see "*Change in Control Benefits*" below.

In connection with the commencement of his employment, Histogenics paid Mr. Gridley \$48,446 to assist with temporary housing and related expenses.

#### ***Stephen Kennedy***

In October 2017, Stephen Kennedy was promoted to Chief Operating Officer. In connection with this promotion, Histogenics entered into an amended and restated employment agreement with Mr. Kennedy. Under this amended agreement, Mr. Kennedy's base salary for 2018 was \$391,875. Mr. Kennedy was eligible to receive an annual cash bonus equal to 40% of his base salary, subject to satisfaction of objective or subjective criteria established by the Histogenics Board. Pursuant to a reduction in force approved by the Histogenics Board in

March 2019, Mr. Kennedy's employment with Histogenics terminated effective March 22, 2019. In connection with the execution of the separation entered into with Mr. Kennedy in connection with his termination, Histogenics and Mr. Kennedy also entered into a consulting agreement pursuant to which Mr. Kennedy provides consulting services to Histogenics through at least June 30, 2019 for an hourly fee of \$220. For a period of twelve months after the termination of his employment, Mr. Kennedy will be subject to certain restrictions on competing with Histogenics and prohibiting the solicitation of Histogenics' employees and customers. Mr. Kennedy had an at-will employment relationship with Histogenics.

Pursuant to his amended and restated employment agreement, Mr. Kennedy received an option to purchase up to 50,000 shares of Histogenics common stock, as described in more detail above under "*Outstanding Equity Awards at 2018 Fiscal Year-End*." The shares subject to the option will vest 25% after the first twelve months of Mr. Kennedy's continuous service after October 10, 2017 with the remainder vesting in equal monthly installments over the next three years of his continuous service. In addition, for information regarding the vesting acceleration provisions applicable to Mr. Kennedy's option, please see "*Histogenics Change in Control Benefits*" below.

#### ***Donald Haut, Ph.D.***

In June 2017, Histogenics entered into an employment agreement with Donald Haut, Ph.D. in connection with his appointment as Histogenics' Chief Business Officer. Under this agreement, Dr. Haut's base salary for 2018 was \$377,415. Dr. Haut was eligible to receive an annual cash bonus with a target amount equal to 35% of his base salary, subject to satisfaction of objective or subjective criteria established by the Histogenics Board. Dr. Haut had an at-will employment relationship with Histogenics. Dr. Haut was terminated without cause in connection with a reduction in force implemented in January 2019. For a period of twelve months after the termination of his employment, Dr. Haut will be subject to certain restrictions on competing with Histogenics and prohibiting the solicitation of Histogenics' employees and customers.

Pursuant to his employment agreement, Dr. Haut received an option to purchase up to 195,000 shares of Histogenics common stock, as described in more detail above under "*Outstanding Equity Awards at 2018 Fiscal Year-End*." The options vested 25% after the first twelve months of Dr. Haut's continuous service, with the remainder vesting in equal monthly installments over the next three years of his continuous service. In connection with his separation from service and pursuant to his employment agreement, Dr. Haut also received an additional nine months of vesting for all outstanding options at the time of separation. For further information regarding the vesting acceleration provisions applicable to Dr. Haut's option, please see "*Histogenics Change in Control Benefits*" below.

#### **Histogenics Severance Benefits**

##### ***Adam Gridley***

As described above, in April 2014, Histogenics entered into a letter agreement with Adam Gridley under which Mr. Gridley agreed to become Histogenics' president and chief executive officer, effective May 12, 2014. Pursuant to a reduction in force approved by the Histogenics Board in March 2019, Mr. Gridley's employment with Histogenics terminated effective March 22, 2019. Under this agreement, if Histogenics terminated Mr. Gridley's employment without cause or Mr. Gridley had resigned for good reason, Histogenics would have been, and are obligated to continue to pay Mr. Gridley his base salary, and he will be entitled to health benefits, for a period of twelve months following the termination of his employment. Such benefits are subject to Mr. Gridley's execution of a general release of all claims he may have against Histogenics and certain related parties. As part of the separation agreement entered into with Mr. Gridley, Histogenics has paid Mr. Gridley his severance benefit of salary continuation for 12 months in one lump sum.

For purposes of Mr. Gridley's letter agreement, cause meant Mr. Gridley's unauthorized use or disclosure of Histogenics' confidential information or trade secrets which would have caused material harm to us; material

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breach of any agreement with us; material failure to comply with Histogenics' written policies or rules after receiving written notification of such failure; sale, possession or use of illegal drugs or habitual intoxication on Histogenics' premises or the premises of a customer or business partner while conducting Histogenics' business; conviction of, or plea of guilty or no contest to, a felony; gross negligence or willful misconduct in the course of service to Histogenics that results in material harm to us; continuing and willful failure to perform reasonably assigned duties after receiving written notification of such failure; or failure to cooperate in good faith with a governmental or internal investigation of Histogenics, if so requested.

For purposes of his letter agreement, good reason meant, without Mr. Gridley's consent, a material reduction in his base salary, a change in his title or position that materially reduces his level of authority or responsibility, relocation of his principal workplace by more than 40 miles or a material breach by Histogenics of the letter agreement.

### ***Stephen Kennedy***

If Histogenics terminated Mr. Kennedy's employment without cause or Mr. Kennedy had resigned for good reason, Histogenics will continue to pay Mr. Kennedy his base salary, and he will be entitled to health benefits, for a period of nine months following the termination of his employment. As part of the separation agreement entered into with Mr. Kennedy, Histogenics has paid Mr. Kennedy his severance benefit of salary continuation for nine months in one lump sum.

For purposes of his employment agreement, cause meant Mr. Kennedy's unauthorized use or disclosure of confidential information or trade secrets which would have caused material harm to Histogenics, a material breach of any agreement between Mr. Kennedy and Histogenics which is not remedied within 15 days after notice from Histogenics, a material failure to comply with the legal directives of the Histogenics Board which is not remedied within 15 days after notice from the Histogenics Board, the sale, possession or use of illegal drugs or habitual intoxication, conviction of, plea of "guilty" or "no contest" to any felony, gross negligence or willful misconduct in the course of performing service to Histogenics, failure to perform reasonably assigned duties after receiving written notification of such failure from the Histogenics Board or failure to cooperate in good faith with a governmental or internal investigation of Histogenics, if Histogenics has requested Mr. Kennedy's cooperation.

For purposes of the employment agreement, resignation for good reason meant a material reduction in Mr. Kennedy's base salary, a change in Mr. Kennedy's title or position with Histogenics that materially reduces his level of authority or responsibility, a relocation of principal workplace by more than 40 miles or a material breach by Histogenics of its obligations under the employment agreement.

### ***Donald Haut, Ph.D.***

If Histogenics terminated Dr. Haut's employment without cause or Dr. Haut resigned for good reason, Histogenics would have been, and are, obligated continue to pay Dr. Haut his base salary, and he will be entitled to health benefits, for a period of nine months following the termination of his employment. Dr. Haut's service with Histogenics was terminated on January 23, 2019 in connection with a reduction in force. As part of the separation agreement entered into with Dr. Haut, Histogenics paid Dr. Haut his severance benefit of salary continuation for nine months in one lump sum.

For purposes of his employment agreement, cause meant Dr. Haut's unauthorized use or disclosure of confidential information or trade secrets which causes material harm to Histogenics, a material breach of any agreement between Dr. Haut and Histogenics, a material failure to comply with the legal directives of the Histogenics Board, the sale, possession or use of illegal drugs or habitual intoxication, conviction of, plea of "guilty" or "no contest" to any felony, gross negligence or willful misconduct in the course of performing service to Histogenics, failure to perform reasonably assigned duties after receiving written notification of such failure

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from the Histogenics Board, or failure to cooperate in good faith with a governmental or internal investigation of Histogenics, if it has requested Dr. Haut's cooperation.

For purposes of the employment agreement, resignation for good reason meant a material reduction in Dr. Haut's base salary, a change in Dr. Haut's title or position with Histogenics that materially reduces his level of authority or responsibility or a relocation of principal workplace by more than 40 miles.

### **Histogenics Change in Control Benefits**

In the event that Histogenics experiences a change in control and within twelve months after such change in control, a named executive officer is terminated by Histogenics without cause or such individual resigns for good reason, then such individual's options will become fully vested and exercisable.

For purposes of the stock option agreements, change in control means an acquisition by any individual, entity or group of 50% or more of Histogenics' voting stock, certain changes in the composition of the Histogenics Board, Histogenics' merger, consolidation, liquidation, dissolution or sale of all or substantially all of Histogenics' assets.

For purposes of the stock option agreements, cause and good reason have substantially the same meanings as under each named executive officer's employment agreement, described above.

### **Executive Retention Bonus Plan**

In September 2018, the Histogenics Board adopted the Executive Officer Retention Bonus Plan (the "Initial Retention Plan"). The Initial Retention Plan provided for payment of a cash retention bonus to the executive officers of Histogenics, including Histogenics' named executive officers, who continued employment with Histogenics through April 30, 2019 (the "Initial Retention Date"). The Initial Retention Plan was intended to help ensure Histogenics' continued operations. The Compensation Committee of the Histogenics Board administered the Initial Retention Plan.

Under the terms of the Initial Retention Plan, each executive officer who continued employment with Histogenics through the Initial Retention Date was eligible to receive a cash bonus payable in a lump sum within 15 days following the Initial Retention Date. Additionally, the retention bonus amount would be payable in the event the executive officer was terminated without cause or resigned for good reason.

The table below sets forth the retention bonus amount for each named executive officer under the Initial Retention Plan:

<u>Executive Officer</u>	<u>Retention Bonus Amount</u>
Adam Gridley	\$ 119,516
Stephen Kennedy	\$ 97,969
Donald Haut, Ph.D.	\$ 94,354

In connection with his separation from service without cause as part of the January 2019 reduction in force, Dr. Haut was paid his retention bonus under the Initial Retention Plan.

Effective January 25, 2019, the Histogenics Board approved an amendment to Initial Retention Plan (the "Retention Plan"). The Retention Plan, as amended, provides for payment of a cash retention bonus to the executive officers of Histogenics, including Histogenics' named executive officers, who continue employment with Histogenics through June 30, 2019 (the Retention Date). The Retention Plan is intended to help ensure Histogenics' continued operations and strategic process. The Compensation Committee of the Histogenics Board administered the Retention Plan.

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Under the terms of the Retention Plan, each executive officer who continues employment with Histogenics through the Retention Date will be eligible to receive a cash bonus payable in a lump sum within 15 days following the Retention Date. Additionally, the retention bonus amount would be payable in the event the executive officer is terminated without cause or resigns for good reason.

The table below sets forth the retention bonus amount for each current executive officer under the Retention Plan assuming all terms and conditions are satisfied:

<u>Executive Officer</u>	<u>Retention Bonus Amount</u>
Adam Gridley	\$ 191,200
Stephen Kennedy	\$ 156,750

For the avoidance of doubt, the amounts set forth above are not in addition to the amounts provided for under the Initial Retention Plan, but are the only amounts payable under the Retention Plan, as amended. In connection with their separation from service without cause as part of the March 2019 reduction in force, Messrs. Gridley and Kennedy were paid their respective retention bonus under the Retention Plan.

### **Retirement Benefits**

Histogenics has established a 401(k) tax-deferred retirement savings plan, which permits participants, including Histogenics' named executive officers, to make contributions by pre-tax salary deduction pursuant to Section 401(k) of the Code. Histogenics is responsible for administrative costs of the 401(k) plan. Histogenics' may, at its discretion, make matching contributions to the 401(k) plan. No employer contributions have been made to date.

### **Employee Benefits and Perquisites**

Histogenics' named executive officers are eligible to participate in its health and welfare plans to the same extent as all full-time employees. Although Histogenics generally does not provide its named executive officers with perquisites or other personal benefits, its offered temporary housing and related assistance to Mr. Gridley in connection with the commencement of his employment with Histogenics, as described in the Summary Compensation Table above.

### **Tax and Accounting Considerations**

Section 162(m) of the Code generally denies a deduction to any publicly-held corporation for compensation paid in a taxable year to its named executive officers exceeding \$1 million. As a result of changes made by the 2017 Tax Cuts and Jobs Act, starting with compensation paid in 2018, Section 162(m) will limit Histogenics from deducting compensation, including performance-based compensation, in excess of \$1 million paid to anyone who serves as Histogenics' chief executive officer, chief financial officer or who is among the three most highly compensated executive officers for any year beginning after December 31, 2016. The only exception to this rule is for compensation that is paid pursuant to a binding contract in effect on November 2, 2017 that would have otherwise been deductible under the prior Section 162(m) rules. Prior to the enactment of the 2017 Tax Cuts and Jobs Act, Section 162(m) limited Histogenics from deducting compensation paid in years prior to 2018, excluding performance-based compensation, in excess of \$1 million paid to anyone who served as the chief executive officer or who was one of the three most highly compensated executive officers for the applicable tax year, excluding the chief financial officer. Histogenics' Compensation Committee considers tax and accounting implications in determining all elements of Histogenics' compensation plans, programs and arrangements. For pre-2018 years, the Compensation Committee retained the discretion to make awards of either bonuses or equity awards that did not satisfy Section 162(m) and, therefore, may not have been deductible. Base salaries, time-vested restricted stock, time-vested retention and transition payments and discretionary or subjectively

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determined bonus awards generally did not qualify as performance-based compensation under the pre-2018 rules. In September 2014, Histogenics' stockholders approved Histogenics' 2013 Equity Incentive Plan that permits it to satisfy the performance-based requirements under Section 162(m) with respect to the grant of stock options.

### **Histogenics Equity Compensation Plan Information**

The following table provides information as of December 31, 2018 with respect to the shares of Histogenics common stock that may be issued under Histogenics' existing equity compensation plans.

<u>Plan Category</u>	<u>Number of Securities to be Issued Upon Exercise of Outstanding Options, RSUs, Warrants and Rights</u>	<u>Weighted Average Exercise Price of Outstanding Options, Warrants and Rights</u>	<u>Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans</u>
Equity compensation plans approved by stockholders	3,339,471 (1)	\$ 1.03	361,973 (2)
Equity compensation plans not approved by stockholders	—	—	—
Total	3,339,471		361,973

- (1) Of these shares, 22,330 were subject to options then outstanding under Histogenics' 2012 Equity Incentive Plan and 3,317,141 were subject to options then outstanding under Histogenics' 2013 Equity Incentive Plan (the "2013 Plan").
- (2) Represents 361,973 shares of common stock available for issuance under the 2013 Plan and 361,973 shares of common stock available for issuance under Histogenics' 2013 Employee Stock Purchase Plan (the "ESPP"). On January 1 of each year, (i) the number of shares reserved under the 2013 Plan is automatically increased by the smaller of 4.0% of the total number of shares of common stock that are outstanding on December 31 of the prior year or such lesser number as may be approved by the Histogenics Board and (ii) the number of shares reserved under Histogenics' ESPP is automatically increased by the least of 1% of the total number of shares of common stock that are outstanding on December 31 of the prior year 51,382 shares of common stock or such lesser number as may be approved by the Histogenics Board. In December 2018, the Histogenics Board determined that no shares would be added to the 2013 Plan or the ESPP on January 1, 2019.

### **Option Repricing**

In addition, on October 1, 2018, the Compensation Committee approved the Repricing of the Options granted prior to September 1, 2018 pursuant to 2013 Plan and 2012 Equity Incentive Plan to executive officers, employees and consultants of Histogenics, including Options held by Adam Gridley, Histogenics' Chief Executive Officer, Jonathan Lieber, Histogenics' Chief Financial Officer, Stephen Kennedy, Histogenics' Chief Operating Officer, Donald Haut, Ph.D., Histogenics' then Chief Business Officer and Lynne Kelley, M.D., FACs, Histogenics' then Chief Medical Officer. The Options had exercise prices between \$0.75628 and \$9.97 per share, which were reduced to \$0.568 per share (the closing price of Histogenics common stock on The Nasdaq Capital Market on October 1, 2018). The number of shares, vesting schedules and expiration period of the Options were not altered. Options to purchase Histogenics' common stock held by non-employee members of the Histogenics Board are not subject to the Repricing and remain unchanged. In light of current market conditions that have affected the publicly traded stock price of Histogenics common stock, the Committee effectuated the Repricing in order to provide the service providers holding the Options with incentives that were not being adequately achieved by the Options based on the exercise prices of the Options prior to the Repricing. The Options were repriced unilaterally, and the consent of holders was neither necessary nor obtained. The impact to Histogenics' financial statements in 2018 was immaterial.

### **Cancellation of Performance Options**

In connection with the Repricing, on October 1, 2018, the Compensation Committee also approved the cancelation of certain options with performance-based vesting conditions (the Performance Options) previously issued to Messrs. Gridley, Lieber and Kennedy. Messrs. Gridley, Lieber and Kennedy were previously granted the Performance Options to purchase 60,000, 30,000 and 30,000 shares of Histogenics common stock, respectively, which would vest in full if Histogenics' stock price was at or above \$19.92 for any consecutive 60-day period within four years of the date of grant as long as the recipient provided continuous service during such consecutive 60-day period (the Performance Criteria). The Committee determined that the probability of achieving the Performance Criteria was unlikely based on the current trading price of Histogenics common stock on The Nasdaq Capital Market and cancelled the Performance Options pursuant to the Committee's authority under the 2013 Plan.



**EXECUTIVE COMPENSATION OF THE COMBINED COMPANY OFFICERS**

Members of Ocugen’s executive management team are expected to serve as executive officers of the combined company after the merger. This section provides an overview of the compensation awarded to, earned by, or paid to Ocugen’s principal executive officer and the two other most highly compensated executive officers for the fiscal year ended December 31, 2018 who are expected to serve as executive officers of the combined company following the completion of the merger. These individuals, referred to collectively as Ocugen’s “named executive officers,” are as follows:

- Shankar Musunuri, Chief Executive Officer;
- Daniel Jorgensen, Chief Medical Officer; and
- Rasappa Arumugham, Chief Scientific Officer.

After completion of the merger, the compensation committee of the combined organization’s board of directors is expected to approve all compensation for the combined organization’s executive officers. For additional information regarding the combined organization’s compensation committee, please see the section entitled “Management Following the Merger—Committees of the Board of Directors—Compensation Committee” in this proxy statement/prospectus/information statement.

**Summary Compensation Table**

The following table sets forth certain summary information with respect to the compensation awarded to, earned by, or paid to Ocugen’s named executive officers during the fiscal year ended December 31, 2018.

<u>Name and Principal Position</u>	<u>Year</u>	<u>Salary (\$)</u>	<u>Option Awards (\$ (1))</u>	<u>Total (\$)</u>
Shankar Musunuri <i>Chief Executive Officer</i>	2018	\$ 420,000	\$ —	\$ 420,000
Daniel Jorgensen <i>Chief Medical Officer</i>	2018	\$ 341,250	\$ 122,238	\$ 463,488
Rasappa Arumugham <i>Chief Scientific Officer</i>	2018	\$ 285,500	\$ 122,238	\$ 407,738

- (1) Amounts reflect the grant date fair value of option awards issued in 2018 in accordance with the Financial Accounting Standard Codification Topic 718 (“ASC 718”). Such grant date fair value does not take into account any estimated forfeitures related to service-vesting conditions. For information regarding assumptions underlying the valuation of equity awards, see Note 2 to Ocugen’s consolidated financial statements for the year ended December 31, 2018 and the discussion under “Ocugen Management’s Discussion and Analysis of Financial Condition and Results of Operations—Critical Accounting Policies and the Use of Estimates—Stock-based compensation” included elsewhere in this prospectus. These amounts do not necessarily correspond to the actual value that may be recognized by the named executive officer upon vesting of applicable awards.

**Narrative Disclosure to Summary Compensation Table****Base Salary**

Historically, Ocugen has used base salaries to recognize the experience, skills, knowledge and responsibilities required of all employees, including the named executive officers. Base salaries are reviewed annually, typically in connection with the annual performance review process, and adjusted from time to time to realign salaries with market levels after taking into account individual responsibilities, performance and experience. In January 2018, the Ocugen Board and Compensation Committee authorized adjustments to the executive management salaries to

bring base salaries closer to the 50<sup>th</sup> percentile of market data for pre-IPO companies. In March 2018, Rasappa Arumugham was promoted to Chief Scientific Officer and his salary was adjusted by Ocugen’s Compensation Committee accordingly.

#### ***Annual Cash Bonus***

While Ocugen historically has not maintained a formal performance-based cash bonus plan, Ocugen’s employment agreements with the named executive officers provide that the executive may be eligible to earn an annual performance bonus of up to a targeted percentage of the executive’s base salary, as described further below under the section entitled “Employment Arrangements and Severance Agreements with Named Executive Officers.” From time to time, the Ocugen Board may approve annual bonuses for the named executive officers based on individual performance, company performance or as otherwise determined to be appropriate. In 2018, annual bonuses were not paid based on Ocugen’s financial situation.

#### ***Equity Compensation***

For 2018, Ocugen did not have a formal policy with respect to the grant of equity incentive awards to the named executive officers, or any formal equity ownership guidelines applicable to them. However, Ocugen believes that equity grants provide the named executive officers with a strong link to long-term performance, creates an ownership culture and help to align the interests of executive officers and stockholders. In addition, Ocugen believes that equity grants with a time-based vesting feature promote a focus on long-term value creation and improved executive retention because this feature incentivizes the named executive officers to remain employed during the vesting period. Accordingly, the Ocugen Board periodically has reviewed the equity incentive compensation of the named executive officers and from time to time may grant equity incentive awards to them in the form of stock options.

Ocugen’s practice has been to grant stock option awards to each executive officer at the start of employment and on an annual basis for performance and retention purposes. Stock options may also be granted for accomplishments of specific company milestones. Stock options are awarded on the date the board of directors approves the grant. The option exercise price and grant date fair value are set based on the per-share estimated valuation on the date of grant.

#### **Employment Arrangements and Severance Arrangements with Ocugen’s Named Executive Officers**

Ocugen has entered into employment agreements with each of its named executive officers. These agreements set for the initial terms and conditions of each executive’s employment, including base salary, target annual bonus opportunity and standard employee benefit plan participation. At the close of the merger, the Ocugen Board will review all employment agreements with its named executive officers and may make any necessary amendments to ensure market competitiveness.

The current employment agreements provide for “at will” employment. The material terms of these employment agreements are described below. The terms “cause” and “change in control” used in each existing employment agreement are defined in each employment agreement.

#### ***Shankar Musunuri***

Dr. Musunuri serves as Ocugen’s Chief Executive Officer and Chairman of the Ocugen Board pursuant to an employment agreement with Ocugen dated January 1, 2018, which amended and restated previous employment agreements. Dr. Musunuri is an at-will employee, and his employment with Ocugen can be terminated by him or Ocugen at any time and for any reason. In January 2018, Dr. Musunuri’s base salary was set at \$420,000 per annum, which is subject to annual review and adjustment by the Ocugen Board. In addition, Dr. Musunuri is eligible to receive a discretionary bonus in a target amount of 40% of his annual base salary, as determined by the Ocugen Board in its sole discretion; no such bonus was paid in 2018.

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Subject to his execution and nonrevocation of a release of claims in Ocugen's favor, in the event of the termination of Dr. Musunuri's employment by Ocugen without cause or by him for good reason, each as defined in his employment agreement, Dr. Musunuri will be entitled to a lump sum payment in an amount equal to (i) twenty-four-months of his then-current annual base salary and (ii) up to eighteen months of COBRA premiums for continued health benefit coverage on the same terms as were applicable to him prior to his termination.

### ***Daniel Jorgensen***

Dr. Jorgensen serves as Ocugen's Chief Medical Officer pursuant to an employment agreement with Ocugen dated April 3, 2017. Dr. Jorgensen is an at-will employee, and his employment with Ocugen can be terminated by him or Ocugen at any time and for any reason. In January 2018, Dr. Jorgensen's base salary was increased from \$325,000 per annum to \$341,250 per annum, which is subject to annual review and adjustment by Ocugen's compensation committee. In addition, Dr. Jorgensen is eligible to receive a discretionary bonus in a target amount of 30% of his annual base salary, as determined by the Ocugen Board in its sole discretion; no such bonus was paid in 2018.

Subject to his execution and nonrevocation of a release of claims in Ocugen's favor, in the event of the termination of Dr. Jorgensen's employment by Ocugen without cause or by him for good reason, each as defined in his employment agreement, Dr. Jorgensen will be entitled to a lump sum payment in an amount equal to (i) six-months of his then-current annual base salary or twelve-months of his then-current annual base salary if such termination occurred within twelve-months after a change in control and (ii) up to eighteen months of COBRA premiums for continued health benefit coverage on the same terms as were applicable to him prior to his termination.

### ***Rasappa Arumugham***

Dr. Arumugham serves as Ocugen's Chief Scientific Officer pursuant to an employment agreement with Ocugen dated March 1, 2018, which amended and restated previous employment agreements. Dr. Arumugham is an at-will employee, and his employment with Ocugen can be terminated by him or Ocugen at any time and for any reason. In March 2018, Dr. Arumugham's base salary was \$287,000 per annum, which is subject to annual review and adjustment by Ocugen's compensation committee. In addition, Dr. Arumugham is eligible to receive a discretionary bonus in a target amount of 30% of his annual base salary, as determined by the Ocugen Board in its sole discretion; no such bonus was paid in 2018.

Subject to his execution and nonrevocation of a release of claims in Ocugen's favor, in the event of the termination of Dr. Arumugham's employment by Ocugen without cause or by him for good reason, each as defined in his employment agreement, Dr. Arumugham will be entitled to a lump sum payment in an amount equal to (i) six-months of his then-current annual base salary or twelve-months of his then-current annual base salary if such termination occurred within twelve-months after a change in control and (ii) up to eighteen months of COBRA premiums for continued health benefit coverage on the same terms as were applicable to him prior to his termination.

## Outstanding Equity Awards at Fiscal Year-End

The following table sets forth information concerning outstanding equity awards held by Ocugen's named executive officers as of December 31, 2018.

Name	OPTION AWARDS				
	Vesting Commencement Date	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price (\$)	Option Expiration Date
Shankar Musunuri	08/26/2015	180,000 (1)	(1)	0.900	08/25/2025
	09/14/2017	15,000 (2)	—	3.624	09/13/2027
Daniel Jorgensen	04/17/2017	36,000 (1)	18,000 (1)	3.020	04/16/2027
	12/15/2017	4,667 (1)	9,333 (1)	3.624	12/14/2027
	08/13/2018	—	5,000 (1)	5.840	08/13/2028
	12/07/2018	—	20,000 (1)	6.480	12/06/2028
Rasappa Arumugham	03/22/2017	32,000 (1)	16,000 (1)	3.020	03/21/2027
	12/15/2017	6,667 (1)	13,333 (1)	3.624	12/14/2027
	08/13/2018	—	5,000 (1)	5.840	08/12/2028
	12/07/2018	—	20,000 (1)	6.480	12/16/2028

- (1) Each option award was granted pursuant to the 2014 Plan. The shares subject to each option vest in three equal installments on the corresponding day of each anniversary of the vesting commencement date.
- (2) Represent immediately exercisable warrants.

## Compensation Risk Assessment

Ocugen believes that although a portion of the compensation opportunities provided to the named executive officers are performance based, its executive compensation program does not encourage excessive or unnecessary risk taking. This is primarily due to the fact that Ocugen's compensation programs are designed to encourage the named executive officers to remain focused on both short- and long-term strategic goals. As a result, Ocugen does not believe that its compensation programs are reasonably likely to have a material adverse effect on it.

## Employee Benefit and Equity Compensation Plans

### 2014 Stock Option Plan

The 2014 Plan was adopted by the Ocugen Board and stockholders in February 2014. The 2014 Plan was most recently amended in September 2017 with the approval of the board of directors and the holders of a majority of outstanding common stock. Under the 2014 Plan, Ocugen has reserved for issuance an aggregate of 1,632,000 shares of common stock. The number of shares of common stock reserved for issuance is subject to adjustment in the event of any merger, consolidation, sale of all or substantially all of Ocugen's assets, reorganization, recapitalization, reclassification, stock dividend, stock split, reverse stock split or other similar transaction. The shares of common stock underlying awards that (i) expire, are terminated or are canceled for any reason prior to the issuance of the underlying shares or (ii) are unvested and then repurchased at a price not greater than the option exercise or direct issue price paid per share will be added back to the shares of common stock available for issuance under the 2014 Plan.

The Ocugen Board has acted as administrator of the 2014 Plan. The administrator has full power to select, from among the individuals eligible for awards, the individuals to whom awards will be granted, and to determine the specific terms and conditions of each award, subject to the provisions of the 2014 Plan. Persons eligible to participate in the 2014 Plan are those employees, officers and directors of, and consultants and advisors to, Ocugen, as selected from time to time by the administrator in its discretion.

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The 2014 Plan permits the grants of (1) options to purchase common stock, including options intended to qualify as incentive stock options under Section 422 of the Code, and (2) shares of common stock directly, either through the immediate purchase of such shares or as a bonus for services rendered. The per share option exercise price of each option will be determined by the administrator but may not be less than par value of the common stock on the date of grant. The term of each option will be fixed by the administrator. The administrator will determine at what time or times each option may be exercised.

The 2014 Plan provides that upon the commencement of a “change in control,” as defined in the 2014 Plan, 100% of the shares subject to outstanding options will vest and become exercisable immediately prior to the effective date of the change in control unless such option is assumed or continued or replaced with a cash retention program which preserves the spread existing on the unvested option shares at the time of the change in control. Immediately following the change in control, all outstanding options shall terminate and cease to be outstanding unless assumed or continued by the successor entity. The Ocugen Board has discretion to provide that all or some of the outstanding options shall vest and become exercisable in full immediately prior to a change in control event, even if such awards are not going to be assumed or continued.

The administrator may amend or modify the 2014 Plan at any time, subject to stockholder approval where such approval is required by applicable law. The administrator of the 2014 Plan may also amend or modify any outstanding awards, provided that no amendment to an award may adversely affect a participant’s rights without his or her consent.

The 2014 Plan will terminate automatically upon the earlier of (i) 10 years from the date on which the 2014 Plan was adopted by the Ocugen Board, (ii) the date on which all shares available for issuance under the 2014 Plan have been issued as vested shares or (iii) the action of the board to terminate all outstanding options in connection with a “change in control.” As of June 6, 2019, options to purchase 1,264,451 shares of common stock were outstanding under the 2014 Plan.

### **401(k) Plan**

Currently, Ocugen maintains the Ocugen, Inc. 401(k) Plan, a tax-qualified retirement plan for Ocugen employees. The 401(k) plan is intended to qualify under Section 401(k) of the Code, so that contributions to the 401(k) plan by employees or by Ocugen, and the investment earnings thereon, are not taxable to the employees until withdrawn from the 401(k) plan, and so that contributions by Ocugen, if any, will be deductible by Ocugen when made. All employees are eligible to participate in the 401(k) plan following one month of their employment. Participants have the option to make two kinds of elective deferral contributions: pre-tax elective deferrals and Roth elective deferrals. Any initial election or change of election by an eligible employee may be made at any time. Participants are always 100% vested in their contributions. Following six months of service, Ocugen matches 100% of employee contributions to the 401(k) plan, up to the first 3% of eligible compensation, and 50% of employee contributions that exceed 3% but do not exceed 5% of eligible compensation. Ocugen believes that providing a vehicle for tax-deferred retirement savings adds to the overall desirability of its executive compensation package and further incentivizes employees, including the named executive officers.

### **Ocugen Director Compensation**

For the fiscal year ended December 31, 2018, Ocugen did not have a formal director compensation policy in place. Following completion of the merger, it is expected that the combined organization will provide compensation to non-employee directors. Histogenics’ current director compensation program will be suspended at the time of the closing of the merger and the director compensation policies for the combined organization following the merger will be re-evaluated by the compensation committee and board of directors of the combined organization following completion of the merger and may be subject to change. Non-employee directors of the combined organization are, however, expected to receive annual cash retainers and equity compensation, although the amount of such compensation has not yet been determined.

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The table below represents the compensation earned by Ocugen’s non-employee directors who served on the Ocugen Board during 2018 who will also serve as directors of the combined organization following the merger. Dr. Musunuri is not listed in the following table since he served as an employee of Ocugen during 2018 as well as a member of the Ocugen Board, and did not receive any additional compensation for serving as a member of the Ocugen Board. Dr. Musunuri’s compensation is described under “Executive Compensation of the Executive Officers of the Combined Organization” above.

<u>Name</u>	<u>Fees Earned or Paid in Cash</u>	<u>Stock Awards (1)</u>	<u>Total</u>
Martin M. Coyne	\$ —	\$123,535	\$123,535
Uday Kompella, Ph.D.	\$ —	\$ —	\$ —
Frank Leo	\$ —	\$ —	\$ —
Manish Potti	\$ —	\$ —	\$ —
Suha Taspolatoglu, M.D.	\$ —	\$ —	\$ —
Junge Zhang	\$ —	\$ —	\$ —

- (1) Amounts reflect the grant date fair value of stock awards granted in 2018 in accordance with the ASC 718. Such grant date fair value does not take into account any estimated forfeitures related to service-vesting conditions. For information regarding assumptions underlying the valuation of equity awards, see Note 2 to Ocugen’s consolidated financial statements for the year ended December 31, 2018 and the discussion under “Ocugen Management’s Discussion and Analysis of Financial Condition and Results of Operations—Critical Accounting Policies and the Use of Estimates—Stock-based compensation” included elsewhere in this proxy statement/prospectus/information statement. These amounts do not necessarily correspond to the actual value that may be recognized by the director upon vesting of applicable awards.

## RELATED PARTY TRANSACTIONS OF DIRECTORS AND EXECUTIVE OFFICERS OF THE COMBINED ORGANIZATION

Described below are any transactions occurring since January 1, 2017 and any currently proposed transactions to which either Histogenics or Ocugen was a party and in which

- the lesser of \$120,000 or 1% of the average of the total assets at year-end for the last two completed fiscal years; and
- a director, executive officer, holder of more than 5% of the outstanding capital stock of Histogenics or Ocugen, or any member of such person's immediate family had or will have a direct or indirect material interest.

### Histogenics Transactions

#### *February 2019 Repricing and Exercise of Warrants*

As described below, as part of the Private Placement, Histogenics sold and issued the 2016 Warrants. The exercise price of the 2016 Warrants was \$2.25 per share. Also as described below, as part of the October 2018 Offering (as defined below), Histogenics sold and issued the 2018 Warrants. The exercise price of the 2018 Warrants was \$0.70 per share, subject to Histogenics' right pursuant to Section 2(e) of the 2018 Warrants to reduce the exercise price to any amount and for any period of time deemed appropriate by Histogenics Board (the "Voluntary Adjustment Right").

On February 8, 2019, Histogenics and certain holders of the 2016 Warrants (the "Participating 2016 Holders") entered into a Warrant Amendment and Exercise Agreement (the "2016 Exercise Agreement") pursuant to which Histogenics agreed to reduce the exercise price of the 2016 Warrants held by such Participating 2016 Holders from \$2.25 to \$0.01 per share (the "2016 Reduced Exercise Price") in consideration for the exercise of the 2016 Warrants held by such Participating 2016 Holders in full at the 2016 Reduced Exercise Price for cash and provided a general release of claims of such Participating 2016 Holders against Histogenics with respect to the 2016 Warrants. Histogenics also agreed to modify the reference to "three (3) Trading Days" in the first sentence of Section 2(d)(i) of the 2016 Warrants held by the Participating 2016 Holders to "two (2) Trading Days." The Participating 2016 Holders own, in the aggregate, 2016 Warrants to purchase a total of 12,957,953 shares of Histogenics common stock. After the full exercise of the 2016 Warrants held by the Participating 2016 Holders, 2016 Warrants to purchase approximately 508,714 shares of Histogenics common stock remained outstanding.

On February 8, 2019, pursuant to the Voluntary Adjustment Right, Histogenics determined to reduce the exercise price of the 2018 Warrants from \$0.70 to \$0.01 per share (the "2018 Reduced Exercise Price") through the close of business on February 8, 2019. Additionally, on February 8, 2019, Histogenics and all of the holders of the 2018 Warrants (the "Participating 2018 Holders" and, together with the Participating 2016 Holders, the "Holders") entered into a Warrant Exercise Agreement (the "2018 Exercise Agreement") pursuant to which in consideration for the 2018 Reduced Exercise Price, the Participating 2018 Holders agreed to exercise the 2018 Warrants held by such Participating 2018 Holders in full at the 2018 Reduced Exercise Price for cash and provided a general release of claims of such Participating 2018 Holders against Histogenics with respect to the 2018 Warrants. The Participating 2018 Holders owned, in the aggregate, 2018 Warrants to purchase a total of 19,616,250 shares of Histogenics' common stock. After the full exercise of the 2018 Warrants held by the Participating 2018 Holders, no 2018 Warrants remain outstanding.

Wilmslow Estate Limited ("Wilmslow"), which is a greater than 5% holder of Histogenics common stock and an affiliate of Michael Lewis, a former member of the Histogenics Board, exercised their outstanding 2016 Warrants and 2018 Warrants pursuant to a 2016 Exercise Agreement and 2018 Exercise Agreement, respectively. Kevin Rakin, a former member of the Histogenics Board, and certain of his affiliated trusts, exercised their outstanding 2016 Warrants and 2018 Warrants pursuant to a 2016 Exercise Agreement and 2018 Exercise Agreement, respectively.

### ***October 2018 Public Offering***

In October 2018, Histogenics closed an underwritten public offering (the “October 2018 Offering”) of 26,155,000 shares of Histogenics common stock and warrants to purchase up to 19,616,250 shares of common stock, at a combined purchase price of \$0.65 per share of common stock and accompanying warrant (the “Securities”). The gross proceeds from this offering were \$17.0 million, before deducting underwriting discounts and commissions, and offering expenses payable by Histogenics. The warrants were exercisable immediately upon issuance at a price of \$0.70 per share of common stock and have a term of five years commencing on the date of issuance.

Wilmslow, which is a greater than 5% holder of Histogenics common stock and an affiliate of Michael Lewis, a member of the Histogenics Board, purchased Securities in the October 2018 Offering. Kevin Rakin, a member of the Histogenics Board, purchased Securities in the October 2018 Offering.

### ***2016 Private Placement***

In September 2016, Histogenics entered into a securities purchase agreement with certain institutional and accredited investors (the “Securities Purchase Agreement”) for the sale and issuance of 2,596,059 shares of Histogenics common stock (the “Common Shares”) and 24,158.8693 shares of Series A Convertible Preferred Stock (the “Preferred Shares”), which Preferred Shares are convertible into an aggregate of 10,737,275 shares of Histogenics common stock, for total consideration of approximately \$30,000,000 (the “Private Placement”). HCW served as the sole placement agent for the Private Placement. As part of the Private Placement, Histogenics provided each purchaser 100% warrant coverage based on an as-converted number of shares of Histogenics common stock issued and issuable upon conversion of the Preferred Shares plus the Common Shares and accordingly issued the investors warrants (the “Purchaser Warrants”) to purchase 13,333,334 shares of Histogenics common stock at an exercise price of \$2.25 per share and exercisable for a period of five years following receipt of the stockholder approval required under the Securities Purchase Agreement. Histogenics also issued HCW a warrant (the “HCW Warrant”) and, together with the Purchaser Warrants, the “Common Stock Warrants”) for the purchase of up to 133,333 shares of common stock at an exercise price of \$2.25 per share and exercisable for a period of five years following receipt of the stockholder approval required under the Securities Purchase Agreement pursuant to the terms of Histogenics’ letter agreement with HCW.

The certificate of designation filed with the Secretary of State of the State of Delaware describing the rights, preference and privileges of the Series A Convertible Preferred Stock provides that, until stockholder approval was obtained, holders could not convert the Preferred Shares if such conversion would result in the purchasers under the Securities Purchase Agreement owning in the aggregate an amount of common stock issued in connection with the Private Placement in excess of 19.99% the number of shares of common stock outstanding immediately prior to the closing of the Private Placement. The Common Stock Warrants provide that until stockholder approval was obtained, holders could not exercise the Common Stock Warrants. Histogenics obtained stockholder approval of the Private Placement on November 22, 2016.

Wilmslow, which is a greater than 5% holder of Histogenics common stock and an affiliate of Michael Lewis, a former member of the Histogenics Board, purchased Common Shares, the Preferred Shares and the Common Stock Warrants in the Private Placement. Certain trusts which are affiliates of Kevin Rakin, a former member of the Histogenics Board, purchased Common Shares, the Preferred Shares and the Common Stock Warrants in the Private Placement.

### ***Former Intrexon Collaboration Agreement and Obligations***

In September 2014, Histogenics entered into its Exclusive Channel Collaboration (“ECC”) with Intrexon governing a “channel collaboration” arrangement. Pursuant to the ECC, Histogenics was responsible for the



research and development costs incurred by Intrexon associated with the development of product candidates developed under its collaboration, the effect of which may increase the level of its overall research and development expenses. In December 2018, Histogenics and Intrexon entered into a mutual termination and release agreement (the “Mutual Termination Agreement”) pursuant to which Histogenics and Intrexon mutually agreed to terminate the ECC. Pursuant to the ECC, Histogenics was responsible for the research and development costs incurred by Intrexon associated with the development of product candidates under the ECC. As of September 30, 2018, Histogenics had accrued approximately \$3.0 million of research and development expenses under the ECC (the “Accrued Expenses”). In connection with the Mutual Termination Agreement, in lieu of payment of the Accrued Expenses, Histogenics agreed and paid to Intrexon an aggregate of up to \$1.5 million, with \$0.375 million paid at the time of entering into the Mutual Termination Agreement and \$1.125 million payable within one year following its submission of a BLA to the FDA for NeoCart. Histogenics adjusted the Accrued Expenses to reflect a \$1.125 million balance as of December 31, 2018 and the related gain on extinguishment of liability of \$1.5 million.

#### ***Investors’ Rights Agreement***

On December 18, 2013, Histogenics entered into a second amended and restated investors’ rights agreement (“Investors’ Rights Agreement”) with the purchasers of its then-outstanding Preferred Stock (which was converted to common stock in connection with Histogenics’ initial public offering), including certain of its existing stockholders who were represented at the time by members of the Histogenics Board, including Wilmslow, Sofinnova Venture Partners VIII, L.P. and Split Rock Partners II, LP. Under the Investors’ Rights Agreement, Histogenics granted information and inspection rights which terminated upon the closing of its initial public offering. In addition, the holders of 4,479,418 shares of Histogenics common stock as of March 31, 2019, who are parties to the Investors’ Rights Agreement, are provided rights to demand registration of shares of common stock and to participate in a registration of Histogenics common stock that Histogenics may decide to do, from time to time. These registration rights survived Histogenics’ initial public offering and may be exercised until their termination on December 3, 2019, unless earlier exercised. Certain of the shares subject to the Investors’ Rights Agreement are held by affiliates of certain of Histogenics directors and by holders of 5% of Histogenics capital stock.

#### ***Indemnification Agreements***

Histogenics has entered, or will enter, into indemnification agreements with its directors, executive officers and certain key employees. Under these agreements, Histogenics agrees to indemnify its directors, executive officers and certain key employees against any and all expenses incurred by them in connection with proceedings because of their status as one of Histogenics’ directors, executive officers or key employees to the fullest extent permitted by Delaware law, subject to certain limitations. In addition, these indemnification agreements provide that, to the fullest extent permitted by Delaware law, Histogenics will pay for all expenses incurred by its directors, executive officers and certain key employees in connection with a legal proceeding arising out of their service to Histogenics.

In addition, as permitted by Section 145 of the Delaware General Corporation Law, Histogenics amended and restated bylaws provide that Histogenics are authorized to enter into indemnification agreements with its directors and executive officers and Histogenics is authorized to purchase directors’ and officers’ liability insurance, which Histogenics currently maintain to cover its directors and executive officers.

#### ***Policies and Procedures for Related Party Transactions***

In November 2013, Histogenics adopted a related party transaction policy under which its directors, executive officers and any person who is known to be the beneficial owner of more than 5% of any class of Histogenics voting securities, including their immediate family members and affiliates, are not permitted to enter into a related party transaction with Histogenics without the prior consent of Histogenics’ Audit Committee or another

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independent committee of the Histogenics Board where it is inappropriate for its Audit Committee to review such transaction due to a conflict of interest. Any request for Histogenics to enter into a transaction with an executive officer, director, or any of such persons' immediate family members or affiliates, in which the amount involved exceeds \$120,000 must first be presented to Histogenics' Audit Committee for review, consideration and approval. All of Histogenics directors and executive officers are required to report to its Audit Committee any such related party transaction. In approving or rejecting the proposed agreement, Histogenics Audit Committee shall consider the relevant facts and circumstances available and deemed relevant to the Audit Committee, including costs, and benefits to Histogenics, the terms of the transaction, the availability of other sources for comparable services or products and, if applicable, the impact on a director's independence. Histogenics' Audit Committee shall approve only those agreements that, in light of known circumstances, are not inconsistent with Histogenics best interests, as Histogenics' Audit Committee determines in the good faith exercise of its discretion.

### **Stock Options**

For information regarding stock options granted to Histogenics' named executive officers and directors, see "Narrative Explanation of Certain Aspects of Histogenics Summary Compensation Table – Long-Term Incentive Compensation"

### **Ocugen Transactions**

#### **May and June 2017 Common Stock and Warrant Financing**

In May and June of 2017, Ocugen completed an issuance of 2,069,539 shares of Ocugen common stock and warrants to purchase up to an aggregate of 103,476 additional shares of Ocugen common stock, for an aggregate purchase price of approximately \$7.5 million. The per share purchase price of Ocugen common stock was \$3.624 and the warrants have an exercise price of \$3.624. As of June 6, 2019, the warrants remained outstanding and exercisable. The table below sets forth the number of shares of common stock and warrants purchased and the purchase price paid by related parties:

<u>Participants</u>	<u>Shares Purchased</u>	<u>Warrants Purchased</u>	<u>Aggregate Purchase Price</u>
Frank Leo	137,969	6,898	\$ 500,000
Gupiao Trust (formerly WXJZ Life Science Limited) (1)	68,985	3,449	\$ 250,000
JSC "Lancaster Group Kazakhstan" (2)	827,815.5	41,391	\$ 3,000,000
Abdi Ibrahim Uluslararası İlaç Yatırımları Sanayi ve Ticaret A.Ş. (3)	827,815.5	41,391	\$ 3,000,000

- (1) Gupiao Trust was a beneficial holder of more than 5% of Ocugen's capital stock at the time of the issuance, and Junge Zhang, Ph.D., one of Ocugen's directors, is the Beneficiary of Gupiao Trust.
- (2) JSC "Lancaster Group Kazakhstan" is a beneficial holder of more than 5% of Ocugen's capital stock.
- (3) Abdi Ibrahim Uluslararası İlaç Yatırımları Sanayi ve Ticaret A.Ş. ("Abdi") is a beneficial holder of more than 5% of Ocugen's capital stock, and Suha Taspolatogula, M.D., one of Ocugen's directors, is the Chief Executive Officer of Abdi.

#### **September 2017 Milestone Warrants**

In September 2017, Ocugen issued warrants to Shankar Musunuri, Ph.D., MBA, its Chief Executive Officer and the chairman of its board of directors, and Charlie Kang to purchase 15,000 and 170,000 shares of Ocugen common stock, respectively, each at an exercise price of \$3.624 per share. The warrants were issued in connection with the achievement of certain Ocugen milestones set forth in Dr. Musunuri and Mr. Kang's employment agreements. As of June 6, 2019, the warrants remained outstanding and exercisable.

### **2018 and 2019 Convertible Promissory Note Financing**

From January 2018 through February 2019, Ocugen issued an aggregate principal amount of \$8.75 million of convertible promissory notes that accrued interest at a rate of 5% per annum (the “2018 Notes”). In connection with the April 2019 common stock issuance described below, all of the 2018 Notes, including all principal and accrued interest, were converted into 2,195,157 shares of Ocugen common stock at a conversion price of \$4.165 per share. The table below sets forth the principal amount of the 2018 Notes purchased by related parties as well as the number of shares of Ocugen common stock acquired by each such related party upon conversion of the 2018 Notes:

<u>Participants</u>	<u>Principal Amount of Notes Purchased (\$)</u>	<u>Shares of Common Stock Issued Upon Conversion</u>
JSC “Lancaster Group Kazakhstan”	\$ 2,500,000	637,755
Abdi Ibrahim Uluslararası İlaç Yatırımları Sanayi ve Ticaret A.Ş.	\$ 2,500,000	637,755
Bharath R. Potti (1)	\$ 200,000	49,874
Manish Potti	\$ 700,000	174,675
Martin Coyne	\$ 150,000	36,615
Vinayak Potti (2)	\$ 100,000	24,510
Sreekanth Madathil (3)	\$ 50,400	12,353

(1) Bharath Potti is the brother of Manish Potti, one of Ocugen’s directors.

(2) Vinayak Potti is the cousin of Manish Potti, one of Ocugen’s directors.

(3) Sreekanth Madathil is the cousin of Manish Potti, one of Ocugen’s directors.

### **April 2019 Common Stock Financing**

In April 2019, each of JSC “Lancaster Group Kazakhstan” and Abdi Ibrahim Uluslararası İlaç Yatırımları Sanayi ve Ticaret A.Ş. purchased 84,034 shares of Ocugen common stock at a per share price of \$5.95 for an aggregate purchase price of \$1.0 million.

### **Employment Agreements and Compensation Arrangements**

For information on employment arrangements and compensation for service on the Ocugen Board, see “Executive Compensation of the Combined Company Officers.”

Ocugen entered into a Consulting Agreement with Frank Leo on June 16, 2016, pursuant to which Ocugen issued Mr. Leo 30,000 options to purchase Ocugen common stock at a purchase price of \$1.41 per share as compensation for certain consulting services. Effective as of March 16, 2017, Ocugen terminated the Consulting Agreement with Mr. Leo.

Ocugen entered into a Consulting Agreement with Scotland Parkway LLC on December 15, 2016, pursuant to which Ocugen issued to Scotland Parkway LLC a warrant to purchase 200,000 shares of common stock at a purchase price of \$3.02 per share as compensation for certain advisory services. The Consulting Agreement with Scotland Parkway LLC is no longer outstanding.

### **Stockholders Agreements**

Substantially all holders of Ocugen common stock, including each beneficial owner of more than 5% of Ocugen voting securities and each of Ocugen’s other officers and directors to the extent they own any of Ocugen’s capital

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stock, are party to the Ocugen Stockholders Agreement which provides for certain registration rights, information rights and pre-emptive rights. As a condition to the closing of the merger, the Ocugen Stockholders Agreement must be terminated prior to the Effective Time.

### ***Indemnification***

Ocugen's certificate of incorporation and bylaws require Ocugen to indemnify its directors and officers to the fullest extent permitted by Delaware law. Ocugen intends to enter into indemnification agreements with each of its directors and officers prior to the effective time of the merger that may be broader in scope than the specific indemnification provisions contained in the Delaware General Corporation Law.

### ***Policy for Approval of Related Party Transactions***

While Ocugen does not have a formal written policy or procedure for the review, approval or ratification of related party transactions, it has been the practice of the Ocugen Board to consider the nature of and business reason for such transactions, how the terms of such transactions compared to those which might be obtained from unaffiliated third parties and whether such transactions were otherwise fair to and in the best interests of, or not contrary to, Ocugen's best interests.

## DESCRIPTION OF HISTOGENICS' CAPITAL STOCK

The following description of Histogenics' capital stock is not complete and may not contain all the information you should consider before investing in Histogenics' capital stock. This description is summarized from, and qualified in its entirety by reference to, Histogenics' sixth amended and restated certificate of incorporation, which has been publicly filed with the SEC. See "Where You Can Find More Information." The following information does not give effect to the Histogenics Reverse Stock Split described in Proposal No. 2 in this proxy statement/prospectus/information statement.

Histogenics' authorized capital stock consists of 110,000,000 shares, with a par value of \$0.01 per share, of which:

- 100,000,000 shares are designated as common stock; and
- 10,000,000 shares are designated as preferred stock.

As of March 31, 2019, Histogenics had outstanding 94,599,601 shares of common stock held of record by 11 stockholders. As of March 31, 2019, 30,000 shares of Preferred Stock were designated Series A Convertible Preferred Stock, 400.4910 of which were outstanding and held of record by one stockholder.

### Common Stock

#### *General*

Each holder of common stock is entitled to one vote per share on all matters submitted to a vote of stockholders. Histogenics has not provided for cumulative voting in the election of directors. Subject to preferences that may apply to shares of preferred stock outstanding at the time, the holders of outstanding shares of Histogenics common stock are entitled to receive dividends out of assets legally available at the times and in the amounts that Histogenics' board of directors may determine from time to time. Upon Histogenics' liquidation, dissolution or winding-up, the holders of common stock are entitled to share ratably in all assets remaining after payment of all liabilities and the liquidation preferences of any outstanding preferred stock. Holders of common stock have no preemptive or conversion rights or other subscription rights. There are no redemption or sinking fund provisions applicable to Histogenics common stock.

#### *Stock Exchange Listing*

Histogenics common stock is listed on The Nasdaq Capital Market under the symbol "HSGX." Following the closing of the merger, it is expected that the combined company will be listed on The Nasdaq Capital Market under the symbol "OCGN."

#### *Transfer Agent and Registrar*

The transfer agent and registrar for Histogenics common stock is Broadridge Corporate Issuer Solutions, Inc.

### Preferred Stock

Histogenics' sixth amended and restated certificate of incorporation authorizes the issuance of up to 10,000,000 shares of preferred stock, 400.4910 of which are issued and outstanding as of March 31, 2019. Histogenics may issue, from time to time in one or more series, the terms of which may be determined at the time of issuance by Histogenics' board of directors, without further action by Histogenics' stockholders, shares of preferred stock and such shares may include voting rights, preferences as to dividends and liquidation, conversion rights, redemption rights and sinking fund provisions. The shares of each series of preferred stock shall have preferences, limitations and relative rights, including voting rights, identical with those of other shares of the same series and, except to the extent provided in the description of such series, of those of other series of preferred stock.

The issuance of preferred stock could decrease the amount of earnings and assets available for distribution to the holders of common stock or adversely affect the rights and powers, including voting rights, of the holders of common stock. The issuance of preferred stock, while providing flexibility in connection with possible acquisitions and other corporate purposes, could, among other things, have the effect of delaying, deferring or preventing a change in control of Histogenics, which could depress the market price of Histogenics common stock.

### **Series A Convertible Preferred Stock**

In September 2016, Histogenics created a new class of preferred stock designated as Series A Convertible Preferred Stock. The rights of the Series A Convertible Preferred Stock are set forth in the Certificate of Designation of Preferences, Rights and Limitations of Series A Convertible Preferred Stock filed with the Secretary of State of the State of Delaware in September 2016 (the “Certificate of Designation”). A total of 30,000 shares of Series A Convertible Preferred Stock are authorized for issuance under the Certificate of Designation. The shares of Series A Convertible Preferred Stock have a stated value of \$1,000 per share and, following stockholder approval of the conversion feature as described below, are convertible into shares of Histogenics common stock at an initial conversion price of \$2.25 per share.

Holders of the Series A Convertible Preferred Stock are entitled to dividends on an as-if-converted basis in the same form as any dividends actually paid on shares of Histogenics common stock.

On September 29, 2016 (the “Closing Date”), Histogenics completed the Private Placement pursuant to a securities purchase agreement (the “Securities Purchase Agreement”) of 2,596,059 shares of common stock, \$0.01 par value per share, 24,158.8693 shares of Series A Convertible Preferred Stock, \$0.01 par value per share (convertible into 10,737,275 shares of Common Stock), and the Common Stock Warrants. In connection with the Private Placement, Histogenics agreed with the purchasers to prepare and file a definitive proxy statement with the SEC after the closing of the offering. Histogenics agreed that the proxy statement would include a proposal to permit the Series A Convertible Preferred Stock to become convertible into shares of Histogenics common stock as set forth in, and to the extent permitted by, the Certificate of Designation and to permit the issuance of the shares of common stock issuable upon such conversion, which issuance of shares, when aggregated with the shares of common stock issued in the Private Placement, could exceed 20% of Histogenics common stock outstanding before the Private Placement. Histogenics’ stockholders approved the conversion feature of the Series A Convertible Preferred Stock on November 22, 2016, which allows the holders of shares of Series A Convertible Preferred Stock to convert their shares of Series A Convertible Preferred Stock into common stock.

Following approval by Histogenics stockholders, the shares of Series A Convertible Preferred Stock are convertible, at the option of each holder, at any time or from time to time into shares of Histogenics common stock at the conversion price in effect at the time of conversion, except that, subject to certain limited exceptions, no holder of Series A Convertible Preferred Stock may convert the Series A Convertible Preferred Stock if, after giving effect to the conversion, the holder and all affiliated persons would own beneficially more than 4.99% of Histogenics common stock (subject to adjustment up to 9.99% solely at the holder’s discretion upon 61 days’ prior notice to Histogenics). The initial conversion price of \$2.25 is subject to appropriate adjustment in the event of a stock split, stock dividend, combination or other recapitalization affecting Histogenics common stock.

Except as otherwise required by law, the holders of Series A Convertible Preferred Stock have no right to vote on matters submitted to a vote of Histogenics’ stockholders. Without the prior written consent of a majority of the outstanding shares of Series A Convertible Preferred Stock, however, Histogenics may not: (i) amend Histogenics’ sixth amended and restated certificate of incorporation (including the Certificate of Designation) in a manner adverse to the Series A Convertible Preferred Stock; (ii) create or authorize the creation of any other security convertible into or exercisable for any equity security ranking as to dividends, redemption or distribution of assets upon a liquidation senior to, the Series A Convertible Preferred Stock, or increase the authorized number of shares of Series A Convertible Preferred Stock; or (iii) enter into any agreement with respect to any of the foregoing.

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In the event of the dissolution and winding up of Histogenics, the proceeds available for distribution to Histogenics' stockholders will be distributable *pari passu* among the holders of the shares of Histogenics common stock and Series A Convertible Preferred Stock, pro rata based upon the number of shares held by each such holder, as if the outstanding shares of Histogenics' Series A Convertible Preferred Stock were convertible, and were converted, into shares of Histogenics common stock.

### **Common Stock Warrants**

As part of the Private Placement, Histogenics issued the Common Stock Warrants. The Common Stock Warrants include a cashless-exercise feature that may be exercised in the event there is no effective registration statement registering, or no current prospectus available for, the resale of the shares of common stock underlying the warrants as of the six-month anniversary of the closing of the Private Placement. As of March 31, 2019, Common Stock Warrants to purchase up to 508,714 shares of Histogenics common stock were outstanding.

The Common Stock Warrants are exercisable, at the option of each holder, at any time or from time to time for shares of Histogenics common stock at an exercise price of \$2.25, except that, subject to certain limited exceptions, no holder may exercise the Common Stock Warrants if, after giving effect to the exercise, the holder and all affiliated persons would own beneficially more than 4.99% of Histogenics common stock (subject to adjustment up to 9.99% solely at the holder's discretion upon 61 days' prior notice to us). The conversion price of \$2.25 is subject to appropriate adjustment in the event of a stock split, stock dividend, combination or other recapitalization affecting Histogenics common stock.

### **Anti-takeover Effects of Delaware Law and Histogenics' Sixth Amended and Restated Certificate of Incorporation and Amended and Restated Bylaws**

Certain provisions of Delaware law, Histogenics' sixth amended and restated certificate of incorporation and Histogenics' amended and restated bylaws could have the effect of delaying, deferring or discouraging another party from acquiring control of Histogenics. These provisions, which are summarized below, are expected to discourage certain types of coercive takeover practices and inadequate takeover bids. These provisions are also designed, in part, to encourage persons seeking to acquire control of Histogenics to first negotiate with its board of directors. Histogenics believes that the benefits of increased protection of Histogenics' potential ability to negotiate with an unfriendly or unsolicited acquirer outweigh the disadvantages of discouraging such proposals, including proposals that are priced above the then-current market value of Histogenics common stock, because, among other reasons, the negotiation of such proposals could result in an improvement of their terms.

### **Sixth Amended and Restated Certificate of Incorporation and Amended and Restated Bylaws**

Histogenics' sixth amended and restated certificate of incorporation and amended and restated bylaws include provisions that:

- authorize the Histogenics Board to issue, without further action by the stockholders, up to 10,000,000 shares of undesignated preferred stock, 30,000 shares of which have been designated Series A Convertible Preferred Stock;
- require that any action to be taken by Histogenics' stockholders be effected at a duly called annual or special meeting and not by written consent;
- specify that special meetings of Histogenics' stockholders can be called only by the Histogenics Board, Histogenics' chairman of the board, or Histogenics' chief executive officer;
- establish an advance notice procedure for stockholder approvals to be brought before an annual meeting of Histogenics' stockholders, including proposed nominations of persons for election to the Histogenics Board;

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- establish that the Histogenics Board is divided into three classes, Class I, Class II and Class III, with each class serving staggered terms;
- provide that any director or the entire the Histogenics Board may be removed from office at any time, but only for cause and only by the affirmative vote of the holders of at least 66 2/3% in voting power of Histogenics' capital stock entitled to vote thereon;
- provide that vacancies on the Histogenics Board may, except as otherwise required by law, be filled only by a majority of directors then in office, even if less than a quorum;
- specify that no stockholder is permitted to cumulate votes at any election of directors;
- provide that Histogenics' amended and restated bylaws may be amended, altered or repealed and new bylaws may be adopted by the affirmative vote of the holders of at least 66 2/3% in voting power of Histogenics' capital stock entitled to vote thereon; and
- require a super-majority of votes to amend certain of the above- mentioned provisions.

### **Delaware Law**

Histogenics is governed by the provisions of Section 203 of the Delaware General Corporation Law (the "DGCL") regulating corporate takeovers. This section prevents some Delaware corporations from engaging, under some circumstances, in a business combination, which includes a merger or sale of at least 10% of the corporation's assets with any interested stockholder, meaning a stockholder who, together with affiliates and associates, owns or, within three years prior to the determination of interested stockholder status, did own 15% or more of the corporation's outstanding voting stock, unless:

- the transaction is approved by the board of directors prior to the time that the interested stockholder became an interested stockholder; or
- subsequent to such time that the stockholder became an interested stockholder the business combination is approved by the board of directors and authorized at an annual or special meeting of stockholders by at least two- thirds of the outstanding voting stock which is not owned by the interested stockholder.

A Delaware corporation may "opt out" of these provisions with an express provision in its original certificate of incorporation or an express provision in its certificate of incorporation or amended and restated bylaws resulting from a stockholders' amendment approved by at least a majority of the outstanding voting shares. Histogenics has not opted out of these provisions. As a result, mergers or other takeover or change in control attempts of Histogenics may be discouraged or prevented.

In general, Section 203 defines an interested stockholder as any entity or person beneficially owning 15% or more of the outstanding voting stock of the corporation and any entity or person affiliated with or controlling or controlled by any of these entities or persons.

### **Exclusive Jurisdiction for Certain Actions**

Histogenics' sixth amended and restated certificate of incorporation provides that, unless Histogenics consents in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware shall, to the fullest extent permitted by law, be the sole and exclusive forum for (i) any derivative action or proceeding brought on Histogenics' behalf, (ii) any action asserting a claim of breach of a fiduciary duty owed by any of Histogenics' directors, officers or other employees to Histogenics or its stockholders, (iii) any action arising pursuant to any provision of the Delaware General Corporation Law, or (iv) any action asserting a claim governed by the internal affairs doctrine.



## **Indemnification**

Histogenics' sixth amended and restated certificate of incorporation includes provisions that limit the liability of Histogenics' directors for monetary damages for breach of their fiduciary duty as directors, except for liability that cannot be eliminated under the DGCL. Accordingly, Histogenics' directors will not be personally liable for monetary damages for breach of their fiduciary duty as directors, except for liabilities:

- for any breach of the director's duty of loyalty to Histogenics or its stockholders;
- for acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law;
- for unlawful payments of dividends or unlawful stock repurchases or redemptions, as provided under Section 174 of the DGCL; or
- for any transaction from which the director derived an improper personal benefit.

Any amendment or repeal of these provisions will require the approval of the holders of shares representing at least two-thirds of the shares entitled to vote in the election of directors, voting as one class.

Histogenics' sixth amended and certificate of incorporation and bylaws also provides that Histogenics will indemnify its directors and officers to the fullest extent permitted by Delaware law. Histogenics' sixth amended and certificate of incorporation and bylaws also permit Histogenics to purchase insurance on behalf of any officer, director, employee or other agent for any liability arising out of his or her actions as its officer, director, employee or agent, regardless of whether Delaware law would permit indemnification. As described above, Histogenics has entered into separate indemnification agreements with its directors and executive officers that require Histogenics, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as directors and to advance their expenses incurred as a result of any proceeding against them as to which they could be indemnified. Histogenics believes that the limitation of liability provision in its sixth amended and certificate of incorporation and the indemnification agreements facilitate its ability to continue to attract and retain qualified individuals to serve as directors and officers. The limitation of liability and indemnification provisions in Histogenics' sixth amended and restated certificate of incorporation and amended and restated bylaws may discourage stockholders from bringing a lawsuit against directors for breach of their fiduciary duties. They may also reduce the likelihood of derivative litigation against directors and officers, even though an action, if successful, might benefit Histogenics and its stockholders. A stockholder's investment may be harmed to the extent Histogenics pays the costs of settlement and damage awards against directors and officers pursuant to these indemnification provisions.

## **Registration Rights**

On December 18, 2013, Histogenics entered into a second amended and restated investors' rights agreement ("Investors' Rights Agreement") with the purchasers of its then-outstanding Preferred Stock (which was converted to common stock in connection with Histogenics' initial public offering), including certain of its existing stockholders who were represented at the time by members of the Histogenics Board, including Wilmslow, Sofinnova Venture Partners VIII, L.P. and Split Rock Partners II, L.P. Under the Investors' Rights Agreement, Histogenics granted information and inspection rights which terminated upon the closing of its initial public offering. In addition, the holders of 4,479,418 shares of Histogenics common stock as of March 31, 2019, who are parties to the Investors' Rights Agreement, are provided rights to demand registration of shares of common stock and to participate in a registration of Histogenics common stock that Histogenics may decide to do, from time to time. These registration rights survived Histogenics' initial public offering and may be exercised until their termination on December 3, 2019, unless earlier exercised. Certain of the shares subject to the Investors' Rights Agreement are held by affiliates of certain of Histogenics directors and by holders of 5% of Histogenics capital stock.

## COMPARISON OF RIGHTS OF HOLDERS OF HISTOGENICS STOCK AND OCUGEN STOCK

Both Histogenics and Ocugen are incorporated under the laws of the State of Delaware and, accordingly, the rights of the stockholders of each are currently, and will continue to be, governed by the DGCL. If the merger is completed, Ocugen's stockholders will become stockholders of Histogenics, and their rights will be governed by the DGCL, the amended and restated bylaws of Histogenics and, assuming Proposal Nos. 2 and 3 are approved by Histogenics' stockholders at the Histogenics special meeting, the sixth amended and restated certificate of incorporation of Histogenics as amended by the amendments thereto attached to this proxy statement/prospectus/information statement as *Annex D* and *Annex E*.

The table below summarizes the material differences between the current rights of Ocugen's stockholders under Ocugen's amended and restated certificate of incorporation and bylaws, and the rights of Histogenics' stockholders, post-merger, under Histogenics' sixth amended and restated certificate of incorporation and amended and restated bylaws, each as amended, as applicable, and as in effect immediately following the merger.

While Histogenics and Ocugen believe that the summary tables cover the material differences between the rights of their respective stockholders prior to the merger and the rights of Histogenics' stockholders following the merger, these summary tables may not contain all of the information that is important to you. These summaries are not intended to be a complete discussion of the respective rights of Histogenics' and Ocugen's stockholders and are qualified in their entirety by reference to the DGCL and the various documents of Histogenics and Ocugen that are referred to in the summaries. You should carefully read this entire proxy statement/prospectus/information statement and the other documents referred to in this proxy statement/prospectus/information statement for a more complete understanding of the differences between being a stockholder of Histogenics or Ocugen before the merger and being a stockholder of Histogenics after the merger. Histogenics has filed copies of its current amended and restated certificate of incorporation and amended and restated bylaws with the SEC and will send copies of the documents referred to in this proxy statement/prospectus/information statement to you upon your request. Ocugen will also send copies of its documents referred to in this proxy statement/prospectus/information statement to you upon your request. See the section entitled "Where You Can Find More Information" in this proxy statement/prospectus/information statement.

### Current Ocugen Rights Versus Post-Merger Histogenics Rights

Provision	Ocugen (Pre-Merger)	Histogenics (Post-Merger)
ELECTIONS; VOTING; PROCEDURAL MATTERS		
Authorized Capital Stock	The amended and restated certificate of incorporation of Ocugen authorizes the issuance of one class of stock. The total number of shares Ocugen is authorized to issue is twenty million (20,000,000) shares, par value of \$0.001 per share, all of which are designated as "Common Stock."	The sixth amended and restated certificate of incorporation of Histogenics permits Histogenics to authorize a total number of shares of all classes of stock of one hundred ten million (110,000,000) (unless Proposal No. 4 is approved by stockholders, in which case the number shall be two hundred ten million (210,000,000)), consisting of one hundred million (100,000,000) shares of Common Stock, par value \$0.01 per share, and Ten Million (10,000,000) shares of preferred stock, par value \$0.01 per share.

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<b>Provision</b>	<b>Ocugen (Pre-Merger)</b>	<b>Histogenics (Post-Merger)</b>
		Pursuant to that certain Certificate of Designation of Preferences, Rights and Limitations of Series A Convertible Preferred Stock, dated September 2016, Histogenics designated up to 30,000 shares, par value \$0.01 per share, and a stated value equal to \$1,000 as Series A Convertible Preferred Stock.
Number of Directors	The bylaws of Ocugen provide that the board of directors shall consist of no less than one (1) or no more than twelve (12) members, as determined from time to time by resolution of the Board subject to the power of the stockholders to change such action of the directors.	The sixth amended and restated certificate of incorporation and the bylaws provide that, subject to the rights of the holders of any series of preferred stock to elect additional directors under specified circumstances, the number of directors of Histogenics shall be fixed from time to time exclusively by the board of directors pursuant to a resolution adopted by a majority of the whole board any may not be fixed by any other person(s). The term whole board refers to the total number of authorized directors whether or not there exist any vacancies in previously authorized directorships.
Stockholder Nominations and Proposals	The amended and restated certificate of incorporation and bylaws of Ocugen do not provide for procedures with respect to stockholder proposals or director nominations.	The amended and restated bylaws of Histogenics provide that nominations of persons for election to the Board of Directors and the proposal of business to be transacted by the stockholders may be made at an annual meeting of stockholders (1) pursuant to Histogenics' notice with respect to such meeting, (2) by or at the direction of the board of directors or (3) by any stockholder of record of Histogenics who was a stockholder of record at the time of the giving of the notice as provided in the bylaws, who is entitled to vote at the meeting and who has complied with the notice procedures set forth in the bylaws.

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<b>Provision</b>	<b>Ocugen (Pre-Merger)</b>	<b>Histogenics (Post-Merger)</b>
Classified Board of Directors	The bylaws of Ocugen provide that the directors shall be elected at the annual meeting of stockholders, except in the case of vacancies, and each Director elected shall hold office until his successor is elected and qualified.	The amended and restated bylaws of Histogenics provide that the directors, other than those who may be elected by the holders of any series of preferred stock under specified circumstances, shall be divided into three classes pursuant to the sixth amended and restated certificate of incorporation. Such classes shall be as nearly equal in number of directors as reasonably possible. Each director shall serve for a term ending on the third annual meeting of stockholders following the annual meeting of stockholders at which such director was elected. Each director shall serve until such director's successor shall have become duly elected and qualified, or until such director's prior death, resignation, retirement, disqualification or other removal.
Removal of Directors	Neither Ocugen's amended and restated certificate of incorporation nor its bylaws provide for the removal of directors.	The sixth amended and restated certificate of incorporation and the amended and restated bylaws of Histogenics establish that, subject to the rights of holders of any series of preferred stock then outstanding, any director, or the entire board of directors, may be removed from office at any time, but only for cause and only by the affirmative vote of the holders of at least two-thirds of the voting power of all of the then-outstanding shares of capital stock of Histogenics entitled to vote generally in the election of directors, voting together as a single class.
Special Meeting of the Stockholders	The bylaws of Ocugen provide that special meetings of stockholders may be called by the Chairman of the Board or the President and shall be called by the President or Secretary at the request in writing of a majority of	The sixth amended and restated certificate of incorporation and the amended and restated bylaws of Histogenics provide that special meetings of stockholders may be called only by the chairman of the board, the chief executive officer

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<u>Provision</u>	<u>Ocugen (Pre-Merger)</u>	<u>Histogenics (Post-Merger)</u>
	the Board of Directors, or at the request in writing of stockholders holding a majority in amount of the entire capital stock of the Corporation issued and outstanding and entitled to vote. Such request shall state the purpose or purposes of the proposed meeting.	or the president or by the board of directors acting pursuant to a resolution adopted by a majority of the whole board.
Cumulative Voting	The amended and restated certificate of incorporation and the bylaws of Ocugen do not have a provision granting cumulative voting rights in the election of its directors.	The amended and restated bylaws of Histogenics does not have a provision granting cumulative voting rights in the election of its directors.
Vacancies	The bylaws of Ocugen provide that vacancies and newly created directorships resulting from any increase in the authorized number of directors may be filled by a majority of the Directors then in office, though less than a quorum, or by a sole remaining director, and the directors so chosen shall hold office until the next annual election and until their successors are duly elected and shall qualify, unless sooner displaced. If there are no directors in office, then an election of directors may be held in the manner provided by statute. If, at the time of filing any vacancy or any newly created directorship, the directors then in office shall constitute less than a majority of the whole Board (as constituted immediately prior to any such increase), the Court of Chancery may, upon application of any stockholder or stockholders holding at least ten percent of the total number of the shares at the time outstanding having the right to vote for such directors, summarily order an election to be held to fill any such vacancies or newly created directorships, or to replace the directors chosen by the directors then in office.	The sixth amended and restated certificate of incorporation and the amended and restated bylaws of Histogenics provide, subject to the rights of any series of preferred stock then outstanding, newly created directorships resulting from any increase in the authorized number of directors or any vacancies in the board of directors resulting from death, resignation, retirement disqualification, removal from office or other cause shall, unless otherwise provided by law or by resolution of the board of directors, be filled only by a majority vote of directors then in office, though less than a quorum (and not by stockholders), and directors so chosen shall hold office for a term expiring at the annual meeting of stockholders at which the term of office of the class to which they have been chosen expires or until such director's successor has been duly elected and qualified. No decrease in the authorized number of directors shall shorten the term of any incumbent director.

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<b>Provision</b>	<b>Ocugen (Pre-Merger)</b>	<b>Histogenics (Post-Merger)</b>
Voting Stock	<p>The amended and restated certificate of incorporation and the bylaws of Ocugen do not have a provision discussing the voting stock of Ocugen.</p>	<p>Under the amended and restated bylaws of Histogenics, at all meetings of stockholders, a stockholder may vote by proxy executed in writing by the stockholder or as may be permitted by law, or by his duly authorized attorney-in-fact. Such proxy must be filed with the Secretary of the Corporation or his representative, or otherwise delivered telephonically or electronically as set forth in the applicable proxy statement, at or before the time of the meeting.</p> <p>Pursuant to that certain Certificate of Designation of Preferences, Rights and Limitations of Series A Convertible Preferred Stock, dated September 2016, the Series A Convertible Preferred Stock has no voting rights.</p>
Stockholders Agreement; Voting Agreement	<p>Ocugen and the stockholders of Ocugen have entered into that certain Amended and Restated Stockholders Agreement, dated May 25, 2017, which provides, among other things, that: (i) the stockholders of Ocugen are divided into three series: Management Stockholders, Series A Stockholders and Series B Stockholders, collectively the Series A and Series B Stockholder are the Investor Stockholders; (ii) establishes a purchase right and a right of forced sale, as more fully described in each respective section herein; and (iii) each stockholder will vote all stock beneficially owned by it for the election of certain directors including: (a) Shankar Musunuri and Uday Kompella, (b) one Series A designee, for so long as the Series A stockholders continue to hold at least five percent of the outstanding stock, and (c) one</p>	<p>Histogenics and certain stockholders of Histogenics have entered into that certain Second Amended and Restated Stockholders' Agreement, dated December 18, 2013.</p>

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<b>Provision</b>	<b>Ocugen (Pre-Merger)</b>	<b>Histogenics (Post-Merger)</b>
	<p>Series B designee, for so long as Series B Stockholders continue to hold any shares of outstanding stock for the five years following the execution of the stockholders agreement and after the end of such five year period, continue to hold at least three percent (3%) of the outstanding stock.</p>	
Drag Along	<p>The stockholders agreement of Ocugen establishes a right of forced sale in the event that the board of directors and stockholders holding at least a majority of the then issued and outstanding stock (the "Requisite Stockholders") approve or otherwise consent in writing to a Sale Transaction that would result in aggregate gross proceeds to Ocugen and/or stockholders (after deduction of underwriting commissions and expenses) at least equivalent to \$7.248 per share of stock then outstanding on a fully diluted basis (as adjusted for stock splits, stock dividend, combinations, recapitalizations of the like) (a "Qualified Sale"), then all other stockholders (the "Drag-Along Stockholders") will be required, if so requested by the Requisite Stockholders, (a) to vote such Drag-Along Stockholders' Stock in favor thereof, and otherwise consent to and raise no objections to such Sale Transaction, and waive any dissenters' rights, appraisal rights or similar rights that such Drag-Along Stockholder may have in connection therewith, (b) to sell the same proportion of stock of Ocugen beneficially held by such Drag-Along Stockholder as is being sold by the Requisite Stockholders to the person to whom the Requisite Stockholders propose to sell their stock, and on the same terms and conditions as</p>	<p>Histogenics does not have drag along terms in place.</p>

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<b>Provision</b>	<b>Ocugen (Pre-Merger)</b>	<b>Histogenics (Post-Merger)</b>
	<p>the Requisite Stockholders, and (c) to take all necessary and desirable actions as reasonably directed by the Requisite Stockholders in connection with the consummation of such Sale Transaction, including, to the extent applicable, executing a purchase agreement and selling, exchanging or otherwise transferring all of the stock (or warrants or other rights to subscribe for or purchase stock) held by such Drag-Along Stockholders on the terms and conditions approved by the Requisite Stockholders and the Board.</p>	
Stockholder Action by Written Consent	<p>The bylaws of Ocugen provide that any action required or permitted to be taken at any annual or special meeting of stockholders may be taken without a meeting, without prior notice and without a vote, if a consent in writing, setting forth the action so taken, shall be signed by the holders of outstanding stock having not less than the minimum number of votes that would be necessary to authorize or take such action at a meeting at which all shares entitled to vote thereon were present and voted. Prompt notice of the taking of corporate action without a meeting by less than unanimous written consent shall be given to those stockholders who have not consented in writing.</p>	<p>The sixth amended and restated certificate of incorporation and the amended and restated bylaws of Histogenics establish that, subject to the rights of the holders of any series of preferred stock, any action required or permitted to be taken by the stockholders of Histogenics must be effectuated at a duly called annual or special meeting of stockholders of Histogenics and may not be effectuated by any consent in writing by such stockholders.</p>
Notice of Stockholder Meeting	<p>The bylaws of Ocugen provide that written notice of the annual meeting stating the place, date and hour of the meeting shall be given to each stockholder entitled to vote at such meeting not less than ten nor more than sixty days before the date of the meeting. Further, written notice of a special</p>	<p>Under the amended and restated bylaws of Histogenics, except as required by law, written, printed or electronic notice stating the place, if any, date and time of the meeting, the means of remote communications, if any, by which the stockholders any proxy holders may be deemed to be</p>



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<u>Provision</u>	<u>Ocugen (Pre-Merger)</u>	<u>Histogenics (Post-Merger)</u>
	meeting stating the place, date and hour of the meeting and the purpose or purposes for which the meeting is called, shall be given not less than ten or more than sixty days before the date of the meeting, to each stockholder entitled to vote at such meeting.	present in person and vote at such meeting, and in the case of a special meeting, the purposes for which the meeting is called shall be prepared and delivered by Histogenics not less than ten (10) days nor more than sixty (60) days before the date of the meeting , either personally, by mail, or in the case of stockholders who have consented to such delivery, by electronic transmission, to each stockholder of record entitled to vote at such meeting.
Conversion Rights and Protective Provisions	The amended and restated certificate of incorporation Ocugen does not provide that holders of Ocugen stock shall have conversion or other protective rights.	Pursuant to that certain Certificate of Designation of Preferences, Rights and Limitations of Series A Convertible Preferred Stock, dated September 2016, if at any time Histogenics grants, issues or sells any common stock equivalents, as defined therein, or rights to purchase stock, warrants, securities or other property pro rata to the record holders of any class of shares of common stock, then the holder will be entitled to acquire, upon the terms applicable to such purchase rights, the aggregate purchase rights which the holder could have acquired if the holder had held the number of shares of common stock acquirable upon complete conversion of such holders preferred stock immediately before the record date of such grant, issuance or sale.
Right of First Offer	The stockholders agreement of Ocugen grants each Investor Stockholder a right of first offer to purchase up to its pro rata share of all equity securities that Ocugen may, from time to time, propose to sell and issue after the date of the stockholders agreement, other than excluded securities, as defined therein.	Histogenics does not have a right of first offer in place.

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<b>Provision</b>	<b>Ocugen (Pre-Merger)</b>	<b>Histogenics (Post-Merger)</b>
Pro Rata Rights	Ocugen does not have a pro rata rights provision in place.	Pursuant to that certain Certificate of Designation of Preferences, Rights and Limitations of Series A Convertible Preferred Stock, dated September 2016, if Histogenics declares or makes any dividend or other distribution of its assets to holders of shares of common stock, by way of return of capital or otherwise, then the holder shall be entitled to participate in such distribution to the same extent that the holder would have participated therein if the holder had held the number of shares of common stock acquirable upon complete conversion of the preferred stock immediately before the record date of such distribution.
Fundamental Transactions	Ocugen does not have a fundamental transaction provision in place.	Pursuant to that certain Certificate of Designation of Preferences, Rights and Limitations of Series A Convertible Preferred Stock, dated September 2016, in the event of a fundamental transaction, as defined therein, the holder shall have the right in any subsequent conversion of the preferred stock to receive, for each conversion share that would have been issuable upon such conversion immediately prior to the occurrence of such fundamental transaction, the number of shares of common stock of the successor or acquiring corporation or of Histogenics, if it is the surviving corporation, and any additional consideration receivable as a result of such fundamental transaction by a holder of the number of shares of common stock of which the preferred stock is convertible immediately prior to such fundamental transaction.

Provision	Ocugen (Pre-Merger)	Histogenics (Post-Merger)
Indemnification	<p>The amended and restated certificate of incorporation and bylaws of Ocugen provide that Ocugen shall indemnify its officers and directors and the officers and directors of its subsidiaries to the maximum extent permitted from time to time under the law of the State of Delaware, and upon request shall advance expenses to any person who is or was a party or is threatened to be made a party to any threatened, pending or completed action, suit, proceeding or claim, whether civil, criminal, administrative or investigative, by reason of the fact that he or she is or was or has agreed to be a director of Ocugen or while a director is or was serving at the request of Ocugen as a director, officer, partner, trustee, employee or agent of any corporation, partnership, joint venture, trust or other enterprise, including service with respect to employee benefit plans, against expenses (including attorney's fees and expenses), judgments, fines, penalties and amounts paid in settlement incurred in connection with the investigation, preparation to defend or defense of such action, suit, proceeding or claim; provided, however, that the foregoing shall not require the Corporation to indemnify or advance expenses to any person in connection with any action, suit, proceeding, claim or counterclaim initiated by or on behalf of such person. Such indemnification shall not be exclusive of other indemnification rights arising under any By-Law, agreement, vote of directors or stockholders or otherwise and shall inure to the benefit of the heirs and legal</p>	<p>The sixth amended and restated certificate of incorporation and the amended and restated bylaws provide that a director of Histogenics shall not be personally liable to Histogenics or its stockholders for monetary damages for breach of fiduciary duty as a director, except for liability (i) for any breach of the director's duty of loyalty to the Corporation or its stockholders, (ii) for acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law, (iii) under Section 174 of the Delaware General Corporation Law, or (iv) for any transaction from which the director derived any improper personal benefit. Histogenics may indemnify to the fullest extent permitted by law any person made or threatened to be made a party to an action or proceeding, whether criminal, civil, administrative or investigative, by reason of the fact that he, she, his or her testator or intestate is or was a director, officer, employee or agent at the request of Histogenics or any predecessor to Histogenics or serves or served at any other enterprise as a director, officer, employee or agent at the request of Histogenics or any predecessor to Histogenics. Any repeal or modification of the indemnification provisions of the sixth amended and restated certificate of incorporation by the stockholders of Histogenics shall not adversely affect any right or protection of a director of Histogenics existing at the time of, or increase the liability of any director of Histogenics with respect to any acts or omissions of</p>

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<u>Provision</u>	<u>Ocugen (Pre-Merger)</u>	<u>Histogenics (Post-Merger)</u>
	representatives of such person. Any person seeking indemnification under the amended and restated certificate of incorporation shall be deemed to have met the standard of conduct required for such indemnification unless the contrary shall be established. Any repeal or modification of the provisions of the certificate of incorporation shall not adversely affect any right or protection of a director or officer of Ocugen existing at the time of such repeal or modification.	such director occurring prior to, such repeal or modification.
Advancement of Expenses	The amended and restated certificate of incorporation of Ocugen provide that Ocugen shall, upon request, advance expenses to any person who is or was a party or is threatened to be made a party to any threatened, pending or completed action, suit, proceeding or claim, whether civil, criminal, administrative or investigative, by reason of the fact that he or she is or was or has agreed to be a director of Ocugen or while a director is or was serving at the request of Ocugen as a director, officer, partner, trustee, employee or agent of any corporation, partnership, joint venture, trust or other enterprise, including service with respect to employee benefit plans, against expenses (including attorney's fees and expenses), judgments, fines, penalties and amounts paid in settlement incurred in connection with the investigation, preparation to defend or defense of such action, suit, proceeding or claim; provided, however, that the foregoing shall not require the Corporation to indemnify or advance expenses to any person in connection with any action, suit,	The amended and restated bylaws of Histogenics provide the right to indemnification conferred there in shall include the right to be paid by Histogenics the expenses (including attorney's fees) incurred in defending any proceeding for which such right to indemnification is applicable in advance of its final disposition; provided, however, that if the Delaware general Corporation Law requires, an advancement of expenses incurred by an indemnitee in his or her capacity as a director or officer shall be made only upon delivery to Histogenics of an undertaking, by or on behalf of such indemnitee, to repay all amounts so advanced if it shall ultimately be determined by final judicial decision from which there is no further right to appeal that such indemnitee is not entitled to be indemnified for such expenses under the bylaws or otherwise.

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<b>Provision</b>	<b>Ocugen (Pre-Merger)</b>	<b>Histogenics (Post-Merger)</b>
<b>DIVIDENDS</b>	proceeding, claim or counterclaim initiated by or on behalf of such person.	
Declaration and Payment of Dividends	The bylaws of Ocugen provide that dividends upon capital stock of Ocugen, subject to the certificate of incorporation, may be declared by the board of directors at any regular or special meeting, pursuant to law. Dividends may be paid in cash, in property, or in shares of the capital stock, subject to the provisions of the Certificate of Incorporation.	The amended and restated bylaws of Histogenics permit the board of directors from time to time, to declare and the corporation to pay dividend on its outstanding share in the manner and upon the terms and conditions provided by law and its certificate of incorporation.
<b>AMENDMENTS TO CERTIFICATE OF INCORPORATION OR BYLAWS</b>		
General Provisions	The amended and restated certificate of incorporation of Ocugen does not provide for its amendment. The bylaws of Ocugen provide that the by-laws may be altered or repealed at any regular meeting of the stockholders or of the board of directors or at any special meeting of the stockholders or of the board of directors if notice of such alteration or repeal be contained in the notice of such special meeting.	Pursuant to the sixth amended and restated certificate of incorporation, Histogenics reserves the right to amend or repeal any provision contained therein in the manner prescribed by the laws of the State of Delaware and all rights conferred upon stockholders are granted subject to this reservation; provided, however, that, notwithstanding any other provision of the sixth amended and restated certificate of incorporation or any provision of law that might otherwise permit a lesser vote or no vote, but in addition to any vote of the holders of any class or series of the stock of Histogenics required by law or by the sixth amended and restated certificate of incorporation (including any preferred stock designation), the affirmative vote of the holders of a majority of the voting power of all of the then-outstanding shares of the capital stock of Histogenics entitled to vote generally in the election of directors, voting together as a single class, shall be required to amend or repeal the provisions of

Provision	Ocugen (Pre-Merger)	Histogenics (Post-Merger)
		<p>the sixth amended and restated certificate of incorporation; provided, however, that any amendment or repeal of Sections C or D or E of Article V, or any provision of Article VI, Article VII, Article VIII or this Article IX shall require the affirmative vote of the holders of at least two-thirds of the voting power of all of the then-outstanding shares of the capital stock of Histogenics entitled to vote generally in the election of directors, voting together as a single class.</p>
		<p>The sixth amended and restated certificate of incorporation and the amended and restated bylaws provide that in furtherance and not in limitation of the powers conferred by statute, the board of directors is expressly empowered to adopt, amend or repeal by laws of Histogenics provided notice of the proposed change was given in the notice of the meeting in a notice given no less than twenty-four (24) hours prior to the meeting. Any adoption, amendment or repeal of the bylaws of the corporation by the board of directors shall require the approval of a majority of the whole board. The Histogenics stockholders shall also have the power to adopt, amend or repeal the bylaws of Histogenics as prescribed by law; provided that notice of the proposed change was given in the notice of the meeting; and further, provided, however, that in addition to any vote of the holders of any class or series of stock of Histogenics required by law or by the sixth amended and restated certificate of incorporation, the affirmative vote of the holders of at least two-thirds of the voting power of all of the then-outstanding shares</p>

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<u>Provision</u>	<u>Ocugen (Pre-Merger)</u>	<u>Histogenics (Post-Merger)</u>
		of the capital stock of Histogenics entitled to vote generally in the election of directors, voting together as a single class, shall be required to adopt, amend or repeal any provision of the bylaws of the corporation.

**PRINCIPAL STOCKHOLDERS OF HISTOGENICS**

The following table sets forth certain information known to Histogenics regarding beneficial ownership of Histogenics common stock as of July 12, 2019 by:

- each person, or group of affiliated persons, who is known by Histogenics to beneficially own more than five percent of Histogenics' outstanding common stock;
- each of Histogenics' named executive officers;
- each of Histogenics' current directors; and
- all of Histogenics' current directors and executive officers as a group.

Applicable percentage ownership is based on 94,599,601 shares of Histogenics common stock outstanding at July 12, 2019.

The table below is based upon information supplied by Histogenics' executive officers, directors and principal stockholders and Schedule 13Gs and 13Ds filed with the SEC through July 12, 2019.

In computing the number of shares of common stock beneficially owned by a person and the percentage ownership of that person, Histogenics deemed to be outstanding all shares of common stock subject to options or warrants held by that person or entity that are currently exercisable or that will become exercisable within 60 days of July 12, 2019. Histogenics did not deem these shares outstanding, however, for the purpose of computing the percentage ownership of any other person. Unless otherwise indicated, the principal address of each of the stockholders below is Histogenics Corporation, c/o Gunderson Dettmer Stough Villeneuve Franklin & Hachigian, LLP, One Marina Park Drive, Suite 900, Boston, MA 02210.

<u>Name and Address of Beneficial Owner</u>	<u>Number of Shares Beneficially Owned</u>	<u>Percentage of Shares Beneficially Owned</u>
<b>5% Stockholders</b>		
Wilmslow Estates Limited c/o Stonehage Group 2 The Forum, Grenville Street St Helier, Jersey, Channel Islands JE1 4HH	5,258,859	5.6%
<b>Directors and Named Executive Officers</b>		
Joshua Baltzell (1)	80,000	*
David Hood (2)	—	—
Susan Washer (3)	10,416	*
Adam Gridley (4)	650,300	*
Stephen Kennedy (5)	228,323	*
Jonathan Lieber (6)	141,241	*
Donald Haut, Ph.D. (7)	—	—
All current executive officers and directors as a group (5 persons) (8)	881,840	*

\* Less than one percent of the outstanding shares of Histogenics common stock.

- (1) Shareholdings include 80,000 shares of common stock issuable upon exercise of options exercisable within 60 days of July 12, 2019.
- (2) Mr. Hood joined the Histogenics Board effective July 19, 2019. Due to the pending merger, the Histogenics Board suspended the equity portion of Histogenics' amended and restated non-employee director compensation policy.
- (3) Shareholdings include 10,416 shares of common stock issuable upon exercise of options exercisable within 60 days of July 12, 2019.



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- (4) Shareholdings include 643,300 shares of common stock issuable upon exercise of options exercisable within 60 days of July 12, 2019. Pursuant to a reduction in force approved by the Histogenics Board in March 2019, Mr. Gridley's employment with Histogenics terminated effective March 22, 2019.
- (5) Shareholdings include 228,323 shares of common stock issuable upon exercise of options exercisable within 60 days of July 12, 2019. Pursuant to a reduction in force approved by the Histogenics Board in March 2019, Mr. Kennedy's employment with Histogenics terminated effective March 22, 2019.
- (6) Shareholdings include 136,124 shares of common stock issuable upon exercise of options exercisable within 60 days of July 12, 2019. Mr. Lieber resigned as Histogenics' Chief Financial Officer effective December 21, 2018. Mr. Lieber was appointed as Histogenics' interim chief financial officer pursuant to a consulting agreement between Histogenics and Danforth Advisors, LLC on December 21, 2018.
- (7) Pursuant to a reduction in force approved by the Histogenics Board in January 2019, Dr. Haut's employment with Histogenics terminated effective January 23, 2019.
- (8) Includes 869,840 shares of common stock issuable upon exercise of options exercisable within 60 days of July 12, 2019.

## PRINCIPAL STOCKHOLDERS OF OCUGEN

The following table sets forth certain information with respect to the beneficial ownership of Ocugen's common stock as of July 12, 2019 (except where otherwise indicated) for:

- each person, or group of affiliated persons, who are known by us to beneficially own more than 5% of the outstanding shares of Ocugen common stock;
- each of Ocugen's directors as of July 12, 2019;
- each of Ocugen's named executive officers, as identified in "The Merger—Interests of Ocugen Directors and Executive Officers in the Merger—Ownership Interests"; and
- all of the current directors and executive officers of Ocugen as a group.

The number of shares beneficially owned by each entity, person, director or executive officer is determined under the rules of the SEC and the information is not necessarily indicative of beneficial ownership for any other purpose. Under such rules, beneficial ownership includes any shares as to which the individual has the sole or shared voting power or investment power and also any shares that the individual has the right to acquire within 60 days of July 12, 2019, through the exercise of any stock option or other right. Unless otherwise indicated, each person has sole investment and voting power, or shares such powers with his or her spouse, with respect to the shares set forth in the following table.

The number of shares of Ocugen common stock outstanding as of July 12, 2019 excludes the securities issuable pursuant to the Pre-Merger Financing and other contingent obligations including:

- 1,258,451 shares of Ocugen common stock issuable upon the exercise of outstanding stock options;
- 1,814,811 shares of Ocugen common stock issuable upon the exercise of outstanding warrants;
- 4,574,272 shares of Ocugen common stock issuable to the Investors immediately prior to the merger (the "Initial Shares"); and
- 4,574,272 shares of Ocugen common stock to be placed into escrow immediately prior to the merger for the benefit of the Investors if 80% of the volume-weighted average trading price of a share of Histogenics common stock as quoted on Nasdaq for the first three trading days immediately following the closing date of the Pre-Merger Financing is lower than the price paid by the Investors for the Initial Shares.

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The percentage of ownership is based on 13,024,138 shares of common stock outstanding on July 12, 2019, adjusted as required by the rules promulgated by the SEC to determine beneficial ownership. Ocugen does not know of any arrangements, including any pledge by any person of securities of Ocugen, the operation of which may at a subsequent date result in a change of control of Ocugen. Unless otherwise noted, the address of each stockholder is c/o Ocugen, Inc., 5 Great Valley Parkway, Suite 160, Malvern, Pennsylvania 19355.

<u>Name and Address of Beneficial Owner</u>	<u>Beneficial Ownership</u>	
	<u>Number of Shares</u>	<u>Percent of Total</u>
<b>5% Stockholders</b>		
KVM Holdings LLC (1)	2,869,539	22.0%
Uday Kompella, Ph.D. (2)	2,998,722	23.0%
Abdi Ibrahim Uluslararası İlaç Yatırımları Sanayi ve Ticaret A.Ş. (3)	1,590,995.5	12.2%
JSC “Lancaster Group Kazakhstan” (4)	1,590,995.5	12.2%
Drishti LLC (5)	861,884	6.2%
Gupiao Trust (6)	747,434	5.6%
<b>Named Executive Officers and Directors</b>		
Junge Zhang (6)	747,434	5.6%
Manish Potti (7)	461,596	3.5%
Frank Leo (8)	254,643	2.0%
Shankar Musunuri, Ph.D., MBA (9)	3,064,539	23.1%
Ramesh Kumar, Ph.D. (10)	—	*0%
Daniel Jorgensen, M.D., M.P.H., MBA (11)	40,667	*0%
Rasappa Arumugham, Ph.D. (12)	38,667	*0%
Suha Taspolatoglu, M.D. (13)	1,590,995.5	12.2%
Uday Kompella, Ph.D. (2)	2,998,722	23.0%
All Directors and Executive Officers as a group (9 persons) (14)	9,233,878.5	66.0%

\* Represents less than 1% of the outstanding shares of Ocugen’s common stock.

- (1) Includes 845 shares of common stock issuable upon exercise of warrants exercisable within 60 days of July 12, 2019. Shankar Musunuri, Ph.D., MBA is a member and officer of KVM Holdings, LLC and has voting and investment power over the shares held by KVM Holdings LLC.
- (2) Includes 1,000,000 shares beneficially owned by Uday Kompella through Kompella LLC, 739 shares of common stock issuable upon exercise of warrants exercisable within 60 days of July 12, 2019 and 15,000 shares of common stock issuable upon exercise of options exercisable within 60 days of July 12, 2019. Uday Kompella’s address is 11614 E. Lake Place, Englewood Colorado, 80111. Mr. Kompella has voting and investment power over the shares held by Kompella LLC. The address of Kompella LLC is 3372 Bel Mira Way, San Jose, CA 95135.
- (3) Includes 41,391 shares of common stock issuable upon exercise of warrants exercisable within 60 days of July 12, 2019. Suha Taspolatogula, M.D., is the Chief Executive Officer of Abdi Ibrahim Uluslararası İlaç Yatırımları Sanayi ve Ticaret A.Ş (“Abdi”) and has voting and investment power over the shares held by Abdi. The address of Abdi is 7-8 Hasan Pasa Yalısı, No. 25, Kanlıca, Beykoz, Istanbul, Turkey.
- (4) Includes 41,391 shares of common stock issuable upon exercise of warrants exercisable within 60 days of July 12, 2019. Venera Barzamova is the president of JSC “Lancaster Group Kazakhstan” and has voting and investment power over the shares held by JSC “Lancaster Group Kazakhstan.” The address of JSC “Lancaster Kazakhstan” is 77/7 Al Farabi Avenue, Esentai Tower, 15th floor, 050040 Almaty, Kazakhstan.
- (5) Includes 819,330 shares of common stock issuable upon exercise of warrants exercisable within 60 days of July 12, 2019. Ravi T. Achar is the CEO of Drishti LLC and has voting and investment power over the shares held by Drishti LLC. The address of Drishti LLC is 1838 Kirsten Lee Drive, Westlake Village, CA 91361.
- (6) Represents shares held by Gupiao Trust, an entity of which Mr. Zhang is the beneficiary and over which he has voting and investment power. Includes 303,449 shares of common stock issuable upon exercise of

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- warrants exercisable within 60 days of July 12, 2019. The address of Gupiao Trust is 5 Great Valley Parkway, Suite 100, Malvern, PA 19355.
- (7) Represents shares held by Scotland Parkway LLC. Includes 204,139 shares of common stock issuable upon exercise of warrants exercisable within 60 days of July 12, 2019. Mr. Potti is a managing member of Scotland Parkway LLC and has voting and investment power over the shares held by Scotland Parkway LLC.
  - (8) Includes 9,539 shares of common stock issuable upon exercise of warrants exercisable within 60 days of July 12, 2019 and 30,000 shares of common stock issuable upon exercise of options exercisable within 60 days of July 12, 2019.
  - (9) Includes (i) holdings of KVM Holdings LLC including (A) 2,868,694 shares and (B) 845 shares of common stock issuable upon exercise of warrants within 60 days of July 12, 2019 and (ii) holdings of Dr. Musunuri including (A) 15,000 shares of common stock issuable upon exercise of warrants within 60 days of July 12, 2019 and (B) 180,000 shares of common stock, each issuable upon exercise of options exercisable within 60 days of July 12, 2019. Dr. Musunuri is a member and officer of KVM Holdings LLC and has voting and investment power over the shares held by KVM Holdings LLC.
  - (10) Dr. Kumar joined the Ocugen Board effective June 24, 2019.
  - (11) Includes 40,667 shares of common stock issuable upon exercise of options exercisable within 60 days of July 12, 2019.
  - (12) Includes 38,667 shares of common stock issuable upon exercise of options exercisable within 60 days of July 12, 2019.
  - (13) Represents shares held by Abdi. Includes 41,391 shares of common stock issuable upon exercise of warrants exercisable within 60 days of July 12, 2019. Dr. Taspolatogula is the Chief Executive Officer of Abdi and has voting and investment power over the shares held by Abdi.
  - (14) Includes 575,102 shares of common stock issuable upon exercise of warrants exercisable within 60 days of July 12, 2019 and 304,334 shares of common stock issuable upon exercise of options exercisable within 60 days of July 12, 2019.

## PRINCIPAL STOCKHOLDERS OF COMBINED ORGANIZATION

*Except where specifically noted, the following information does not give effect to the Histogenics Reverse Stock Split described in Histogenics Proposal No. 2.*

The following table and the related notes present certain information with respect to the beneficial ownership of the common stock of the combined organization upon consummation of the merger, assuming the closing of the merger occurred on July 12, 2019, by:

- each director and named executive officer of the combined organization;
- all of the combined organization's directors and executive officers as a group; and
- each person or group who is known to the management of Ocugen or Histogenics to become the beneficial owner of more than 5% of the common stock of the combined organization upon the consummation of the merger.

Unless otherwise indicated in the footnotes to this table, Ocugen and Histogenics believe that each of the persons named in this table have sole voting and investment power with respect to the shares indicated as beneficially owned.

The following table assumes an exchange ratio of 28.7650 and that the closing of the merger occurred on July 12, 2019. Immediately prior to the merger, Histogenics will have 94,599,601 shares of common stock outstanding and Ocugen will have 17,598,410 shares of common stock outstanding (which includes 4,574,272 shares of Ocugen common stock issuable to the Investors immediately prior to the merger (the "Initial Shares")). Upon the closing of the merger, the 17,598,410 shares of Ocugen common stock will be converted into the right to receive an aggregate of 506,218,264 shares of Histogenics common stock, and, assuming no exercise of outstanding options to purchase shares of Histogenics common stock prior to the closing of the merger, there will be a total of approximately 600,817,865 shares of Histogenics common stock outstanding upon the closing of the merger, not giving effect to the Histogenics Reverse Stock Split.

The following table does not give effect to the issuance of the following securities pursuant to the Pre-Merger Financing, other Ocugen and Histogenics contingent obligations and related adjustments:

- 4,574,272 shares of Ocugen common stock (131,578,934 shares of Histogenics common stock after the merger assuming an exchange ratio of 28.7650) to be placed into escrow immediately prior to the merger for the benefit of the Investors if 80% of the volume-weighted average trading price of a share of Histogenics common stock as quoted on Nasdaq for the first three trading days immediately following the closing date of the Pre-Merger Financing is lower than the price paid by the Investors for the Initial Shares;
- Such number of Histogenics common stock as is equal to at least 9,148,544 shares of Ocugen common stock, as adjusted for the exchange ratio, that will be issuable upon exercise of the Series A Warrants; and
- Additional shares of Histogenics' common stock that may be issuable upon exercise of the Series B Warrants.

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The following table does not give effect to the Histogenics Reverse Stock Split to be implemented prior to the closing of the merger. Shares of Histogenics' common stock that may be acquired by an individual or group within 60 days of July 12, 2019, pursuant to the exercise of options or warrants, are deemed to be outstanding for the purpose of computing the percentage ownership of such individual or group, but are not deemed to be outstanding for the purpose of computing the percentage ownership of Histogenics' common stock of any other person shown in the table. Unless otherwise indicated, the principal address of each of the stockholders below is c/o Ocugen, Inc., 5 Great Valley Parkway, Suite 160, Malvern, PA 19355.

<b>5% Stockholders</b>	<b>Number of Shares</b>	<b>Approximate Percent Owned</b>
KVM Holdings LLC (1)	82,542,290	13.7%
Uday Kompella, Ph.D. (2)	86,258,238	14.4%
Abdi İbrahim Uluslararası İlaç Yatırımları Sanayi ve Ticaret A.Ş. (3)	45,764,985	7.6%
JSC "Lancaster Group Kazakhstan" (4)	45,764,985	7.6%

<b>Directors and Named Executive Officers</b>	<b>Number of Shares</b>	<b>Approximate Percent Owned</b>
Junge Zhang (5)	21,499,940	3.5%
Manish Potti (6)	13,277,809	2.2%
Frank Leo (7)	7,324,806	1.2%
Shankar Musunuri, Ph.D., MBA (8)	88,151,465	14.5%
Ramesh Kumar, Ph.D. (9)	—	*0%
Daniel Jorgensen, M.D., M.P.H., MBA (10)	1,169,786	*0%
Rasappa Arumugham, PH.D. (11)	1,112,256	*0%
Suha Taspolatoglu, M.D. (12)	45,764,985	7.6%
Uday Kompella, Ph.D. (2)	86,258,238	14.4%
All Directors and Executive Officers as a group (9 persons) (13)	265,612,515	42.4%

\* Represents beneficial ownership of less than 1% of the shares of common stock.

- (1) Includes 24,307 shares of common stock issuable upon exercise of warrants exercisable within 60 days of July 12, 2019. Shankar Musunuri, Ph.D., MBA is a member and officer of KVM Holdings, LLC and has voting and investment power over the shares held by KVM Holdings LLC. The address of KVM Holdings, LLC is 482 Byers Road, Chester Springs, PA 19425.
- (2) Includes 28,765,000 shares beneficially owned by Uday Kompella through Kompella LLC, 21,257 shares of common stock issuable upon exercise of warrants exercisable within 60 days of July 12, 2019 and 431,475 shares of common stock issuable upon exercise of options exercisable within 60 days of July 12, 2019. Uday Kompella's address is 11614 E. Lake Place, Englewood Colorado, 80111.
- (3) Includes 1,190,612 shares of common stock issuable upon exercise of warrants exercisable within 60 days of July 12, 2019. Suha Taspolatoglu, M.D., is the Chief Executive Officer of Abdi İbrahim Uluslararası İlaç Yatırımları Sanayi ve Ticaret A.Ş. ("Abdi") and has voting and investment power over the shares held by Abdi. The address of Abdi is 7-8 Hasan Pasa Yalısı, No. 25, Kanlıca, Beykoz, Istanbul, Turkey.
- (4) Includes 1,190,612 shares of common stock issuable upon exercise of warrants exercisable within 60 days of July 12, 2019. Venera Barzamova is the president of JSC "Lancaster Group Kazakhstan" and has voting and investment power over the shares held by JSC "Lancaster Group Kazakhstan." The address of JSC "Lancaster Kazakhstan" is 77/7 Al Farabi Avenue, Esentai Tower, 15<sup>th</sup> floor 050040 Almaty Kazakhstan.
- (5) Represents shares held by Gupiao Trust. Includes 8,728,711 shares of common stock issuable upon exercise of warrants exercisable within 60 days of July 12, 2019. Mr. Zhang is the beneficiary of Gupiao Trust and has voting and investment power over the shares held by Gupiao Trust. The address of Gupiao Trust is 4465 South Jones Boulevard, Las Vegas, NV 89103.

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- (6) Represents shares held by Scotland Parkway LLC. Includes 5,872,058 shares of common stock issuable upon exercise of warrants exercisable within 60 days of July 12, 2019. Mr. Potti is a managing member of Scotland Parkway LLC and has voting and investment power over the shares held by Scotland Parkway LLC.
- (7) Includes 274,389 shares of common stock issuable upon exercise of warrants and 862,950 shares of common stock issuable upon exercise of options exercisable within 60 days of July 12, 2019.
- (8) Includes (i) holdings of KVM Holdings LLC including (A) 82,517,983 shares and (B) 24,307 shares of common stock issuable upon exercise of warrants exercisable within 60 days of July 12, 2019 and (ii) holdings of Dr. Musunuri including (A) 431,475 shares of common stock issuable upon exercise of warrants within 60 days of July 12, 2019 and (B) 5,177,700 shares of common stock issuable upon exercise of options exercisable within 60 days of July 12, 2019. Dr. Musunuri is a member and officer of KVM Holdings LLC and has voting and investment power over the shares held by KVM Holdings LLC.
- (9) Dr. Kumar joined the Ocugen Board effective June 24, 2019.
- (10) Includes 1,169,786 shares of common stock issuable upon exercise of options exercisable within 60 days of July 12, 2019.
- (11) Includes 1,112,256 shares of common stock issuable upon exercise of options exercisable within 60 days of July 12, 2019.
- (12) Represents shares held by Abdi. Includes 1,190,165 shares of common stock issuable upon exercise of warrants exercisable within 60 days of July 12, 2019. Dr. Taspolatogula is the Chief Executive Officer of Abdi and has voting and investment power over the shares held by Abdi.
- (13) Includes 16,542,809 shares of common stock issuable upon exercise of warrants exercisable within 60 days of July 12, 2019 and 8,754,167 shares of common stock issuable upon exercise of options exercisable within 60 days of July 12, 2019.

## LEGAL MATTERS

Gunderson Dettmer Stough Villeneuve Franklin & Hachigian, LLP will pass on the validity of Histogenics common stock offered by this proxy statement/prospectus/information statement.

## EXPERTS

The audited financial statements of Histogenics Corporation included in this prospectus and elsewhere in the registration statement have been so included in reliance upon the report of Grant Thornton LLP, independent registered public accountants, upon the authority of said firm as experts in accounting and auditing.

The consolidated financial statements of Ocugen, Inc. at December 31, 2018 and 2017, and for the years then ended, included in the Proxy Statement of Histogenics Corporation, which is referred to and made a part of this Prospectus and Registration Statement, have been audited by Ernst & Young LLP, independent registered public accounting firm, as set forth in their report (which contains an explanatory paragraph describing conditions that raise substantial doubt about Ocugen, Inc.'s ability to continue as a going concern as described in Note 1 to Ocugen, Inc.'s consolidated financial statements) appearing elsewhere herein, and are included in reliance upon such report given on the authority of such firm as experts in accounting and auditing.

## WHERE YOU CAN FIND MORE INFORMATION

Histogenics files annual, quarterly and special reports, proxy statements and other information with the SEC. Histogenics SEC filings are available on the website maintained by the SEC at <http://www.sec.gov>. Reports, proxy statements and other information concerning Histogenics also may be inspected at the offices of the National Association of Securities Dealers, Inc., Listing Section, 1735 K Street, Washington, D.C. 20006.

As of the date of this proxy statement/prospectus/information statement, Histogenics has filed a registration statement on Form S-4 to register with the SEC Histogenics common stock that Histogenics will issue to Ocugen's stockholders in the merger. This proxy statement/prospectus/information statement is a part of that registration statement and constitutes a prospectus of Histogenics, as well as a proxy statement of Histogenics for its special meeting and an information statement for the purpose of Ocugen for its written consent.

Histogenics has supplied all information contained in this proxy statement/prospectus/information statement relating to Histogenics and its business, and Ocugen has supplied all information contained in this proxy statement/prospectus/information statement relating to Ocugen and its business.

If you would like to request documents from Histogenics or Ocugen, please send a request in writing or by telephone to either Histogenics or Ocugen at the following addresses:

Histogenics Corporation  
c/o Gunderson Dettmer Stough Villeneuve Franklin & Hachigian, LLP  
One Marina Park Drive, Suite 900  
Boston, MA 02210  
(781) 312-5013  
Attn: Investor Relations

Ocugen, Inc.  
5 Great Valley Parkway, Suite 160  
Malvern, PA 19355  
(484) 328-4701  
Attn: Kelly Beck



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You may also request additional copies from Histogenics' proxy solicitor using the following contact information:

INNISFREE M&A INCORPORATED  
501 Madison Avenue, 20th Floor  
New York, NY 10022  
Stockholders Call Toll-Free: 888-750-5834  
Banks and Brokers Call Collect: 212-750-5833

## TRADEMARK NOTICE

“Histogenics” is a registered and unregistered trademark of Histogenics in the United States and other jurisdictions. “Ocugen,” the Ocugen logo and other trademarks, service marks, and trade names of Ocugen are registered and unregistered marks of Ocugen, Inc. Other third-party logos and product/trade names are registered trademarks or trade names of their respective companies.

### **Delinquent Section 16(a) Reports**

Section 16(a) of the Securities Exchange Act requires Histogenics’ executive officers, directors and persons who beneficially own greater than 10% of a registered class of its equity securities to file certain reports with the SEC with respect to ownership and changes in ownership of the Histogenics common stock and Histogenics’ other equity securities.

To Histogenics’ knowledge, based solely on its review of the copies of such reports filed with the SEC, its officers, directors and greater than 10% stockholders timely complied with these Section 16(a) filing requirements during the fiscal year ended December 31, 2018.

### **Stockholder Proposals**

*Requirements for Stockholder Proposals to Be Considered for Inclusion in Histogenics’s Proxy Materials.* Stockholders of Histogenics may submit proposals on matters appropriate for stockholder action at meetings of Histogenics’s stockholders in accordance with Rule 14a-8 promulgated under the Exchange Act. For such proposals to be included in Histogenics’s proxy materials relating to the 2020 Annual Meeting of Stockholders, all applicable requirements of Rule 14a-8 must be satisfied and such proposals must be received at Histogenics’s executive offices no later than 120 calendar days before the anniversary of the date the proxy statement is released to stockholders in connection with the 2019 Annual Meeting of Stockholders. Histogenics has not yet set the date for its 2019 Annual Meeting of Stockholders, but if the Histogenics 2020 Annual Meeting of Stockholders is not held within 30 days from the anniversary of the 2019 Annual Meeting of Stockholders, then the deadline will be a reasonable time prior to the time Histogenics begins to print and send its proxy materials. All such proposals must comply with all applicable requirements of Rule 14a-8. Prior to the consummation of the merger, such proposals must be sent to the Histogenics Corporate Secretary at Histogenics Corporation, c/o Gunderson Dettmer Stough Villeneuve Franklin & Hachigian, LLP, One Marina Park Drive, Suite 900, Boston, MA 02210 by the close of business on the required deadline. After the consummation of the merger, such proposals must be sent to the combined company’s Corporate Secretary at Ocugen, Inc., 5 Great Valley Parkway, Suite 160, Malvern, PA 19355 by the close of business on the required deadline.

*Requirements for Stockholder Proposals and Director Nominations at the 2020 Annual Meeting.* Pursuant to Histogenics’s amended and restated bylaws (the “Histogenics bylaws”), stockholders wishing to submit proposals or director nominations, except in the case of proposals made in accordance with Rule 14a-8, must, in addition to complying with applicable laws and regulations and the requirements of the Histogenics bylaws, provide timely notice thereof in writing to the Histogenics Corporate Secretary. To be timely for the 2020 annual meeting of stockholders, a stockholder must notify the Histogenics Corporate Secretary, in writing, not later than the close of business on the one hundred twentieth (120th) day prior to the anniversary of the date of the proxy statement is delivered to stockholders in connection with the 2019 annual meeting of stockholders. Histogenics also advises stockholders to review its amended and restated bylaws, which contain additional requirements about advance notice of stockholder proposals and director nominations. Histogenics has not yet set the date for its 2019 annual meeting of stockholders, but if the Histogenics 2020 annual meeting of stockholders is not held within 30 days from the one year anniversary of the 2019 Annual Meeting of Stockholders, such nominations and proposals must be received no later than the close of business on the later of (a) the 90<sup>th</sup> day prior to Histogenics’ 2019 annual meeting of stockholders and (b) the 10<sup>th</sup> day following the day Histogenics’ first publicly announce the date of its 2019 annual meeting of stockholders. A stockholder’s notice to the Histogenics Corporate

Secretary must set forth the information required by its amended and restated bylaws with respect to each director nominee or proposal the stockholder proposes to bring before the annual meeting. If the stockholder does not also satisfy the requirements of Rule 14a-4 promulgated under the Exchange Act, the persons named as proxies will be allowed to use their discretionary voting authority when and if the matter is raised at the 2020 annual meeting of stockholders. A copy of the Histogenics amended and restated bylaws may be obtained by writing to the Histogenics Corporate Secretary at the address listed above. In addition, the proxy solicited by the Histogenics Board for the 2020 Annual Meeting of Stockholders will confer discretionary voting authority with respect to (i) any proposal presented by a stockholder at that meeting for which Histogenics has not been provided with timely notice and (ii) any proposal made in accordance with Histogenics's amended and restated bylaws, if the proxy statement for the 2020 annual meeting of stockholders briefly describes the matter and how management proxy holders intend to vote on it, if the stockholder does not comply with the requirements of Rule 14a-4(c)(2) promulgated under the Exchange Act.

### **Stockholder Communication with the Histogenics Board**

Stockholders may communicate with the Histogenics Board, including the independent members of the Histogenics Board, by sending a letter to Histogenics Corporation, c/o Gunderson Dettmer Stough Villeneuve Franklin & Hachigian, LLP, One Marina Park Drive, Suite 900, Boston, MA 02210, Attention: Corporate Secretary. Each such communication should set forth (1) the name and address of such stockholder, as they appear on Histogenics' books and, if the shares of Histogenics' stock are held by a nominee, the name and address of the beneficial owner of such shares, and (2) the number of shares of Histogenics' stock that are owned of record by such record holder and beneficially by such beneficial owner. The Corporate Secretary will review all communications from stockholders, but may, in his or her sole discretion, disregard any communication that he or she believes is not related to the duties and responsibilities of the Histogenics Board. If deemed an appropriate communication, the Corporate Secretary will submit a stockholder communication to a chairman of a committee of the Histogenics Board, or a particular director, as appropriate.

The Histogenics Board has also adopted internal policies and procedures, with the assistance of outside legal counsel, for responding to communications from Histogenics' stockholders, including litigation demand letters (a "Litigation Demand"), which provide that:

- any Litigation Demand is promptly forwarded to the independent Chairman of the Histogenics Board and outside legal counsel;
- investigations of any Litigation Demand will be directed and supervised by one or more disinterested and independent (*i.e.*, non-management) members of the Histogenics Board and such supervision will not be delegated to any member of the Company's management team (though in appropriate cases members of management may otherwise assist an investigation);
- the Histogenics Board has standing authority to retain and be advised by disinterested and independent outside legal counsel and other advisers, as needed;
- the Histogenics Board may authorize a special demand review committee to investigate a Litigation Demand, which committee would ensure the preparation of a written record of the resolution creating the demand review committee, its purpose, composition, structure, duties, responsibilities and scope of authority; and
- upon completion of its investigation, the Board will receive a recommendation from the independent and disinterested members of the Board who investigated the Litigation Demand and vote on whether to adopt that recommendation and inform the demanding stockholder accordingly.

The Histogenics Board's Litigation Demand policy notes that every Litigation Demand situation is unique and that flexibility is required in responding thereto. Failure to adhere to any of the particular processes above is not deemed a breach of any Board member's fiduciary duties.

### **Code of Business Conduct**

Histogenics has adopted a Code of Business Conduct that applies to each of its directors, officers and employees, including its principal executive officer, principal financial officer, principal accounting officer or controller and persons performing similar functions. The Code of Business Conduct addresses various topics, including: (1) compliance with applicable laws, rules and regulations; (2) conflicts of interest; (3) public disclosure of information; (4) insider trading; (5) corporate opportunities; (6) competition and fair dealing; (7) gifts; (8) discrimination, harassment and retaliation; (9) health and safety; (10) record-keeping; (11) confidentiality; (12) protection and proper use of company assets; (13) payments to government personnel; and (14) the reporting of illegal and unethical behavior.

The Code of Business Conduct is available on the “Investors” section of Histogenics’ corporate website located at <http://ir.histogenics.com>. Any waiver of the Code of Business Conduct for an executive officer or director may be granted only by the Histogenics Board or a committee thereof and must be timely disclosed as required by applicable law. Histogenics intends to disclose future amendments to certain provisions of our Code of Business Conduct, or waivers of those provisions, applicable to any principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions on our website, [www.histogenics.com](http://www.histogenics.com).

Histogenics has implemented whistleblower procedures that establish formal protocols for receiving and handling complaints from employees. Any concerns regarding accounting or audit matters reported under these procedures will be communicated promptly to the Histogenics Audit Committee.

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UNAUDITED PRO FORMA CONDENSED COMBINED FINANCIAL INFORMATION**

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## UNAUDITED PRO FORMA CONDENSED COMBINED FINANCIAL INFORMATION

### Introduction

*The unaudited pro forma net loss per common share does not give effect to the Histogenics Reverse Stock Split described in Proposal No. 2 in the proxy statement/prospectus/information statement.*

The following unaudited pro forma condensed combined financial information has been prepared to reflect the adjustments to the financial condition and results of operations of Ocugen, Inc. (“Ocugen”) to give the estimated effects of the reverse merger transaction with Histogenics Corporation (“Histogenics”). For accounting purposes, Ocugen is considered to be acquiring Histogenics and the merger (as defined in Note 1 below) is expected to be accounted for as an equity transaction. Ocugen is considered the accounting acquirer even though Histogenics will be the issuer of the common stock in the merger.

To determine the accounting for this transaction under U.S. Generally Accepted Accounting Principals (“GAAP”), a company must assess whether an integrated set of assets and activities should be accounted for as an acquisition of a business, an asset acquisition or equity transaction. The transaction between Ocugen and Histogenics represents an equity transaction rather than a business combination under Accounting Standards Codification 805, Business Combinations (“ASC 805”). Therefore, no goodwill or intangible assets will be recognized as a result of the transaction. The transaction is considered an equity transaction where in substance Ocugen is exchanging equity for the net monetary assets of Histogenics.

The unaudited pro forma condensed combined balance sheet data assume that the merger took place on March 31, 2019, and combines the historical balance sheets of Histogenics and Ocugen as of such date. The unaudited pro forma condensed combined statements of operations data assume that the merger took place as of January 1, 2018, and for the three months ended March 31, 2019 and the year ended December 31, 2018. The unaudited pro forma condensed combined financial information was prepared in accordance with GAAP and pursuant to the rules and regulations of Article 11 of Regulation S-X promulgated by the Securities and Exchange Commission (the “SEC”). The historical financial statements of Histogenics and Ocugen have been adjusted to give pro forma effect to events that are (i) directly attributable to the transaction, (ii) factually supportable, and (iii) with respect to the unaudited pro forma condensed combined statements of operations, expected to have a continuing impact on the combined company’s results.

In addition to the reverse merger, the unaudited combined pro forma financial statements give effect to the following related adjustments:

- Financing transaction to raise \$25.0 million in funds, offset by \$5.29 million due under senior secured convertible notes, and the issuance of warrants to purchase common stock of the combined entity;
- Conversion of convertible promissory notes to Ocugen’s stockholders issued in 2018 totaling \$7.3 million; and
- Conversion of convertible promissory notes to Ocugen’s stockholders issued in January and February 2019 totaling \$1.45 million.

The merger will be accounted for as an equity transaction. This assessment was based on the determination that in substance the transaction is an exchange of equity for the net monetary assets of Histogenics and there are no significant non-monetary assets. The financial statements of the combined entity represent a continuation of the financial statements of the accounting acquirer. As such, the assets and liabilities of Ocugen are recognized at their historic carrying value. For accounting purposes, Histogenics is considered the “acquired” company and Ocugen is considered the “acquirer.” Histogenics assets, liabilities and results of operations will be consolidated with Ocugen as of the closing date of the reverse merger. For periods prior to the transaction, stockholders’ equity of the combined company is presented based on the historical equity.

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The unaudited pro forma condensed combined financial information is based on the assumptions and adjustments that are described in the accompanying notes. These pro forma adjustments are preliminary, subject to further revision as additional information becomes available and additional analyses are performed, and have been made solely for the purpose of providing unaudited pro forma condensed combined financial information. Differences between these preliminary estimates and the final accounting, expected to be completed after the closing of the merger, will occur and these differences could have a material impact on the accompanying unaudited pro forma condensed combined financial information and the combined company's future results of operations and financial position.

The unaudited pro forma condensed combined financial information does not give effect to the potential impact of current financial conditions, regulatory matters, operating efficiencies (if any) or other savings or expenses that may be associated with the integration of the two companies. The unaudited pro forma condensed combined financial information is preliminary and has been prepared for illustrative purposes only and is not necessarily indicative of the financial position or results of operations in future periods or the results that actually would have been realized had Histogenics and Ocugen been a combined company during the specified periods. The actual results reported in periods following the merger may differ significantly from those reflected in the unaudited pro forma condensed combined financial information presented herein for a number of reasons, including, but not limited to, differences in the assumptions used to prepare this pro forma financial information.

The unaudited pro forma condensed combined financial information, including the notes thereto, should be read in conjunction with the separate historical financial statements of Histogenics and Ocugen, and their respective management's discussion and analysis of financial condition and results of operations included elsewhere in this proxy statement/prospectus/information statement. The unaudited pro forma condensed combined financial statements should be read together with Histogenics' historical financial statements, which are included in Histogenics' Annual Report on Form 10-K for the year ended December 31, 2018, filed with the SEC on March 22, 2019 and the March 31, 2019 results included in Histogenics' Quarterly Report on Form 10-Q, filed with the SEC on May 15, 2019, and Ocugen's historical information included herein.

Accounting rules require evaluation of certain assumptions, estimates, or determination of financial statement classifications which are completed during the measurement period as defined in current accounting standards. The accounting policies of Histogenics may materially vary from those of Ocugen. During preparation of the unaudited pro forma condensed combined financial information, Ocugen management has performed a preliminary analysis and is not aware of any material differences, and accordingly, the unaudited pro forma condensed combined financial information assumes no material differences in accounting policies. Following the acquisition, Ocugen management will conduct a final review of Histogenics' accounting policies in order to determine if differences in accounting policies require adjustment or reclassification of Histogenics' results of operations or reclassification of assets or liabilities to conform to Ocugen's accounting policies and classifications. As a result of this review, management may identify differences that, when conformed, could have a material impact on these unaudited pro forma condensed combined financial statements.

**Unaudited Pro Forma Condensed Combined Balance Sheet**  
**As of March 31, 2019**  
(In thousands)

	<u>Historical Histogenics Corporation</u>	<u>Historical Ocugen, Inc.</u>	<u>Histogenics Pro Forma Adjustments</u>	<u>Ocugen Pro Forma Adjustments</u>	<u>Pro Forma Ocugen, Inc. Combined</u>
<b>ASSETS</b>					
<b>Current assets</b>					
Cash and cash equivalents	\$ 7,376	\$ 309	\$ 6,500 (a)	\$ 22,500 (f)	\$ 37,895
				4,600 (g)	
				(5,290) (g)	
				1,900 (h)	
Prepaid expenses and other current assets	764	314	(764) (b)	—	314
<b>Total current assets</b>	<b>8,140</b>	<b>623</b>	<b>5,736</b>	<b>23,710</b>	<b>38,209</b>
Property and equipment, net	135	244	—	—	379
Restricted cash	137	151	—	—	288
Other assets, long-term	6,426	564	(6,426) (b)	—	564
<b>Total assets</b>	<b>\$ 14,838</b>	<b>\$ 1,582</b>	<b>\$ (690)</b>	<b>\$ 23,710</b>	<b>\$ 39,440</b>
<b>LIABILITIES AND STOCKHOLDERS' DEFICIT</b>					
<b>Current liabilities</b>					
Accounts payable	\$ 1,100	\$ 5,383	\$ —	\$ —	\$ 6,483
Accrued expenses	99	998	1,400 (c)	1,600 (i),(g)	4,097
Short term debt, net	—	9,042	—	(9,042) (j)	—
Derivative liabilities	—	3,003	—	(3,003) (j)	—
Operating lease obligation – current portion	1,118	261	(1,118) (b)	—	261
Financing lease obligation – current portion	—	21	—	—	21
Deferred grant proceeds	—	184	—	—	184
<b>Total current liabilities</b>	<b>2,317</b>	<b>18,892</b>	<b>282</b>	<b>(10,445)</b>	<b>11,046</b>
<b>Non-Current Liabilities</b>					
Accrued expenses due to Intrexon Corporation	1,125	—	—	—	1,125
Operating lease obligations, less current portion	6,918	238	(6,918) (b)	—	238
Financing lease obligation, less current portion	—	28	—	—	28
Deferred revenue	10,000	—	(10,000) (d)	—	—
Deferred rent	—	—	—	—	—
Long Term Debt	—	1,031	—	—	1,031
Warrant liability	10	—	—	6,200 (f)	6,210
<b>Total Non-Current Liabilities</b>	<b>18,053</b>	<b>1,297</b>	<b>(16,918)</b>	<b>6,200</b>	<b>8,632</b>
<b>Total liabilities</b>	<b>20,370</b>	<b>20,189</b>	<b>(16,636)</b>	<b>(4,245)</b>	<b>19,678</b>
Common stock	839	10	4,703(e)	1,343 (l)	6,895 (k)
Accumulated other comprehensive income	—	—	—	—	—
Additional paid-in capital	219,874	18,932	(213,602) (e)	24,332 (l)	49,536
Accumulated deficit	(226,245)	(37,549)	224,845 (c),(e)	2,280 (g),(j)	(36,669)
<b>Total stockholders' equity</b>	<b>(5,532)</b>	<b>(18,607)</b>	<b>15,946</b>	<b>27,955</b>	<b>19,762</b>
<b>Total liabilities and stockholders' equity</b>	<b>\$ 14,838</b>	<b>\$ 1,582</b>	<b>\$ (690)</b>	<b>\$ 23,710</b>	<b>\$ 39,440</b>



## Unaudited Pro Forma Condensed Combined Statements of Operations

For the year ended December 31, 2018

(In thousands, except share and per share data)

	Historical Histogenics Corporation	Historical Ocugen, Inc.	Histogenics Pro Forma Adjustments	Ocugen, Inc. Pro Forma Adjustments	Pro Forma Ocugen, Inc. Combined
Revenue	\$ —	\$ —	\$ —	\$ —	\$ —
Operating expenses:					
Research and development	15,634	10,321	(15,634) (a)		10,321
General and administrative	10,204	5,819	(1,194) (a)		14,829
Loss due to asset impairment	4,270	—			4,270
Total operating expenses	<u>30,108</u>	<u>16,140</u>	<u>(16,828)</u>	<u>—</u>	<u>29,420</u>
Income (loss) from operations	(30,108)	(16,140)	16,828		(29,420)
Other income (expense):					
Interest income (expense), net	163	(3,732)		2,893 (h),(g)	(676)
Other income (expense), net	(106)	(12)			(118)
Gain due to extinguishment of liability	1,540	—			1,540
Warrant expense	(733)	— (m)			(733)
Change in fair value of derivative liabilities	20,601	1,665			22,266
Total other income (expense), net	<u>21,465</u>	<u>(2,079)</u>	<u>—</u>	<u>2,893</u>	<u>22,279</u>
Net loss	<u>\$ (8,643)</u>	<u>\$ (18,219)</u>	<u>\$ 16,828</u>	<u>\$ 2,893</u>	<u>\$ (7,141)</u>
Net loss per Common Share - Basic	\$ (0.23)	\$ (1.76)			\$ (0.01)
Net loss per Common Share - Diluted	\$ (0.79)	\$ (1.76)			\$ (0.01)
Weighted Average Common Shares					
Outstanding - Basic	36,398,450	10,347,418			689,460,553 (k)
Weighted Average Common Shares					
Outstanding - Diluted	37,090,197	10,347,418			689,460,553 (k)

**Unaudited Pro Forma Condensed Combined Statements of Operations****For the three months ended March 31, 2019**

(In thousands, except share and per share data)

	<b>Historical Histogenics Corporation</b>	<b>Historical Ocugen, Inc.</b>	<b>Histogenics Pro Forma Adjustments</b>	<b>Ocugen, Inc. Pro Forma Adjustments</b>	<b>Pro Forma Ocugen, Inc. Combined</b>
Revenue	\$ —	\$ —	\$ —	\$ —	\$ —
Operating expenses:					
Research and development	1,583	3,793	(1,583) (a)		3,793
General and administrative	2,929	1,048	(180) (o)	(100) (o)	3,697
Restructuring	2,789				2,789
Loss due to asset impairment	750				750
Total operating expenses	8,051	4,841	(1,763)	(100)	11,029
Loss from operations	(8,051)	(4,841)	1,763	100	(11,029)
Other income (expense):					
Interest income (expense), net	48	(695)		565 (n)	(82)
Other income (expense), net	(5)	—			(5)
Change in fair value of derivative liabilities	(1,407)	(777) (m)			(2,184)
Total other income (expense), net	(1,364)	(1,472)	—	565	(2,271)
Net loss	\$ (9,415)	\$ (6,313)	\$ 1,763	\$ 665	\$ (13,330)
Net loss per Common Share - Basic and Diluted	\$ (0.12)	\$ (0.61)			\$ (0.02)
Weighted Average Common Shares Outstanding - Basic and Diluted	80,484,113	10,347,418			689,460,553 (k)

Note 1 – Description of Transaction

On April 5, 2019, Histogenics and Ocugen entered into an Agreement and Plan of Merger and Reorganization, as amended on June 13, 2019 (the “Merger Agreement”), pursuant to which a wholly-owned subsidiary of Histogenics will merge with and into Ocugen, with Ocugen surviving as a wholly-owned subsidiary of Histogenics (the “merger”). Ocugen and Histogenics believe that the merger will result in a clinical-stage biopharmaceutical company focused on developing innovative therapies to address rare and underserved eye diseases.

At the effective time of the merger (the “Effective Time”), each share of common stock of Ocugen, \$0.001 par value (“Ocugen common stock”), will be converted into the right to receive 28.7650 shares of common stock of Histogenics, \$0.01 par value (“Histogenics common stock”), subject to adjustment for the reverse stock split of Histogenics common stock to be implemented prior to the consummation of the merger as discussed elsewhere in this proxy statement/prospectus/information statement. Histogenics will assume outstanding and unexercised warrants and options to purchase shares of Ocugen capital stock, and in connection with the merger they will be converted into warrants and options, as applicable, to purchase shares of Histogenics common stock. At the Effective Time, Histogenics’ stockholders will continue to own and hold their existing shares of Histogenics common stock, and all outstanding and unexercised warrants to purchase shares of Histogenics common stock will remain in effect pursuant to their terms. As of immediately prior to the Effective Time, all outstanding and unexercised options to purchase shares of Histogenics common stock will be cancelled and have no further force and effect. In connection with the merger, on June 13, 2019, Ocugen and Histogenics entered into a securities purchase agreement, as amended (the “Securities Purchase Agreement”), with certain accredited investors (the “Investors”) pursuant to which, among other things, Ocugen agreed to issue to the Investors shares of Ocugen common stock immediately prior to the merger and Histogenics agreed to issue to the Investors warrants to purchase shares of Histogenics common stock on the fifth trading day following the consummation of the merger (the “Investor Warrants”) in a private placement transaction for an aggregate purchase price of approximately \$25.0 million (subject to setoff for amounts outstanding of approximately \$5.29 million under certain senior secured notes previously issued or to be issued prior to consummation of the merger to certain of the Investors by Ocugen) (the “Pre-Merger Financing”). Immediately after the merger, after giving effect to the Pre-Merger Financing and based on the exchange ratio of 28.7650, current holders of Ocugen’s capital stock and options and warrants to purchase shares of Ocugen common stock, are expected to own, or hold rights to acquire, in the aggregate approximately 86.24% of the fully-diluted common stock of Histogenics, which for these purposes is defined as the outstanding common stock of Histogenics plus Series A Convertible Preferred Stock and outstanding warrants of Histogenics excluding the Investor Warrants (the “Fully-Diluted Common Stock of Histogenics”), and Histogenics’ current stockholders and warrantholders are expected to own, or hold rights to acquire, in the aggregate approximately 13.76% of the Fully-Diluted Common Stock of Histogenics.

The closing of the merger is subject to satisfaction or waiver of certain conditions including, among other things, (i) the required approvals by the parties’ stockholders, (ii) the accuracy of the representations and warranties, subject to certain materiality qualifications, (iii) compliance by the parties with their respective covenants, (iv) no law or order preventing the merger and related transactions, and (v) the listing of the shares to be issued in the merger on The Nasdaq Capital Market.

The Merger Agreement contains certain termination rights for both Histogenics and Ocugen, and further provides that, upon termination of the Merger Agreement under specified circumstances, Histogenics may be required to pay to Ocugen a termination fee of \$600,000 or Ocugen may be required to pay to Histogenics a termination fee of \$700,000, and in other circumstances each party may be required to reimburse the other party’s expenses incurred, up to a maximum of \$300,000.

Note 2 – Basis of Presentation

The unaudited pro forma condensed combined financial information was prepared assuming the transaction will be accounted for as an equity transaction. This unaudited pro forma condensed combined financial information

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gives effect to certain other transactions after March 31, 2019, such as the financing agreements, including senior secured convertible notes, warrants to purchase common stock, and conversion of convertible notes entered into prior to March 31, 2019.

The merger is expected to be treated as an equity transaction. To determine the accounting for this transaction under U. S. GAAP, a company must assess whether an integrated set of assets and activities should be accounted for as an acquisition of a business, asset acquisition or an equity transaction. The transaction between Ocugen and Histogenics represents an equity transaction rather than a business combination under ASC 805. Therefore, no goodwill or intangible assets will be recognized as a result of the transaction. The transaction has been determined to be an equity transaction where in substance Ocugen is exchanging equity for the net monetary assets of Histogenics.

### Note 3 – Pro Forma Adjustments

- (a) On May 8, 2019, Histogenics entered into an asset purchase agreement with Medavate Corp., a Colorado corporation (the “Asset Purchase Agreement”), pursuant to which Histogenics agreed to sell substantially all of its assets relating to its NeoCart program, including, without limitation, intellectual property, business and license agreements and clinical trial data (the “Assets”) in return for a cash payment of \$6.5 million. The closing of the sale of the Assets is subject to and conditioned upon the consummation of the planned merger with Ocugen.

The expenses related to the NeoCart program are eliminated from the unaudited pro forma condensed combined statement of operations as follows (in thousands):

	Year ended December 31, 2018	Three months ended March 31, 2019
Research and development	\$ 15,634	\$ 1,583
General and administrative	1,194	
Total operating expenses	<u>\$ 16,828</u>	<u>\$ 1,583</u>

- (b) Reflects Histogenics purchase price adjustments, including the removal of the lease liability and related right of use asset resulting from termination of the leases.
- (c) Reflects an increase in accrued expenses of \$1.4 million for estimated transaction costs incurred by Histogenics subsequent to March 31, 2019.
- (d) In December 2017, Histogenics entered into a License and Commercialization Agreement (the “License Agreement”) with MEDINET Co., Ltd. (“MEDINET”) to grant MEDINET a license under certain patents, patent applications, know-how, and technology to develop and commercialize certain therapeutic products to replace or repair damaged, worn, or defective cartilage in humans and non-human animals.

In exchange for the license, MEDINET agreed to pay Histogenics an upfront cash payment of \$10.0 million which Histogenics received in January 2018. As of March 31, 2019, the contract with MEDINET was wholly unperformed and all revenue under the License Agreement has been deferred and has not been recognized. As of March 31, 2019, the aggregate amount of the transaction price allocated to remaining performance obligations was \$10.0 million. Because the License Agreement was not terminated as of March 31, 2019, the authoritative accounting literature requires that the \$10.0 million of deferred revenue remain a liability on Histogenics’ balance sheet. The License Agreement with MEDINET and the related rights and obligations will be included in the sale of the Assets pursuant to the Asset Purchase Agreement upon the closing of the merger with Ocugen and the \$10.0 million in deferred revenue will be eliminated as part of the purchase accounting adjustments related to the merger.

As described in footnote (a), the associated asset will be sold and the related obligations will be assumed by the purchaser of the asset.

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- (e) To eliminate historical equity of Histogenics. Also, the Histogenics pro forma adjustment to additional paid-in capital reflects part of the adjustment related to purchase price allocation as follows (in thousands):

Additional paid-in capital	\$(219,874)
Part of equity transaction considerations*	6,272
Pro forma Adjustment to Additional paid-in capital	<u>\$(213,602)</u>

- \* Total transaction consideration of \$11.8 million consists of net monetary assets acquired in the equity transaction. A portion of this amount is included in common stock and the remaining amount is included in additional paid-in capital.

The transaction consideration of \$11.8 million was determined as follows (in thousands):

Cash and cash equivalents	\$13,876
Property and equipment, net	135
Restricted cash	137
Total identifiable assets acquired	<u>14,148</u>
Accounts payable and accrued expenses	2,334
Total liabilities assumed	<u>2,334</u>
<b>Net identifiable assets acquired</b>	<b><u>\$ 11,814</u></b>

From \$11.8 million, \$5.5 million was allocated to common stock to arrive at the ending par value of common stock of \$6,895 noted in footnote (k) in whole numbers as follows (in thousands):

Historical Common Stock of Ocugen	\$ 10
Pro forma adjustments for Ocugen	<u>1,343</u>
Total Par value of Ocugen Common Stock	1,353
Amount allocated to Histogenics common stock pro forma adjustment*	<u>5,542</u>
<b>Par value of total shares outstanding</b>	<b><u>\$6,895</u></b>

- \* includes \$839 in value related to historical common stock of Histogenics. The amount allocated to Histogenics pro forma common stock adjustment reflects a difference between the par value of Ocugen common stock (\$1,353) and par value of the ending common stock expected to be issued upon consummation of the merger (\$6,895). The remaining amount of \$6,272 is allocated to additional paid-in capital.

- (f) Ocugen and Histogenics entered into the Pre-Merger Financing in June 2019 with the Investors for an equity financing of \$25.0 million. The Pre-Merger Financing includes shares of Ocugen common stock and Series A, Series B and Series C warrants to purchase Histogenics common stock. The Series A warrants are classified as equity with 5 year terms, the Series B warrants are classified as liability with 45 day terms and an estimated fair value of \$6.2 million, and the Series C warrants are classified as equity with 1 year terms.

As described in footnote (g), a financial advisor agreed to invest \$2.5 million in Ocugen. This financial advisor also provided services to Ocugen for the same amount. Subsequently, Ocugen and the financial advisor reached an agreement to provide an option to the financial advisor to accept the outstanding amount in equity. As such, the outstanding amount will likely not be paid in cash. Consequently, \$2.5 million is not included in overall expected equity financing of \$25.0 million. It is possible that the financial advisor will elect to provide cash related to its commitment under the equity financing agreement, however, this is not considered likely.

Additional paid-in capital also increased by \$14.9 million due to the expected issuance of 131,578,934 (\$1,316.0 common stock at par value in thousands) shares of Histogenics common stock as a result of the

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Pre-Merger Financing based on the merger exchange ratio of 28.7650, subject to adjustment for a reverse stock split of Histogenics to be implemented prior to the consummation of the merger.

- (g) Ocugen obtained a bridge loan of \$4.6 million from certain investors in the Pre-Merger Financing, and is obligated to repay as an offset to the proceeds of the Pre-Merger Financing a total of \$5.29 million of senior secured convertible notes previously issued or to be issued prior to the consummation of the merger. Ocugen is required to repay the notes upon the earliest to occur of: (i) the closing of any fundamental transaction, (ii) the Public Company Date (as defined in the notes), (iii) the date of deemed repayment pursuant to the Pre-Merger Financing, and (iv) September 20, 2019. Note that this loan does not have a stated interest rate, and the notes are issued with an original issue discount of \$0.69 million (total amount due under this loan is \$5.29 million and proceeds received of \$4.6 million). This activity resulted in net impact of \$0.69 million on accumulated deficit. Also, the senior secured notes are also convertible into equity, however, equity conversion is not reflected as it is not considered likely.

The merger and Pre-Merger Financing also resulted in the issuance to Ocugen's financial advisor of 160,974 (\$1.0 common stock at par value in thousands) shares of Ocugen common stock in June 2019 (valued at \$5.95 per share, or \$0.96 million) and will result in the payment at the consummation of the merger and Pre-Merger Financing of \$3.5 million in fees to Ocugen's financial advisor, which has agreed to invest \$2.5 million (\$2.0 common stock at par value of common stock in thousands) in the Pre-Merger Financing. Consequently, the cash amount payable to Ocugen's financial advisor upon consummation of the merger is expected to be \$1.0 million (\$0.5 million each for the merger and the Pre-Merger Financing). These fees resulted in an increase in accrued expenses and decrease in additional paid-in capital totaling \$1.0 million.

- (h) Subsequent to March 31, 2019, Ocugen raised \$1.9 million as detailed below:

1. In April 2019, Ocugen entered into a subscription agreement with existing investors for the sale of 168,068 (\$1.0 common stock at par value in thousands) shares of common stock for \$1.0 million.
2. In April 2019, Ocugen issued a convertible note in the amount of \$0.9 million, which was converted into equity (152,521 shares with \$1.0 par value of common stock in thousands) on May 16, 2019 upon agreement between Ocugen and the other party.

These transactions resulted in a \$1.9 million increase in additional paid-in capital.

- (i) Reflects an increase in accrued expenses of \$0.60 million for estimated transaction costs incurred by Ocugen subsequent to March 31, 2019. These transaction expenses also resulted in a decrease to equity for the same amount.
- (j) On April 4, 2019, convertible notes dated January 2018, June 2018, November 2018, December 2018, January 2019, and February 2019 were converted in accordance with the terms of the convertible notes agreements. As a result of this conversion, Ocugen issued 2,195,157 shares of common stock on the date of conversion, which resulted in a gain of \$2.97 million. As a result of this conversion, additional paid-in capital increased and short-term debt, net decreased by \$9.0 million.

Also, in accordance with ASC 815-15, Embedded Derivatives, there were embedded derivatives identified related to the convertible notes at inception. As a result of the conversion to equity, fair values of embedded derivatives totaling \$3.003 million were removed at the carrying value in connection with the extinguishment accounting.

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The determination of share detail below assumes the issuance of 83% of the common stock of the combined company to Ocugen equityholders and 17% of the common stock to be held by the pre-merger Histogenics equityholders, in each case prior to the Pre-Merger Financing.

	<u>Number of Shares</u>	<u>Par Value</u>
Histogenics outstanding shares	94,839,908	\$ 948,399
Shares issued to Ocugen stockholders	463,041,711	4,630,417
Shares issued to the Investors*	131,578,934	1,315,789
	<u>689,460,553</u>	<u>\$6,894,606</u>

\* Based on variable factors, there is a potential issuance of additional shares to the Investors up to an additional 131,578,934 shares within three to four days post closing of the transaction. The issuance of such shares, due to its variable nature, has not been included in the loss per share calculation.

**(l)** The table below reflects reconciliation of various amounts included in the unaudited pro forma condensed combined balance sheet (in thousands):

<u>Footnote Reference</u>	<u>Additional paid-in capital</u>	<u>Common stock</u>
(g)	\$ (1,003)	\$ 3
(f)	14,984	1,316
(i)	(600)	—
(j)	9,053	22
(h)	1,898	2
	<u>\$ 24,332</u>	<u>\$ 1,343</u>

**(m)** The mark-to-market adjustments related to the warrant liability of \$6.2 million within the Unaudited Pro Forma Condensed Combined Balance Sheet as of March 31, 2019 have not been reflected in the pro forma condensed statement of operations.

**(n)** Removal of the debt discount amortization and related interest expense for convertible notes, see footnote (j).

**(o)** Reflects the elimination of a total of \$0.3 million in transaction related costs incurred (\$0.2 million incurred by Histogenics and \$0.1 million incurred by Ocugen) during the three months ended March 31, 2019 as these are non-recurring in nature.

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**Histogenics Corporation**  
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HSGX K-1



## Report of Independent Registered Public Accounting Firm

Board of Directors and Shareholders  
Histogenics Corporation

Opinion on the financial statements

We have audited the accompanying consolidated balance sheets of Histogenics Corporation (a Delaware corporation) and subsidiaries (the "Company") as of December 31, 2018 and 2017, the related consolidated statements of operations, convertible preferred stock and stockholders' equity (deficit), and cash flows for each of the two years in the period ended December 31, 2018, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2018 and 2017, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2018, in conformity with accounting principles generally accepted in the United States of America.

Going concern

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company has incurred net losses from inception, including a net loss of approximately \$8.6 million during the year ended December 31, 2018, and as of that date, its total liabilities exceeded its total assets by approximately \$458,000. These conditions, along with other matters as set forth in Note 1, raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ GRANT THORNTON LLP

We have served as the Company's auditor since 2012

Hartford, Connecticut  
March 21, 2019

HSGX K-2

**Histogenics Corporation**  
**Consolidated Balance Sheets**  
**(In thousands, except share and per share data)**

	<u>December 31,</u>	
	<u>2018</u>	<u>2017</u>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 15,542	\$ 7,081
Marketable securities	—	900
Prepaid expenses and other current assets	858	194
Total current assets	<u>16,400</u>	<u>8,175</u>
Property and equipment, net	141	2,723
Other assets	750	—
Restricted cash	137	137
Total assets	<u>\$ 17,428</u>	<u>\$ 11,035</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)</b>		
Current liabilities:		
Accounts payable	\$ 1,590	\$ 776
Accrued expenses	1,000	2,705
Current portion of deferred rent	45	35
Current portion of deferred lease incentive	238	111
Current portion of equipment loan	—	178
Total current liabilities	<u>2,873</u>	<u>3,805</u>
Accrued expenses due to Intrexon Corporation	1,125	3,040
Deferred revenue	10,000	—
Deferred rent	351	280
Deferred lease incentive	1,025	499
Warrant liability	2,512	14,679
Total liabilities	<u>17,886</u>	<u>22,303</u>
Commitments and contingencies (Note 7)		
Convertible preferred stock and stockholders' equity (deficit):		
Convertible preferred stock, \$0.01 par value; 30,000 shares authorized, 400.4910 and 4,605.6533 shares issued and outstanding at December 31, 2018 and 2017, respectively	—	—
Common stock, \$0.01 par value; 100,000,000 shares authorized, 62,025,398 and 24,571,029 shares issued and outstanding at December 31, 2018 and 2017, respectively	513	159
Additional paid-in capital	215,859	196,760
Accumulated deficit	(216,830)	(208,187)
Total stockholders' equity (deficit)	<u>(458)</u>	<u>(11,268)</u>
Total liabilities and stockholders' equity (deficit)	<u>\$ 17,428</u>	<u>\$ 11,035</u>

The accompanying notes are an integral part of these consolidated financial statements.

**Histogenics Corporation**  
**Consolidated Statements of Operations**  
**(In thousands, except share and per share data)**

	<b>Year Ended December 31,</b>	
	<b>2018</b>	<b>2017</b>
Revenue	\$ —	\$ —
Operating expenses:		
Research and development	15,634	15,566
General and administrative	10,204	9,384
Loss due to asset impairment	4,270	—
Total operating expenses	<u>30,108</u>	<u>24,950</u>
Loss from operations	(30,108)	(24,950)
Other income (expense):		
Interest income (expense), net	163	134
Other income (expense), net	(106)	(116)
Gain due to extinguishment of liability	1,540	—
Warrant expense	(733)	—
Change in fair value of warrant liability	20,601	(1,482)
Total other income (expense), net	<u>21,465</u>	<u>(1,464)</u>
Net loss	<u>\$ (8,643)</u>	<u>\$ (26,414)</u>
Loss attributable to common stockholders—basic	\$ (8,522)	\$ (22,499)
Loss attributable to common stockholders—diluted	\$ (29,123)	\$ (22,499)
Loss per common share—basic	\$ (0.23)	\$ (0.99)
Loss per common share—diluted	\$ (0.79)	\$ (0.99)
Weighted-average shares used to compute loss per common share—basic	<u>36,398,450</u>	<u>22,669,819</u>
Weighted-average shares used to compute loss per common share—diluted	<u>37,090,197</u>	<u>22,669,819</u>

The accompanying notes are an integral part of these consolidated financial statements.

## Histogenics Corporation

### Consolidated Statements of Convertible Preferred Stock and Stockholders' Equity (Deficit) (In thousands, except share and per share data)

	Series A Convertible Preferred Stock \$0.01 Par Value		Common Stock \$0.01 Par Value		Restricted Stock \$0.01 Par Value		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders Equity (Deficit)
	Shares	Amount	Shares	Amount	Shares	Amount			
Balance at December 31, 2016	13,416	\$ —	20,645,723	\$ 159	1,889	\$ —	\$ 195,181	\$ (181,773)	\$ 13,567
Stock-based compensation expense	—	—	—	—	—	—	1,573	—	1,573
Exercise of common stock options	—	—	7,497	—	—	—	6	—	6
Vesting of restricted stock	—	—	1,889	—	(1,889)	—	—	—	—
Conversion of Series A convertible preferred stock	(8,811)	—	3,915,920	—	—	—	—	—	—
Net loss	—	—	—	—	—	—	—	(26,414)	(26,414)
Balance at December 31, 2017	<u>4,605</u>	<u>\$ —</u>	<u>24,571,029</u>	<u>\$ 159</u>	<u>—</u>	<u>\$ —</u>	<u>\$ 196,760</u>	<u>\$ (208,187)</u>	<u>\$ (11,268)</u>
Stock-based compensation expense	—	—	—	—	—	—	1,625	—	1,625
Exercise of common stock options	—	—	919	—	—	—	2	—	2
Exercise of warrants	—	—	104,092	—	—	—	1	—	1
Issuance of common stock, net	—	—	35,480,397	354	—	—	17,471	—	17,825
Conversion of Series A convertible preferred stock	(4,205)	—	1,868,961	—	—	—	—	—	—
Net loss	—	—	—	—	—	—	—	(8,643)	(8,643)
Balance at December 31, 2018	<u>400</u>	<u>\$ —</u>	<u>62,025,398</u>	<u>\$ 513</u>	<u>—</u>	<u>\$ —</u>	<u>\$ 215,859</u>	<u>\$ (216,830)</u>	<u>\$ (458)</u>

The accompanying notes are an integral part of these consolidated financial statements.

**Histogenics Corporation**  
**Consolidated Statements of Cash Flows**  
**(In thousands, except share and per share data)**

	<u>Year Ended December 31,</u>	
	<u>2018</u>	<u>2017</u>
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>		
Net loss	\$ (8,643)	\$ (26,414)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	450	1,534
Amortization of discount of investments	—	54
Deferred revenue	10,000	—
Deferred rent and lease incentive	734	(543)
Stock-based compensation	1,625	1,573
Warrant expense	733	—
Change in warrant liability	(20,601)	1,482
Loss due to asset impairment	4,270	—
Gain on extinguishment of liability due to Intrexon Corporation	(1,540)	—
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(664)	(21)
Other long term assets	(750)	—
Accounts payable	689	(849)
Accounts payable due to Intrexon Corporation	—	(360)
Accrued expenses due to Intrexon Corporation	(375)	—
Accrued expenses	(1,705)	524
Net cash used in operating activities	<u>(15,777)</u>	<u>(23,020)</u>
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>		
Purchases of property and equipment	(2,013)	(276)
Proceeds from maturities of marketable securities	900	7,050
Purchases of marketable securities	—	(8,004)
Net cash used in investing activities	<u>(1,113)</u>	<u>(1,230)</u>
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>		
Proceeds from issuance of common stock, net of issuance costs	25,526	—
Repayments on equipment term loan	(178)	(583)
Proceeds from exercise of stock options and warrants	3	6
Net cash provided by (used in) financing activities	<u>25,351</u>	<u>(577)</u>
Net increase (decrease) in cash and cash equivalents	8,461	(24,827)
Cash and cash equivalents and restricted cash—Beginning of period	7,218	32,045
Cash and cash equivalents and restricted cash—End of period	<u>\$ 15,679</u>	<u>\$ 7,218</u>
Supplemental Disclosure of Non-Cash Items:		
Purchases of property and equipment in accounts payable	\$ 125	\$ —
Public offering costs in accounts payable	\$ 99	\$ —
Supplemental Disclosure of Cash Flow information:		
Cash paid for taxes	\$ 105	\$ 197
Cash paid for interest	\$ 1	\$ 30

The accompanying notes are an integral part of these consolidated financial statements.

**Histogenics Corporation**  
**Notes to Consolidated Financial Statements**

**1. NATURE OF BUSINESS**

**Organization**

Histogenics Corporation (the “Company”) was incorporated under the laws of the Commonwealth of Massachusetts on June 28, 2000 and has its principal operations in Waltham, Massachusetts. In 2006, the Company’s board of directors approved a corporate reorganization pursuant to which the Company incorporated as a Delaware corporation. The Company historically focused on the development of restorative cell therapies (RCTs). RCTs refer to a new class of products that are designed to offer patients rapid-onset pain relief and restored function through the repair of damaged or worn tissue. The Company’s lead product, NeoCart<sup>®</sup>, is an innovative cell therapy designed to treat tissue injury in the field of orthopedics, specifically cartilage damage in the knee. In the third quarter of 2018, the Company announced that its Phase 3 clinical trial of NeoCart did not meet the primary endpoint in the Phase 3 clinical trial. Histogenics subsequently initiated a dialogue with the United States Food and Drug Administration (FDA) to discuss the regulatory path forward for NeoCart with a goal of determining whether the FDA would accept a submission of a Biologics License Application (BLA) for NeoCart without data from an additional Phase 3 clinical trial. In December 2018, the Company received final feedback from the FDA indicating the need for an additional Phase 3 clinical trial prior to the FDA’s acceptance of a NeoCart BLA submission. However, considering the time and funding required to conduct such a trial, the Company discontinued the development of NeoCart and is not planning to submit a BLA. In addition, the Company initiated a process to evaluate strategic alternatives to maximize value for all of its stakeholders. The process is being conducted with the assistance of financial and legal advisors and is evaluating the full range of potential strategic alternatives, including but not limited to, acquisitions, business combinations, joint ventures, public and private capital raises and recapitalization and sale transaction options, including a sale of assets or intellectual property. Since these efforts may not be successful and given our limited cash reserves, we are also considering other possible alternatives, including a wind-down of operations, or Chapter 11 bankruptcy protection to complete or execute a restructuring transaction or liquidation.

On May 13, 2011, the Company completed the acquisition of ProChon Biotech Ltd. (“ProChon”), a privately-held biotechnology company focused on modulating the fibroblast growth factor system for consideration of \$2.2 million to enable it to create more effective solutions for tissue regeneration. ProChon’s products combine cell regeneration technologies with proprietary growth factors and biocompatible scaffolds to restore injured or chronically damaged tissues. The acquisition led to the initial recognition of goodwill, which was subsequently written off in 2011, and intangible assets including IPR&D and a licensing agreement which were fully impaired in 2016 as discussed in Note 2.

On September 29, 2016, the Company closed a private placement of common stock, preferred stock and warrants, contemplated by a securities purchase agreement dated September 15, 2016, with certain institutional and accredited investors. The net proceeds after deducting placement agent fees and other transaction-related expenses were \$27.6 million. See Note 8, Capital Stock, for further discussion of the private placement.

In January 2018, the Company closed a registered direct offering where the Company issued 2,691,494 shares of common stock at a price of \$2.35 per share. The underwriter option to purchase additional shares of 351,064 were fully exercised. The total net proceeds of the offering were approximately \$5.9 million after deducting underwriting discounts and commissions.

In March 2018, the Company entered into an equity distribution agreement (“ATM Agreement”) with Canaccord Genuity Inc. (“Canaccord”), pursuant to which the Company may, from time to time, sell shares of its common stock having an aggregate offering price of up to \$10.0 million (the “Shares”) through Canaccord, as sales agent. During the year ended December 31, 2018, the Company sold an aggregate of 6,633,903 shares of common stock and received \$4.5 million after deducting commissions related to the ATM Agreement and other offering costs.

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In October 2018, the Company closed an underwritten public offering of 26,155,000 shares of its common stock and warrants to purchase up to 19,616,250 shares of common stock, at a combined purchase price of \$0.65 per share of common stock and accompanying warrant. The gross proceeds to Histogenics from this offering were \$17.0 million, before deducting underwriting discounts and commissions, and offering expenses payable by the Company. The warrants are exercisable immediately upon issuance at a price of \$0.70 per share of common stock and have a term of five years commencing on the date of issuance.

Since its inception, the Company has devoted substantially all of its efforts to product development, recruiting management and technical staff, raising capital, starting up production and building infrastructure and has not yet generated product revenues. Expenses have primarily been for research and development and related administrative costs.

The Company is subject to a number of risks including the successful development of therapeutics, the ability to obtain adequate financing, the ability to obtain FDA approval and reimbursement for any products we may develop, protection of intellectual property, fluctuations in operating results, dependence on key personnel and collaborative partners, rapid technological changes inherent in the target markets of any products the Company may develop, the introduction of substitute products and competition from larger companies.

### **Liquidity**

The consolidated financial statements have been prepared on a going-concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. As shown in the accompanying consolidated financial statements, the Company has incurred losses and cash flow deficits from operations since inception, resulting in an accumulated deficit at December 31, 2018 of \$216.8 million. The Company has financed operations to date primarily through public and private placements of equity securities, and borrowings under debt agreements. The Company anticipates that it will continue to incur net losses for the foreseeable future. The Company believes that its existing cash, cash equivalents and marketable securities will only be sufficient to fund its projected cash needs into the middle of 2019. Accordingly, these factors, among others, raise substantial doubt about the Company's ability to continue as a going concern. To meet future capital needs, the Company would need to raise additional capital through debt or equity financing or other strategic transactions. However, any such financing may not be on favorable terms or available to the Company. The failure of the Company to obtain sufficient funds on commercially acceptable terms when needed will have a material adverse effect on the Company's business, results of operations and financial condition. The forecast of cash resources is forward-looking information that involves risks and uncertainties, and the actual amount of our expenses could vary materially and adversely as a result of a number of factors. The Company has based its estimates on assumptions that may prove to be wrong, and the Company's expenses could prove to be significantly higher than it currently anticipates.

## **2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

### **Basis of Accounting**

The consolidated financial statements are prepared in conformity with accounting principles generally accepted in the United States of America ("U.S. GAAP"). The consolidated financial statements include the accounts of Histogenics Corporation and its wholly-owned subsidiaries, ProChon and Histogenics Securities Corporation. All significant intercompany accounts and transactions are eliminated in consolidation.

### **Use of Estimates**

The preparation of the Company's consolidated financial statements requires it to make estimates and assumptions that impact the reported amounts of assets, liabilities, revenues and expenses and the disclosure of contingent assets and liabilities in the Company's consolidated financial statements and accompanying notes.

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The most significant estimates in the Company's consolidated financial statements relate to the valuation of equity awards, warrant liability, recoverability of deferred tax assets, estimated useful lives of fixed assets. The Company bases estimates and assumptions on historical experience when available and on various factors that it believes to be reasonable under the circumstances. The Company evaluates its estimates and assumptions on an ongoing basis. The Company recorded in 2018 a loss on impairment of fixed assets. See Note 5 Property and Equipment. The Company's actual results may differ from these estimates under different assumptions or conditions.

### **Foreign Currency Translation**

The Company's consolidated financial statements are prepared in U.S. dollars. The Company's foreign subsidiary uses the U.S. dollar as its functional and reporting currency, as management determined that the U.S. dollar is the primary currency of the economic environment in which the subsidiary operates. When transactions are required to be paid in the local currency of the foreign subsidiary, any resulting foreign currency transaction gain or loss is recorded as a component of "Other income (expense), net" in the consolidated statements of operations.

### **Segment and Geographic Information**

Operating segments are defined as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision-maker ("CODM") or decision-making group in making decisions regarding resource allocation and assessing performance. The Company operates in two geographic regions: the United States (Massachusetts) and Israel (Tel Aviv) and views its operations as two operating segments: Histogenics Corporation (United States) and ProChon (Israel) as the CODM reviews separate discrete financial information in making decisions regarding resource allocations and assessing performance. Operating segments that have similar economic characteristics can be aggregated. As the nature of the products, customers, and methods to distribute products are the same and the nature of the regulatory environment, the production processes and historical and estimated future margins are similar, the two operating segments have been aggregated into one reporting segment as they have similar economic characteristics.

### **Fair Value Measurements**

The carrying amounts reported in the Company's consolidated financial statements for cash and cash equivalents, accounts payable, equipment loan, and accrued liabilities approximate their respective fair values because of the short-term nature of these accounts.

Fair value is defined as the price that would be received if selling an asset or paid to transfer a liability in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date.

Fair value should be based on the assumptions that market participants would use when pricing an asset or liability and is based on a fair value hierarchy that prioritizes the information used to develop those assumptions. Fair value measurements should be disclosed separately by level within the fair value hierarchy. For assets and liabilities recorded at fair value, it is the Company's policy to maximize the use of observable inputs (quoted prices in active markets) and minimize the use of unobservable inputs (Company assumptions) when developing fair value measurements, in accordance with established fair value hierarchy.

Fair value measurements for assets and liabilities where there exists limited or no observable market data are based primarily upon estimates, and often are calculated based on the economic and competitive environment, the characteristics of the asset or liability and other factors. Therefore, the results cannot be determined with precision and may not be realized in an actual sale or immediate settlement of the asset or liability. Additionally, there may be inherent weaknesses in any valuation technique, and changes in the underlying assumptions used, including discount rates and estimates of future cash flows, could significantly affect the results of current or future values.



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Additionally, from time to time, the Company may be required to record at fair value other assets on a nonrecurring basis, such as assets held for sale and certain other assets. These nonrecurring fair value adjustments typically involve application of lower-of-cost-or-market accounting or write-downs of individual assets.

The fair value hierarchy gives the highest priority to unadjusted quoted prices in active markets for identical assets (Level 1), and the lowest priority to unobservable inputs (Level 3). The Company's financial assets are classified within the fair value hierarchy based on the lowest level of inputs that is significant to the fair value measurement. The three levels of the fair value hierarchy, and its applicability to the Company's financial assets, are described below.

*Level 1:* Unadjusted quoted prices in active markets that are accessible at the measurement date of identical, unrestricted assets.

*Level 2:* Quoted prices for similar assets, or inputs that are observable, either directly or indirectly, for substantially the full term through corroboration with observable market data. Level 2 includes investments valued at quoted prices adjusted for legal or contractual restrictions specific to the security.

*Level 3:* Pricing inputs are unobservable for the assets, that is, inputs that reflect the reporting entity's own assumptions about the assumptions market participants would use in pricing the assets. Level 3 includes private investments that are supported by little or no market activity.

Level 3 valuations are for instruments that are not traded in active markets or are subject to transfer restrictions and may be adjusted to reflect illiquidity and/or non-transferability, with such adjustment generally based on available market evidence. In the absence of such evidence, management's best estimate is used.

An adjustment to the pricing method used within either Level 1 or Level 2 inputs could generate a fair value measurement that effectively falls in a lower level in the hierarchy. The Company had no assets or liabilities classified as Level 1 or Level 2 as of December 31, 2018 and 2017 other than the money market fund described in the "Cash and Cash Equivalents" section and the asset-backed securities in the "Marketable securities" section below. There were no material re-measurements of fair value with respect to financial assets and liabilities, during the periods presented, other than those assets and liabilities that are measured at fair value on a recurring basis. The Company's only assets or liabilities classified as level 3 are the warrants issued in connection with the September 2016 private placement and the October 2018 underwritten public offering. There were no transfers between Levels 1, 2 and 3 during the twelve months ended December 31, 2018 and 2017.

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The fair value of the warrants issued in connection with the September 2016 private placement was determined using a Monte Carlo simulation model. This model incorporated several assumptions at each valuation date including: the price of the Company's common stock on the date of valuation, the historical volatility of the price of the Company's common stock, the remaining contractual term of the warrant and estimates of the probability of a fundamental transaction occurring. The fair value of the warrants issued in connection with the October 2018 underwritten public offering was determined using the Black Scholes model. See Note 8, Capital Stock, for further discussion of the private placement and underwritten public offering.

<u>Description</u>	<u>Total</u>	<u>Quoted prices in active markets (Level 1)</u>	<u>Significant other observable inputs (Level 2)</u>	<u>Significant unobservable inputs (Level 3)</u>
(in thousands)				
<b>December 31, 2018</b>				
<b>Assets:</b>				
Cash Equivalents				
Money market funds	9,711	9,711	—	—
<b>Liabilities:</b>				
Warrant liability	2,512	—	—	2,512
<b>December 31, 2017</b>				
<b>Assets:</b>				
Cash Equivalents				
Money market funds	5,547	5,547	—	—
Marketable securities:				
Asset-backed securities	900	—	900	—
<b>Liabilities:</b>				
Warrant liability	14,679	—	—	14,679

The following table provides a reconciliation of all liabilities measured at fair value using Level 3 significant unobservable inputs:

	<u>As of December 31, 2018</u>
	(in thousands)
Beginning balance, January 1, 2018	\$ 14,679
Issuance of warrants	8,434
Change in fair value of warrant liability	(20,601)
Ending balance	<u>\$ 2,512</u>

### **Cash and Cash Equivalents**

Cash and cash equivalents include cash in readily available checking and savings accounts and money market funds. The Company considers all highly liquid investments with an original maturity of three months or less from the date of purchase to be cash equivalents.

### **Marketable Securities**

The Company classifies marketable securities with a remaining maturity when purchased of greater than three months as available for sale. The Company considers all available for sale securities, including those with maturity dates beyond 12 months, as available to support current operational liquidity needs and therefore classifies all securities including those with maturity dates beyond 90 days at the date of purchase as current assets within the consolidated balance sheets. Available for sale securities are maintained by the Company's

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investment managers and may consist of commercial paper, high-grade corporate notes, U.S. Treasury securities, U.S. government agency securities, and certificates of deposit. Available for sale securities are carried at fair value with the unrealized gains and losses included in other comprehensive income (loss) as a component of stockholders' equity (deficit) until realized. Any premium or discount arising at purchase is amortized and/or accreted to interest income and/or expense over the life of the instrument. Realized gains and losses are determined using the specific identification method and are included in other income (expense).

If any adjustment to fair value reflects a decline in value of the investment, the Company considers all available evidence to evaluate the extent to which the decline is "other-than-temporary" and, if so, marks the investment to market through a charge to the Company's consolidated statement of operations and comprehensive loss.

The Company did not hold any available for sale securities prior to the first quarter of 2017. The amortized cost of available for sale securities is adjusted for amortization of premiums and accretion of discounts to maturity. At December 31, 2018, the balance in the Company's accumulated other comprehensive loss was composed solely of activity related to the Company's available for sale marketable securities.

The aggregate fair value of available for sale securities held by the Company for less than twelve months as of December 31, 2017 was \$0.9 million which matured in 2018. The Company did not hold any available for sale securities and there were no sales of such during the year ended December 31, 2018. The Company determined that there was no material change in the credit risk of any of its investments. As a result, the Company determined it did not hold any investments with any other-than-temporary impairment as of December 31, 2017. The weighted average maturity of the Company's portfolio was less than one month at December 31, 2017.

### **Concentration of Credit Risk**

Financial instruments, which potentially subject the Company to significant concentration of credit risk, consist primarily of cash and cash equivalents. The Company maintains deposits in federally insured financial institutions in excess of federally insured limits. The Company has not experienced any losses in such accounts and management believes that the Company is not exposed to significant credit risk due to the financial position of the depository institutions in which those deposits are held. The Company has no financial instruments with off-balance sheet risk of loss.

### **Property and Equipment**

Property and equipment are recorded at historical cost. Costs for capital assets not yet placed into service are capitalized as construction in progress, and are depreciated in accordance with the below guidelines once placed into service. Maintenance and repair costs are expensed as incurred. Costs which materially improve or extend the lives of existing assets are capitalized. The Company provides for depreciation and amortization using the straight-line method over the estimated useful lives of the assets, which are as follows:

<u>Asset Category</u>	<u>Estimated Useful Lives</u>
Office equipment	3 to 5 years
Laboratory equipment	3 to 5 years
Leasehold improvements	Shorter of the remaining lease term or useful life

Upon retirement or sale, the cost of assets disposed and the related accumulated depreciation are removed from the accounts and any resulting gain or loss is recorded in the consolidated statements of operations.

### **Impairment of Long-Lived Assets**

Long-lived assets consist primarily of property and equipment and identifiable intangible assets. When impairment indicators exist, the Company's management evaluates long-lived assets for potential impairment.

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An impairment loss is recorded if and when events and circumstances indicate that assets might be impaired and the undiscounted cash flows estimated to be generated by those assets are less than the carrying amount of those assets. In 2018 a triggering event caused an impairment of the Company's property and equipment. The triggering event related to the Company's announcement that the NeoCart program was discontinued and the subsequent 73% reduction in stock price. An impairment loss of \$4.3 million was recognized in earnings. See Note 5 Property and Equipment.

### **Restricted Cash**

Restricted cash represents cash held in a depository account at a financial institution to collateralize a conditional stand-by letter of credit related to the Company's Lexington, Massachusetts facility lease agreement. Restricted cash is reported as non-current unless the restrictions are expected to be released in the next twelve months.

### **Deferred Rent**

Deferred rent consists of the difference between cash payments and the recognition of rent expense on a straight-line basis for the facilities the Company occupies. The Company's leases for its Waltham, Massachusetts and Lexington, Massachusetts facilities provide for fixed increases in minimum annual rental payments. The total amount of rental payments due over each lease term is being charged to rent expense ratably over the life of each lease, respectively.

### **Financial Instruments Indexed to and Potentially Settled in the Company's Common Stock**

The Company evaluates all financial instruments issued in connection with its equity offerings when determining the proper accounting treatment for such instruments in the Company's financial statements. The Company considers a number of generally accepted accounting principles under U.S. GAAP to determine such treatment and evaluates the features of the instrument to determine the appropriate accounting treatment. The Company utilizes the Probability Weighted Expected Return Method ("PWERM"), Option Pricing Model ("OM") or other appropriate methods to determine the fair value of its derivative financial instruments, such as the warrant liability. For financial instruments indexed to and potentially settled in the Company's common stock that are determined to be classified as liabilities on the consolidated balance sheet, changes in fair value are recorded as a gain or loss in the Company's consolidated statement of operations with the corresponding amount recorded as an adjustment to the liability on its consolidated balance sheet.

### **Revenue Recognition**

In May 2014, the Financial Accounting Standards Board (the "FASB") issued a new standard related to revenue recognition, Accounting Standard Update ("ASU") No. 2014-09, Revenue from Contracts with Customers. This new accounting standard replaced most current U.S. GAAP guidance on this topic and eliminated most industry-specific guidance. It provides a unified model to determine when and how revenue is recognized. The core principle is that an entity should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration for which the entity expects to be entitled in exchange for those goods or services. Entities may adopt the new standard either retrospectively to all periods presented in the financial statements (the full retrospective method) or as a cumulative-effect adjustment as of the date of adoption (modified retrospective method) in the year of adoption without applying to comparative years' financial statements. Further, in August 2015, the FASB issued ASU No. 2015-14, Revenue from Contracts with Customers: Deferral of the Effective Date, to defer the effective adoption date by one year to December 15, 2017 for annual reporting periods beginning after that date and permitted early adoption of the standard, but not before fiscal years beginning after the original effective date of December 15, 2016. The Company elected to early adopt the guidance in 2017 using the modified retrospective method.

Revenue is recognized when, or as, performance obligations are satisfied, which occurs when control of the promised products or services is transferred to customers. Revenue is measured as the amount of consideration

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the Company expects to receive in exchange for transferring products or services to a customer (“transaction price”). To the extent that the transaction price includes variable consideration, the Company estimates the amount of variable consideration that should be included in the transaction price utilizing the most likely amount method. Variable consideration is included in the transaction price if, in the Company’s judgment, it is probable that a significant future reversal of cumulative revenue under the contract will not occur. Estimates of variable consideration and determination of whether to include estimated amounts in the transaction price are based largely on an assessment of the Company’s anticipated performance and all information (historical, current and forecasted) that is reasonably available.

If the contract contains a single performance obligation, the entire transaction price is allocated to the single performance obligation. Contracts that contain multiple performance obligations require an allocation of the transaction price to each performance obligation based on a relative standalone selling price basis unless the transaction price is variable and meets the criteria to be allocated entirely to a performance obligation or to a distinct service that forms part of a single performance obligation. The Company’s revenues are generated primarily through collaborative research, development and commercialization agreements. The terms of these agreements may contain multiple promises which may include: (i) licenses to the Company’s technology; (ii) services related to the transfer and update of know-how; and (iii) manufacturing supply services. Payments to the Company under these arrangements typically include one or more of the following: non-refundable upfront license fees; milestone payments; royalties on future product sales; and fees for manufacturing supply services. None of the Company’s contracts as of December 31, 2018 contained a significant financing component.

The Company assesses the promises to determine if they are distinct performance obligations. Once the performance obligations are determined, the transaction price is allocated based on a relative standalone selling price basis. Milestone payments and royalties are typically considered variable consideration at the outset of the contract and are recognized in the transaction price either upon occurrence or when the constraint of a probable reversal is no longer applicable.

### *Collaboration Revenue*

While no revenue has been recognized as of December 31, 2018, the Company has collaboration and license agreements with strategic partners for the development and commercialization of product candidates. The collaboration and license agreements are within the scope of Accounting Standards Codification (ASC 606) Revenue from Contracts with Customers.

In determining the appropriate amount of revenue to be recognized as it fulfills its obligations under the agreements, the Company performs the following steps: (i) identification of the promised goods or services in the contract; (ii) determination of whether the promised goods or services are performance obligations including whether they are distinct in the context of the contract; (iii) measurement of the transaction price, including the constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations; and (v) recognition of revenue when (or as) the Company satisfies each performance obligation. As part of the accounting for the arrangement, the Company must develop assumptions that require judgment to determine the stand-alone selling price for each performance obligation identified in the contract. The Company uses key assumptions to determine the stand-alone selling price, which may include market conditions, reimbursement rates for personnel costs, development timelines and probabilities of regulatory success.

*Licenses of intellectual property:* If the license to the Company’s intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, the Company recognizes revenues from non-refundable, up-front fees allocated to the license when the license is transferred to the customer and the customer is able to use and benefit from the license. For licenses that are bundled with other promises, the Company utilizes judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue from non-refundable, up-front fees. The

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Company evaluates the measure of progress each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition.

*Manufacturing Supply Services:* If the promise to supply products for clinical and/or commercial development are determined to be distinct from the other performance obligations identified in the arrangement, the Company recognizes revenues from the fees allocated to the supply when or as the supply is transferred to the customer, generally upon delivery to the customer. If the promise to supply products for clinical and/or commercial development are not determined to be distinct from the other performance obligations identified in the arrangement, the Company utilizes judgement to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue, including amounts from non-refundable, up-front fees. The Company evaluates the measure of progress each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition.

*Milestone Payments:* At the inception of each arrangement that includes developmental and regulatory milestone payments, the Company evaluates whether the achievement of each milestone specifically relates to the Company's efforts to satisfy a performance obligation or transfer a distinct good or service within a performance obligation. If the achievement of a milestone is considered a direct result of the Company's efforts to satisfy a performance obligation or transfer a distinct good or service and the receipt of the payment is based upon the achievement of the milestone, the associated milestone value is allocated to that distinct good or service and revenue is recognized in the period in which the milestone is achieved. If the milestone payment is not specifically related to the Company's effort to satisfy a performance obligation or transfer a distinct good or service, the Company evaluates the milestone to determine whether the milestone is considered probable of being reached and estimates the amount to be included in the transaction price using either the most likely amount or the expected value method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price to be allocated. At the end of each subsequent reporting period, the Company re-evaluates the probability of achievement of such development milestones and any related constraint, and if necessary, adjusts its estimate of the overall allocation. Any such adjustments are recorded on a cumulative catch-up basis, which would affect license, collaboration and other revenues and earnings in the period of adjustment.

*Royalties:* For arrangements that include sales-based or usage-based royalties, including milestone payments based on the level of sales, and the license is deemed to be the predominant item to which the royalties relate, the Company will recognize revenue at the later of: (i) when the related sales occur; or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied).

### **License and Collaboration Arrangements**

#### ***MEDINET Co., Ltd.***

In December 2017 the Company entered into the License and Commercialization Agreement (the "License Agreement") with MEDINET Co., Ltd. ("MEDINET") to grant MEDINET a license under certain patents, patent applications, know-how, and technology to develop and commercialize certain therapeutic products to replace or repair damaged, worn, or defective cartilage.

In exchange for the license, MEDINET agreed to pay the Company an non-refundable upfront cash payment of \$10.0 million which was received in January 2018. As of December 31, 2018, the contract with MEDINET was wholly unperformed. MEDINET also agreed to pay the Company tiered royalties, at percentages ranging from the low single digits to low double digits, of net sales of MEDINET products governed by the License Agreement. The Company is eligible to receive up to ¥330 million (\$3.0 million as of December 31, 2018) in development milestone payments, \$1.0 million and ¥720 million (\$6.5 million as of December 31, 2018) in regulatory payments and up to an aggregate of ¥7,100 million (\$64.3 million as of December 31, 2018) for the achievement of certain commercial milestones related to the sales of MEDINET products governed by the License Agreement.

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The Company assessed the promised goods and services to determine if they are distinct. Due to the unique nature of the clinical manufacturing services, there are no third-party vendors from which MEDINET can obtain such services from currently. The Company expects to be the only vendor capable of providing the commercial manufacturing services for a period of at least one to two years, which is approximately the estimated length of the clinical trial period in Japan. After this point, if the Company were to transfer to a third-party its technology and know-how related to the commercial manufacturing services that third-party vendor would be capable of providing the commercial manufacturing services, and therefore MEDINET would be able to choose whether to utilize the Company or another vendor for such services. The Company determined that the option to obtain commercial manufacturing services does not represent a material right, as the fees charged to MEDINET by the Company are expected to approximate the fair market value for manufacturing services. As noted, with the assistance of the Company, third-party vendors could have the capability to perform such services by this time, and the Company expects the contract value to approximate the market price. Due to MEDINET's limitations in obtaining the clinical manufacturing services from a third-party, as well as MEDINET's limited ability to obtain the benefits of the licensed intellectual property without the clinical manufacturing services, the licensed intellectual property and clinical manufacturing services are determined to be a combined performance obligation. Based on this assessment, the Company determined that the promised goods and services do not have standalone value and are highly interrelated. Accordingly, the promised goods and services represent one performance obligation.

Based on the assessment of the combined performance obligation, the Company determined that the predominant promise in the arrangement is the transfer of the license and associated knowhow which are expected to occur over the length of the clinical trial. The Company determined that MEDINET will be simultaneously receiving and consuming the benefits of the Company's performance of the clinical trial. Therefore, the revenue associated with the combined performance obligation will be recognized over time.

In determining the correct measure of progress to use when recognizing revenue over time, the Company assessed whether an input or output based measure of progress would be appropriate. The Company determined that an output based measure of progress would be appropriate to use when recognizing revenue associated with the combined performance obligation. The Company will recognize revenue based on the clinical manufacturing services completed to date. At the outset of the clinical trial in Japan to be conducted by MEDINET, the Company will have quantifiable estimates of total clinical candidates, and therefore, of total estimated performance. The Company will recognize revenue based on performance completed to date, as evidenced by the estimated number of clinical trial enrollees. The Company expects to provide the clinical manufacturing services to MEDINET over an estimated period of two years. Therefore, the estimated two-year clinical manufacturing period is the appropriate timing of revenue recognition for the combined performance obligation. Revenue will be recognized using the output method, as the clinical manufacturing services are delivered, over the estimated two-year year proportional performance service period. Upon the conclusion of the clinical manufacturing period, the Company expects other third-party vendors to have the capabilities to provide similar services. At this point, the license would effectively become a distinct performance obligation, with no remaining undelivered obligations. Therefore, the Company determined that the up-front payment associated with the licensed intellectual property should be fully recognized by the conclusion of the clinical manufacturing service period. Upon conclusion of the clinical manufacturing service period, the Company will have no remaining performance obligations, and MEDINET will be able to obtain commercial manufacturing services from other vendors.

At contract inception, the Company determined that the \$10.0 million non-refundable upfront amount constituted the entirety of the consideration to be included in the transaction price as the development, regulatory, and commercial milestones represent variable consideration and were fully constrained. As part of its evaluation of the constraint, the Company considered numerous factors, including that receipt of the milestones is outside the control of the Company and contingent upon success in future clinical trials and the licensees' efforts. Any consideration related to sales-based milestones (including royalties) will be recognized when the related sales occur. The Company will re-evaluate the transaction price in each reporting period and as uncertain events are resolved or other changes in circumstances occur. The Company also determined that consideration associated

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with the clinical trials, which are payable by MEDINET on per-patient basis represent variable consideration, will be included in the transaction price upon occurrence, or once the associated clinical manufacturing service(s) for the patient are concluded.

The upfront transaction price of \$10.0 million will be recognized over a period of approximately two-years, commencing at the start of the clinical trial which, in management's judgement represents the Company's best estimate of the period of performance for satisfying the performance obligation of supply of clinical trial materials and transfer of license to MEDINET. Management has included \$10.0 as non-current based on the feedback from the FDA and subsequent suspension of the NeoCart program. MEDINET relies on Company's NeoCart product to supply clinical trial patients. MEDINET has suspended development of its clinical trial. Management will reevaluate that estimate at each reporting period. Revenue is being recognized using the output method, as the clinical manufacturing services are delivered, over the estimated two year proportional performance clinical manufacturing period.

### **Transaction Price Allocated to Future Performance Obligations**

Remaining performance obligations represents the transaction price of contracts for which work has not been performed (or has been partially performed) and excludes unexercised contract options. As of December 31, 2018, the aggregate amount of the transaction price allocated to the remaining performance obligations was \$10.0 million. The contract with MEDINET is wholly unperformed, and the Company recognized no revenue associated with the agreement during the years ended December 31, 2018 and 2017, respectively.

### **Research and Development Costs**

Research and development costs are charged to expense as incurred. These costs include, but are not limited to: license fees related to the acquisition of in-licensed products; employee-related expenses, including salaries, benefits and travel; expenses incurred under agreements with contract research organizations and investigative sites that conduct clinical trials and preclinical studies; the cost of acquiring, developing and manufacturing clinical trial materials; facilities, depreciation and other expenses, which include direct and allocated expenses for rent and maintenance of facilities; insurance and other supplies; and costs associated with preclinical activities and regulatory operations.

Costs for certain development activities, such as clinical trials, are recognized based on an evaluation of the progress to completion of specific tasks using data such as patient enrollment, clinical site activations, or information provided to the Company by its vendors with respect to their actual costs incurred. Payments for these activities are based on the terms of the individual arrangements, which may differ from the pattern of costs incurred, and are reflected in the consolidated financial statements as prepaid or accrued research and development expense.

### *Collaboration Arrangements*

Costs reimbursed to a collaborator for work that it performs are recorded as research and development expenses. These reimbursements can include payments for work performed, or a milestone for which a payment is due, the reimbursements or development milestone achievement are recorded as research and development expense.

In September 2014, the Company entered into a collaboration agreement with Intrexon Corporation ("Intrexon") for the development and commercialization of allogeneic cell therapeutics for the treatment or repair of damaged articular hyaline cartilage in humans, utilizing Intrexon's proprietary technology (the "Collaboration Agreement"). Under the terms of the Collaboration Agreement, the Company is responsible for the costs of development and commercialization, with some exceptions. This agreement was terminated in December 2018. In connection with the Mutual Termination Agreement, in lieu of payment of the Accrued Expenses, the Company agreed to pay Intrexon an aggregate of up to \$1.5 million, with \$0.375 million paid at the time of



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entering into the Mutual Termination Agreement and \$1.125 million payable within one year following any submission of a BLA to the FDA for NeoCart. We adjusted the accrued expenses to reflect \$1.125 million balance as of December 31, 2018 and gain on extinguishment of liability of \$1.5 million.

### **License Agreements**

Costs associated with licenses of technology are expensed as incurred and are included in research and development expenses.

### **Patent Costs**

Costs related to filing and pursuing patent applications are recorded as general and administrative expense as incurred since the recoverability of such expenditures is uncertain.

### **Stock-Based Compensation**

The Company accounts for grants of stock options and restricted stock based on their grant date fair value and recognizes compensation expense over their vesting period. The Company estimates the fair value of stock options as of the date of grant using the Black-Scholes option pricing model and restricted stock based on the fair value of the underlying common stock as determined by management or the value of the services provided, whichever is more readily determinable.

Stock-based compensation expense represents the cost of the grant date fair value of employee stock option grants recognized over the requisite service period of the awards (usually the vesting period) on a straight-line basis, net of estimated forfeitures. The expense is adjusted for actual forfeitures at year end. Stock-based compensation expense recognized in the consolidated financial statements is based on awards that are ultimately expected to vest.

For stock option grants with performance-based milestones, the expense is recorded over the remaining service period after the point when the achievement of the milestone is probable or the performance condition has been achieved. For stock option grants with both performance-based milestones and market conditions, expense is recorded over the derived service period after the point when the achievement of the performance-based milestone is probable or the performance condition has been achieved. The Company did not issue performance-based awards in 2018 or 2017.

The Company accounts for stock options and restricted stock awards to non-employees using the fair value approach. Stock options and restricted stock awards to non-employees are subject to periodic revaluation over their vesting terms.

On October 1, 2018, the Compensation Committee of the Board of Directors approved a repricing (the "Repricing") of 3,807,779 stock options (the "Options") granted prior to September 1, 2018 pursuant to the 2013 Equity Incentive Plan and the 2012 Equity Incentive Plan to executive officers, employees and consultants of the Company. The Options had exercise prices between \$0.75628 and \$9.97 per share, which were reduced to \$0.568 per share (the closing price of the Company's common stock on The Nasdaq Capital Market on October 1, 2018). The number of shares, vesting schedules and expiration period of the Options were not altered. The impact to the Company's financial statements in 2018 was immaterial.

### **Income Taxes**

The Company accounts for income taxes under the liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements. Under this method, deferred tax assets and liabilities are determined on the basis of the

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differences between the financial statements and tax basis of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. The effect of a change in tax rates on deferred tax assets and liabilities is recognized in income in the period that includes the enactment date.

The Company recognizes net deferred tax assets to the extent that the Company believes these assets are more likely than not to be realized. In making such a determination, management considers all available positive and negative evidence, including future reversals of existing taxable temporary differences, projected future taxable income, tax-planning strategies, and results of recent operations. If management determines that the Company would be able to realize its deferred tax assets in the future, in excess of its net recorded amount, management would make an adjustment to the deferred tax asset valuation allowance, which would reduce the provision for income taxes.

The Company records uncertain tax positions on the basis of a two-step process whereby (1) management determines whether it is more likely than not that the tax positions will be sustained on the basis of the technical merits of the position and (2) for those tax positions that meet the more likely than not recognition threshold, management recognizes the largest amount of tax benefit that is more than 50 percent likely to be realized upon ultimate settlement with the related tax authority. The Company recognizes interest and penalties related to unrecognized tax benefits within income tax expense. Any accrued interest and penalties are included within the related tax liability.

### **Loss per Common Share**

Loss per common share is calculated using the two-class method, which is an earnings allocation formula that determines loss per share for the holders of the Company's common shares and participating securities. All series of preferred stock contain participation rights in any dividend paid by the Company and are deemed to be participating securities. Earnings available to common stockholders and participating convertible redeemable preferred shares are allocated to each share on an as-converted basis as if all of the earnings for the period had been distributed. The participating securities include a contractual obligation to share in losses of the Company and are included in the calculation of net loss per share in the periods that have a net loss.

Diluted earnings per share is computed using the more dilutive of (a) the two-class method, or (b) the if-converted method. The Company allocates earnings first to preferred stockholders based on dividend rights and then to common and preferred stockholders based on ownership interests. The weighted-average number of common shares included in the computation of diluted loss gives effect to all potentially dilutive common equivalent shares, including outstanding stock options, warrants, convertible redeemable preferred stock and the potential issuance of stock upon the conversion of the Company's convertible notes. Common stock equivalent shares are excluded from the computation of diluted loss per share if their effect is antidilutive.

### **Warrant Accounting**

As noted in Note 9, the Company classifies warrants to purchase shares of its common stock as a liability on its consolidated balance sheet if the warrant is a free-standing financial instrument that may require the Company to transfer consideration upon exercise. Each warrant of this type is initially recorded at fair value on date of grant using a Monte Carlo simulation or Black Scholes model and net of issuance costs, and is subsequently re-measured to fair value at each subsequent balance sheet date. Changes in fair value of the warrants are recognized as a component of other income (expense), net in the consolidated statement of operations. The Company will continue to adjust the liability for changes in fair value until the earlier of the exercise or expiration of the warrants.

In the first quarter of 2019 the Company reduced the exercise price of all but 508,714 warrants issued in connection with the 2016 private placement and all of the warrants issued in connection with the October 2018 underwritten public offering. Refer to Note 15, *Subsequent Events* for further details on the amendments.

## **Recent Accounting Pronouncements**

In November 2018, the FASB issued ASU No. 2018-18, Collaborative Arrangements (Topic 808): Clarifying the Interaction between Topic 808 and Topic 606. The amendments in this update provide guidance on whether certain transactions between collaborative arrangement participants should be accounted for with revenue under Topic 606. The guidance also provides more comparability in the presentation of revenue for certain transactions between collaborative arrangement participants. For public business entities, the amendments in this update are effective for fiscal years and interim periods within those fiscal years, beginning after December 15, 2019. Early adoption is permitted, including adoption in any interim period, for public business entities for periods for which financial statements have not yet been issued. The Company is currently evaluating the impact that the adoption of this guidance will have on the Company's consolidated financial statements and related disclosures.

In August 2018, the FASB issued ASU No. 2018-13, Fair Value Measurement (Topic 820): Changes to the Disclosure Requirements for Fair Value Measurement. The amendments in this update modify the disclosure requirements on fair value measurements based on the concepts in the Concepts Statement, including the consideration of costs and benefits. The amendments in this update are effective for all entities for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2019 with early adoption permitted upon issuance of this Update. The Company is currently evaluating the impact that the adoption of this guidance will have on the Company's consolidated financial statements and related disclosures.

In August 2018, the SEC adopted the final rule under SEC Release No. 33-10532, Disclosure Update and Simplification. This final rule amends certain disclosure requirements that are redundant, duplicative, overlapping, outdated or superseded. In addition, the amendments expand the disclosure requirements on the analysis of stockholders' equity for interim financial statements. Under the amendments, an analysis of changes in each caption of stockholders' equity presented in the balance sheet must be provided in a note or separate statement. The analysis should present a reconciliation of the beginning balance to the ending balance of each period for which a statement of comprehensive income is required to be filed. This final rule is effective for the Company for all filings made on or after November 5, 2018. The SEC staff clarified that the first presentation of the changes in shareholders' equity may be included in the first Form 10-Q for the quarter that begins after the effective date of the amendments. The adoption of the final rule did not have a material impact on the Company's consolidated financial statements. In June 2018, the FASB issued ASU No. 2018-07, Compensation-Stock Compensation (Topic 718): Improvements to Nonemployee Share- Based Payment Accounting. This update is to simplify the aspects of accounting for nonemployee share-based payment transactions for acquiring goods or services from nonemployees. The amendments in this update are effective for fiscal years beginning after December 15, 2018, including interim periods within that year. The Company has concluded that this guidance has no material impact on the Company's consolidated financial statements and related disclosures.

In July 2017, the FASB issued ASU No. 2017-11, Earnings Per Share (Topic 260): Distinguishing Liabilities from Equity (Topic 480); Derivatives and Hedging (Topic 815): (PART I) Accounting for certain financial instruments with down round features. This update addresses the complexity of accounting for certain financial instruments with down round features. The guidance is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2018. The Company has concluded that this guidance has no impact on the presentation of its results of operations, financial position and disclosures.

In May 2017, the FASB issued ASU No. 2017-09, Compensation-Stock Compensation (Topic 718): Scope of Modification Accounting. This standard provides guidance on changes to the terms or conditions of a share-based payment award that requires an entity to apply modification accounting. The guidance is effective prospectively for annual periods beginning after December 15, 2017, and for interim periods and annual periods thereafter. The Company has concluded that this guidance has an immaterial no impact on the presentation of its results of operations, financial position and disclosures.

In November 2016, the FASB issued ASU 2016-18, Statement of Cash Flows: Restricted Cash ("ASU 2016-18"). The amendments in this update require that amounts generally described as restricted cash and

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restricted cash equivalents be included within cash and cash equivalents when reconciling the beginning-of-period and end-of-period total amounts shown on the statement of cash flows. ASU 2016-18 was effective January 1, 2018. As a result of adopting ASU 2016-18, the Company includes its restricted cash balance in the cash and cash equivalents reconciliation of operating, investing and financing activities. The following table provides a reconciliation of cash, cash equivalents, and restricted cash within the statement of financial position that sum to the total of the same such amounts shown in the statement of cash flows.

	As of December 31,	
	2018	2017
	(in thousands)	
Cash and cash equivalents	\$15,542	\$7,081
Restricted cash	137	137
Total cash, cash equivalents, and restricted cash shown in the statement of cash flows	<u>\$15,679</u>	<u>\$7,218</u>

In February 2016, the FASB issued ASU No. 2016-02- Leases (Topic 842). This standard requires companies to recognize on the balance sheet the assets and liabilities for the rights and obligations created by leased assets. ASU 2016-02 will be effective for the Company in the first quarter of 2019, with early adoption permitted. The Company estimates that it will recognize approximately \$8 million to \$10 million of right-of-use assets and corresponding lease liabilities on the balance sheet upon adoption. However, the population of contracts subject to balance sheet recognition and their initial measurement remains under evaluation; and the final impact on the balance sheet will depend on the lease portfolio as the time of adoption. The Company does not expect that adoption will have a material impact on its results of operations or statement of cash flows.

In May 2014, the FASB issued ASU No. 2014-09, Revenue from Contracts with Customers (“Topic 606”), which requires an entity to recognize the amount of revenue to which it expects to be entitled for the transfer of promised goods or services to customers. In the fourth quarter of 2017, the Company early adopted ASC 606 and this standard applies to all contracts with customers, except for contracts that are within the scope of other standards, such as leases, insurance, collaboration arrangements and financial instruments. The Company had only one revenue arrangement as of the adoption date. Topic 606 requires an entity to recognize the amount of revenue to which it expects to be entitled for the transfer of promised goods or services to customers. Topic 606 provides a five-step model for determining revenue recognition for arrangements that are within the scope of the standard: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation. The Company only applies the five-step model to contracts when it is probable that the entity will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer. At contract inception, once the contract is determined to be within the scope of Topic 606, the Company assesses the goods or services promised within each contract and determines those that are performance obligations, and assesses whether each promised good or service is distinct. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied. For a complete discussion of accounting for revenues, see Note 1, Summary of Significant Accounting Policies—Revenue Recognition

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### 3. LOSS PER COMMON SHARE

Basic and diluted loss per common share are calculated as follows:

	For the Year Ended	
	2018	2017
(In thousands, except share and per share data)		
Numerator:		
Net loss	\$ (8,643)	\$ (26,414)
Net Loss attributable to Series A Preferred Stock (a)	(121)	(3,915)
Numerator for basic EPS—loss attributable to common stockholders	<u>\$ (8,522)</u>	<u>\$ (22,499)</u>
Effect of dilutive securities:		
Deduct change in fair value of warrant liability	\$ (20,601)	\$ —
Numerator for diluted EPS—loss attributable to common stockholders after assumed conversions	<u>\$ (29,123)</u>	<u>\$ (22,499)</u>
Denominator:		
Weighted-average number of common shares used in loss per share—basic	36,398,450	22,669,819
Effect of dilutive securities:		
Nonparticipating warrants	691,747	—
Denominator for diluted EPS—adjusted weighted average shares	<u>37,090,197</u>	<u>22,669,819</u>
Loss per share—basic	<u>\$ (0.23)</u>	<u>\$ (0.99)</u>
Loss per share—diluted	<u>\$ (0.79)</u>	<u>\$ (0.99)</u>

(a) The Series A Preferred Stock participates in income and losses

The following potentially dilutive securities have been excluded from the computation of diluted weighted-average shares outstanding, as they would be anti-dilutive (in common stock equivalent shares):

	As of December 31,	
	2018	2017
Unvested restricted stock and options to purchase common stock	3,339,471	2,158,348
Series A preferred stock unconverted	177,996	2,046,957
Warrants exercisable into common stock	—	13,633,070

### 4. PREPAID EXPENSES AND OTHER CURRENT ASSETS

Prepaid expenses and other current assets consisted of the following:

	As of December 31,	
	2018	2017
(in thousands)		
Insurance	686	72
Other current assets	172	122
Prepaid expenses and other current assets	<u>\$ 858</u>	<u>\$ 194</u>

## 5. PROPERTY AND EQUIPMENT

Property and equipment consisted of the following:

	December 31, 2018	December 31, 2017
	(in thousands)	
Office equipment	\$ 266	\$ 279
Laboratory equipment	4,561	4,565
Leasehold improvements	5,504	7,712
Construction in progress	—	990
Software	96	96
Total property and equipment	10,427	13,642
Less: accumulated depreciation	(10,286)	(10,919)
Property and equipment, net	<u>\$ 141</u>	<u>\$ 2,723</u>

Depreciation expense related to property and equipment amounted to \$0.5 million and \$1.5 million for the years ended December 31, 2018 and 2017, respectively.

For year ended December 31, 2018 the company deemed the value of its property and equipment to be impaired based on the triggering event that occurred in December 2018. In connection with the impairment, the Company reduced the net book value of its property and equipment to an estimated fair value which was calculated based on the present value of expected future cash flows from these assets. As a result, the Company incurred a charge of \$4.3 million that was recorded in the Statement of Operations.

## 6. ACCRUED EXPENSES

Accrued expenses consisted of the following:

	As of December 31,	
	2018	2017
	(in thousands)	
Accrued compensation	\$ 514	\$ 1,671
Accrued audit fees	159	133
Accrued license fees	90	70
Accrued clinical expenses	86	199
Accrued other	151	632
Total accrued expenses	<u>\$ 1,000</u>	<u>\$ 2,705</u>

## 7. COMMITMENTS AND CONTINGENCIES

### Operating Leases

The Company leases its office and research facilities in Waltham and Lexington, Massachusetts under non-cancellable operating leases. The Lexington, Massachusetts facility lease expires in June 2023. The lease provided for one extension term of five years. The Waltham, Massachusetts facility lease was extended in April 2017 with an effective date of January 2018. Under the terms of the extension, the lease will expire in December 2024 with one additional extension term of five years. Terms of the agreements generally provide for an initial rent-free period and future rent escalation, and provide that in addition to minimum lease rental payments, the Company is responsible for a pro-rata share of common area operating expenses.

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Aggregate minimum annual lease commitments of the Company under its non-cancellable operating leases as of December 31, 2018, are as follows:

<b>For the Year Ended December 31,</b>	
	<b>(in thousands)</b>
2019	\$ 1,845
2020	1,892
2021	1,941
2022	1,991
2023	1,728
Thereafter	1,460
<b>Total minimum lease payments</b>	<b>\$ 10,857</b>

Rent expense under operating lease agreements amounted to \$1.6 million and \$1.0 million for the years ended December 31, 2018 and 2017, respectively.

As an inducement to enter into the Waltham facility lease extension, the lessor agreed to provide the Company with a construction allowance of up to \$0.9 million towards the total cost of tenant improvements. As an inducement to enter into its Lexington facility lease, the lessor agreed to provide the Company with a construction allowance of up to \$1.0 million towards the total cost of tenant improvements. The Company has recorded these costs in the consolidated balance sheet as leasehold improvements, with the corresponding liability as deferred lease incentive. These liabilities are amortized on a straight-line basis over the term of the lease as a reduction of rent expense.

### **License Agreements**

From time to time, the Company enters into various licensing agreements whereby the Company may use certain technologies in conjunction with its product research and development. Licensing agreements and the Company's commitments under the agreements are as follows:

#### *Hydrogel License*

In May 2005, the Company entered into an exclusive license agreement with Angiotech Pharmaceuticals (US), Inc. for the use of certain patents, patent applications, and knowledge related to the manufacture and use of a hydrogel material in conjunction with NeoCart and certain other products ("Hydrogel License Agreement"). As of December 31, 2018, the Company has paid an aggregate \$3.2 million in commercialization milestones under the terms of the Hydrogel License Agreement, which has been expensed to research and development.

Under the terms of the Hydrogel License Agreement, the Company's future commitments include:

- A one-time \$3.0 million payment upon approval of an eligible product by the FDA; and
- Single digit royalties on the net sales of NeoCart and certain other future products.

#### *Tissue Regeneration License*

In April 2001, the Company entered into an exclusive license agreement with The Board of Trustees of the Leland Stanford Junior University ("Stanford University") for the use of certain technology to develop, manufacture and sell licensed products in the field of growth and regeneration of cartilage ("Tissue Regeneration License Agreement"). The term of the Tissue Regeneration License Agreement extends to the expiration date of Stanford University's last to expire domestic or foreign patents. As of December 31, 2018, the Company has paid an aggregate \$0.8 million in patent reimbursement costs, royalty fees, and commercialization milestone payments under the terms of the Tissue Regeneration License Agreement, which have been recorded to research and development expense.

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Under the terms of the Tissue Regeneration License Agreement, the Company's future commitments include:

- A one-time \$0.3 million payment upon approval of an eligible product by the FDA;
- An annual minimum non-refundable royalty fee of \$10 thousand for the life of the license that may be used to offset up to 50% of each earned royalty described below; and
- Low single digit royalties on net sales.

### *Tissue Processor Sub-License*

In December 2005, the Company entered into an exclusive agreement to sub-license certain technology from Purpose, Co. ("Purpose"), which is owned by a stockholder of the Company ("Sub-License Agreement"). Purpose entered into the original license agreement ("Original Agreement") with Brigham and Women's Hospital, Inc. ("Brigham and Women's") in August 2001. The Original Agreement shall remain in effect for the licensed patents owned by Brigham and Women's unless extended or terminated as provided for in the agreement. The technology is to be used to develop, manufacture, use and sell licensed products that cultivate cell or tissue development. The Sub-License Agreement extends to the expiration date of the last to expire domestic or foreign patents covered by the agreement. As of December 31, 2018, the Company has paid an aggregate \$1.0 million in royalty and sub-license payments under the terms of the Sub-License Agreement.

The Sub-License Agreement was amended and restated in June 2012. Under the amended and restated agreement, the Company made Purpose the sole supplier of equipment the Company uses in its manufacturing processes, and granted Purpose distribution rights of the Company's products for certain territories. In exchange, Purpose allowed for the use of its technology (owned or licensed) and manufactured and serviced exogenous tissue processors used by the Company. Under the terms of the agreement, as amended, Purpose granted the Company: (a) exclusive rights to all of Purpose's technology (owned or licensed) related to the exogenous tissue processors, (b) continued supply of exogenous tissue processors during the Company's clinical trials, and (c) rights to manufacture the exogenous tissue processors at any location the Company chooses. In exchange for such consideration, the Company granted Purpose an exclusive license in Japan for the use of all of the Company's technology and made a payment of \$0.3 million to reimburse Purpose for development costs on a next generation tissue processor.

In May 2016, the Original Agreement was amended whereby the Company acquired the development and commercialization rights to NeoCart for the Japanese market from Purpose. Under the terms of the amended agreement, the Company assumes sole responsibility for and rights to the development and commercialization of NeoCart in Japan. In exchange for the transfer of development and commercialization rights, the Company will pay a success-based milestone to Purpose upon conditional approval of NeoCart in Japan, as well as commercial milestones and a low single digit royalty on Japanese sales of NeoCart, upon full approval, if any, in Japan

In addition to the above, the Company's future commitments under the terms of the Original Agreement and Sub-License Agreement include:

- A minimum non-refundable annual royalty fee of \$20 thousand, for the life of the license;
- An additional, non-refundable annual royalty fee of \$30 thousand from 2016 through 2019;
- \$10.2 million in potential milestone payments; and
- Low single digit royalties on net sales of a licensed product.

### **Collagen Supply Agreement**

In September 2015, the Company entered into an agreement with Collagen Solutions (UK) Limited (the "Supplier") to purchase soluble collagen that meets specifications provided by the Company. The initial term of



the agreement is three years and will automatically renew from year to year thereafter unless otherwise terminated with at least 180 days' notice by either party. In February 2017, the Company entered into an amendment with the Supplier. Pursuant to the amendment, the Company agreed to pay the Supplier approximately \$0.1 million in exchange for eliminating the minimum annual order of material and/or services and any other amounts due Supplier. The payment of \$0.1 million will be made over the 18 months following the date of the amendment. As of December 31, 2018, the Company has paid all of the required payments totaling \$0.1 million under the terms of the amendment.

## **8. CAPITAL STOCK.**

In October 2018, the Company closed a underwritten public offering of 26,155,000 shares of its common stock and warrants to purchase up to 19,616,250 shares of common stock, at a combined purchase price of \$0.65 per share of common stock and accompanying warrant. The gross proceeds to Histogenics from this offering were \$17.0 million, before deducting underwriting discounts and commissions, and offering expenses payable by the Company. The warrants are exercisable immediately upon issuance at a price of \$0.70 per share of common stock and have a term of five years commencing on the date of issuance. The exercise price of the Warrants is subject to adjustment upon the occurrence of specific events, including stock dividends, stock splits, combinations and reclassifications of the Company's Common Stock. In the event of certain fundamental transactions of the Company, a warrant holder may demand redemption of its warrant for cash in accordance with a Black-Scholes option pricing model. A fundamental transaction is defined as a merger, sale of assets, sale of the Company, recapitalization of stock and a sale of stock whereby any owner after the transaction would own greater than 50% of the outstanding common stock in the Company. The Company determined the warrants are classified as a liability on the consolidated balance sheet because of the provision whereby in a fundamental transaction (as described above), the holder can elect to receive either the amount they are entitled to on an as-if-exercised basis or an amount based on the Black-Scholes value of the warrants at the time of the fundamental transaction. At the issuance date, the warrants were recorded at the fair value of \$8.4 million

In March 2018, the Company entered into an equity distribution agreement ("the Equity Distribution Agreement") with Canaccord Genuity Inc. ("Canaccord"), pursuant to which the Company may, from time to time, sell shares of its common stock having an aggregate offering price of up to \$10.0 million (the "Shares") through Canaccord, as sales agent. During the year ended December 31, 2018, the Company sold an aggregate of 6,633,903 shares of common stock and received \$4.5 million after deducting commissions related to the Equity Distribution Agreement and other offering costs.

In January 2018, the Company closed a registered direct offering where the Company issued 2,691,494 shares of common stock at a price of \$2.35 per share. The underwriter option to purchase additional shares of 351,064 were fully exercised. The total net proceeds of the offering were approximately \$5.9 million after deducting underwriting discounts and commissions.

In September 2016, the Company closed the private placement contemplated by the securities purchase agreement (the "Purchase Agreement"), dated September 15, 2016, between the Company and certain institutional and accredited investors in which the Company received gross proceeds of \$30.0 million (the "Private Placement"). The net proceeds after deducting placement agent fees and other transaction-related expenses was \$27.6 million. At the closing, the Company issued 2,596,059 shares of the Company's common stock at a per share price of \$2.25 and 24,158,8693 shares of the Company's newly-created Series A Convertible Preferred Stock ("Series A Preferred Stock"), which are convertible into approximately 10,737,275 shares of common stock. As of December 31, 2018, there were 400,4910 shares of Series A Preferred Stock outstanding, which remain convertible into 177,996 shares of the Company's common stock. As part of the Private Placement, the investors received warrants to purchase up to 13,333,334 shares of the Company's common stock at an exercise price of \$2.25 per share. The placement agent for the Private Placement, H.C. Wainwright & Co. LLC ("HCW"), and certain of its affiliates were also granted warrants to purchase 133,333 shares of the Company's common stock at an exercise price of \$2.25 per share in exchange for the services provided by HCW. The

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placement agent warrants were considered a financing cost of the Company and included in warrant expense within the consolidated statements of operations.

The warrants include a cashless-exercise feature that may be exercised solely in the event there is no effective registration statement, or no current prospectus available for, the resale of the shares of common stock underlying the warrants as of the six-month anniversary of the closing of the Private Placement. Upon a fundamental transaction, the holders of the warrant may require the Company to purchase any unexercised warrants in an amount equal to the Black-Scholes value of the option. A fundamental transaction is defined as a merger, sale of assets, sale of the Company, recapitalization of stock and a sale of stock whereby any owner after the transaction would own greater than 50% of the outstanding common stock in the Company. The warrants became exercisable following approval of the Private Placement by our stockholders in the fourth quarter of 2016 and expire five years after the date of such stockholder approval. The Company determined the warrants are classified as a liability on the consolidated balance sheet because they contain a provision whereby in a fundamental transaction (as described above), the holder can elect to receive either the amount they are entitled to on an as-if-exercised basis or an amount based on the Black-Scholes value of the warrants at the time of the fundamental transaction. At the issuance date, the warrants were recorded at the fair value of \$30.7 million.

Concurrent with the closing of the Private Placement, the Company's Certificate of Incorporation was amended by the filing of a Certificate of Designation to create the Series A Preferred Stock. The Series A Preferred Stock has a par value of \$0.01 and each share is convertible into 444.44 shares of common stock, at a conversion price of \$2.25 per share, at the option of the holder. The Series A Preferred Stock has no voting rights and is only entitled to dividends as declared on an as-converted basis. The Series A Preferred Stock contains no liquidation preferences or redemption rights and shares in distributions of the Company on an as-converted basis with the common stock.

As part of the Private Placement, affiliates of certain members of the Company's Board of Directors purchased an aggregate of 283,046 shares of common stock, an aggregate of 2,563.1439 shares of Series A Preferred Stock and received warrants to purchase up to 1,422,221 shares of common stock at an exercise price of \$2.25 per share in the Private Placement. These amounts are included in the amounts noted above.

### **Common Stock -100,000,000 shares authorized**

The holders of shares of common stock are entitled to one vote per share. The holders of shares of common stock are not entitled to receive dividends, unless declared by the Company's board of directors out of legally available funds, if ever.

#### *Reserved for future issuance*

The Company has reserved for future issuance the following number of shares of common stock:

	As of December 31,	
	2018	2017
Options to purchase common stock	3,339,471	2,158,348
Common stock warrants	33,145,228	13,633,070
<b>Total</b>	<b>36,484,699</b>	<b>15,791,418</b>

### **Preferred Stock -30,000 shares authorized**

#### **Series A Convertible Preferred Stock**

On September 29, 2016, the Company issued 24,158.8693 shares of newly-created Series A Convertible Preferred Stock, which were convertible into approximately 10,737,275 shares of common stock at an initial

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conversion price of \$2.25. The Series A Preferred Stock has a par value of \$0.01 and each share is convertible into 444.44 shares of common stock at the option of the holder. The holders of Series A Preferred Stock have no voting rights, share in both income and losses and are only entitled to dividends as declared on an as-converted basis. The Series A Preferred Stock contains no liquidation preferences or redemption rights and shares in the distribution of the Company on an as-converted basis with the common stock. The Series A Preferred Stock shall not be converted if, after giving effect to the conversion, the holder and its affiliated persons would own beneficially more than 4.99% of our common stock (subject to adjustment up to 9.99% solely at the holder's discretion upon 61 days' prior notice to us or, solely as to a holder, if such limitation is waived by such holder upon execution of the private placement agreement). As of December 31, 2018, there were 400,4910 shares of Series A Preferred Stock outstanding, which remain convertible into 177,996 shares of the Company's common stock.

## 9. WARRANTS

<u>Issued</u>	<u>Classification</u>	<u>Warrants Outstanding</u>	<u>Exercise Price</u>	<u>Expiration</u>
October 2018	Liability	19,616,250	\$ 0.70	October 2028
September 2016	Liability	13,466,667	2.25	November 2022
March 2015	Equity	3,699	9.75	March 2025
July 2014	Equity	6,566	7.99	July 2024
July 2012	Equity	52,046	0.01	July 2022

In the first quarter of 2019 the Company reduced the exercise price for all but 508,714 of the warrants issued in September 2016 and all of the warrants issued in October 2018. Refer to Note 15, *Subsequent Events* for further details on the amendments.

## 10. EQUIPMENT LOAN PAYABLE

As of December 31, 2018 and 2017, the Company had the following outstanding borrowing obligations:

	<u>December 31,</u> <u>2018</u>	<u>December 31,</u> <u>2017</u>
	<u>(in thousands)</u>	
Silicon Valley Bank Equipment Loan Payable	\$ —	\$ 178
Less: current portion	—	(178)
Long-term debt, net	\$ —	\$ —

In July 2014, the Company entered into a loan and security agreement with Silicon Valley Bank, which provided for a line of credit to finance certain equipment purchases up to an aggregate of \$1.8 million through March 31, 2015. The line has been fully drawn and is payable in 36 monthly installments of principal and interest, with an annual interest rate of 2.75% plus the greater of 3.25% or the prime rate in effect at the time of each draw, as published in the Wall Street Journal. The outstanding balance on the line of credit is secured by a first priority lien over all equipment purchased using the line of credit.

In accordance with the terms of the equipment line of credit, the Company issued a warrant to Silicon Valley Bank in July 2014 to purchase 6,566 shares of our common stock at an exercise price per share of \$7.99.

The equipment line of credit includes customary operating but non-financial covenants, including limitations on the Company's ability to incur additional indebtedness, issue dividends, sell assets, engage in any business other than its current business, merge or consolidate with other entities, create liens on our assets, make investments, repurchase stock in certain instances, enter into transactions with affiliates, make payments on subordinated indebtedness and transfer or encumber any collateral securing the debt. The loan matured and was fully repaid in 2018.

## **11. STOCK-BASED COMPENSATION**

### **Restricted Stock Awards and Stock Options**

The Company adopted the 2012 Equity Incentive Plan, as amended (“2012 Plan”) in July 2012 pursuant to which 609,389 shares of common stock were authorized for issuance to employees, officers, directors, consultants and advisors of the Company as of December 31, 2014. Upon the closing of the IPO on December 3, 2014, no further grants were made under the 2012 Plan as the 2013 Equity Incentive Plan (“2013 Plan”) replaced the 2012 Plan on this date. The 2012 Plan provided for the grant of incentive stock options, non-statutory stock options, rights to purchase restricted stock, stock appreciation rights, phantom stock awards and stock units. In connection with the issuance of restricted common stock, the Company maintains a repurchase right and shares of restricted common stock are released from such repurchase right over a period of time of continued service by the recipient. Recipients of incentive stock options shall be eligible to purchase shares of the Company’s common stock at an exercise price equal to no less than the estimated fair value of such stock on the date of grant. Stock options generally vest 25% on the first anniversary of the original vesting date, with the balance vesting monthly over the remaining three years, unless they contain specific performance and/or market-based vesting provisions. The maximum term of stock options granted under the 2012 Plan is ten years.

In determining the exercise prices for options granted, the board of directors considered the fair value of the common stock as of the measurement date. The fair value of the common stock was determined by the board of directors based on a variety of different factors, including valuations prepared by third party valuation specialists, the Company’s financial position, the status of development efforts within the Company, the composition and ability of the current scientific and management teams, the current climate in the marketplace, the illiquid nature of the Company’s common stock, any arm’s length sale of the Company’s preferred stock, the effect of the rights and preferences of the preferred stockholders, and the prospects of a liquidity event, among others.

### **2013 Equity Incentive Plan**

The Company’s board of directors adopted the 2013 Plan in November 2013 which the stockholders approved in October 2014. The 2013 Plan provides for the grant of incentive stock options, non-statutory stock options, rights to purchase restricted stock, stock appreciation rights and stock units. In connection with the issuance of restricted common stock, the Company maintains a repurchase right and shares of restricted common stock are released from such repurchase right over a period of time of continued service by the recipient. Recipients of stock options shall be eligible to purchase shares of the Company’s common stock at an exercise price equal to no less than the estimated fair value of such stock on the date of grant. Stock options generally vest 25% on the first anniversary of the original vesting date, with the balance vesting monthly over the remaining three years, unless they contain specific performance and/or market-based vesting provisions. The maximum term of stock options granted under the 2013 Plan is ten years. In June 2016, the Company’s stockholders approved an amendment to the EIP to increase the number of shares of common stock available for issuance under the 2013 Plan by 300,000 shares and increase the number of shares of common stock automatically added to the 2013 Plan on January 1 of each year during the term of the 2013 Plan, starting with January 1, 2017 (the “EIP Amendment”). Following adoption of the EIP Amendment, the number of shares of common stock available for issuance under the 2013 Plan is subject to an automatic annual increase on the first day of the Company’s calendar year beginning in 2017 equal to the lesser of (a) 4.0% of the total number of shares of common stock outstanding on December 31 of the prior year or, (b) the number determined by the Company’s Board of Directors. Accordingly, the number of shares of common stock available for issuance under the EIP was increased by 825,904 shares on January 1, 2017 and an additional 982,841 shares on January 1, 2018. To the extent any awards under the 2013 Plan are forfeited, terminate, expire, lapse without the issuance of shares, or if the Company repurchases shares subject to awards under the 2013 Plan, those shares will again become available for issuance under the 2013 Plan.

## 2013 Employee Stock Purchase Plan

The Company's board of directors adopted the 2013 Employee Stock Purchase Plan ("2013 ESPP") in November 2013 which the stockholders approved in October 2014. The 2013 ESPP became effective upon the closing of the IPO on December 3, 2014. The Company's 2013 ESPP qualifies under Section 423 of the Internal Revenue Code of 1986, as amended (the "Code"). Under the 2013 ESPP, 103,665 shares of the Company's common stock are authorized for issuance to eligible employees. The number of shares reserved for issuance under the 2013 ESPP is automatically increased on the first business day of each of the Company's fiscal years, commencing in 2015, by a number equal to the lowest of (a) 51,832 shares of common stock, (b) 1% of the shares of common stock outstanding on the last business day of the prior fiscal year; or (c) the number of shares determined by the Company's Board of Directors. Accordingly, the number of authorized shares of the Company's common stock authorized for issuance to eligible employees under the 2013 ESPP was increased by 206,476 shares on January 1, 2017 and an additional 51,832 shares on January 1, 2018. The number of shares reserved under the 2013 ESPP will automatically be adjusted in the event of a stock split, stock dividend or a reverse stock split (including an adjustment to the per-purchase period share limit). The Company's 2013 ESPP permits each eligible employee to purchase common stock through payroll deductions. There was no activity under the Plan in 2018 and 2017.

Stock option activity under the 2012 and 2013 plans is summarized as follows:

	Number of Options	Weighted- Average Exercise Price	Weighted- Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2017	2,158,348	\$ 4.40	8.1	\$ 436
Granted	4,311,090	1.21		
Exercised	(919)	2.56		
Cancelled	(3,129,048)	3.60		
Outstanding at December 31, 2018	<u>3,339,471</u>	<u>\$ 1.03</u>	<u>8.1</u>	<u>\$ —</u>
Vested and expected to vest at December 31, 2018	<u>3,314,542</u>	<u>\$ 1.03</u>	<u>8.1</u>	<u>\$ —</u>
Exercisable at December 31, 2018	<u>1,603,725</u>	<u>\$ 1.37</u>	<u>7.1</u>	<u>\$ —</u>

As of December 31, 2018 and 2017, the unrecognized compensation cost related to outstanding options was \$2.3 million and \$1.4 million, respectively, and is expected to be recognized as expense over approximately 2.50 years and 1.70 years, respectively. The intrinsic value of options exercised during the years ended December 31, 2018 and 2017 was \$0 and \$8 thousand, respectively.

As of December 31, 2018, the weighted average grant date fair value of vested options was \$0.76 and the weighted average grant date fair value of options outstanding was \$0.52.

Additional information about the Company's stock option activity is as follows:

	Year Ended December 31,	
	2018	2017
Weighted-average grant date fair value per share of employee option grants within the year	\$ 0.59	\$ 1.02
Cash received upon exercise of options	2	6

As of December 31, 2016, the unrecognized compensation cost related to restricted stock awards was \$1 thousand which was recognized as expense during the year ended December 31, 2017.

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### Stock-Based Compensation Expense

The Company granted stock options to employees for the years ended December 31, 2018 and 2017. The Company estimates the fair value of stock options as of the date of grant using the Black-Scholes option pricing model and restricted stock based on the fair value of the award. Stock options and restricted stock issued to non-board member, non-employees are accounted for using the fair value approach and are subject to periodic revaluation over their vesting terms.

For all periods from inception to date, stock-based compensation for all options granted and restricted stock awards are classified as research and development expense and general and administrative expense. Stock compensation expense amounted to approximately \$1.6 million and \$1.6 million for the years ended December 31, 2018 and 2017, respectively.

Stock-based compensation is as follows:

	Year Ended December 31,	
	2018	2017
	(in thousands)	
Research and development	\$ 488	\$ 411
General and administrative	1,137	1,162
Total stock-based compensation expense	<u>\$ 1,625</u>	<u>\$ 1,573</u>

The weighted-average assumptions used in the Black-Scholes option pricing model to determine the fair value of the employee stock option grants were as follows:

	Year Ended December 31,	
	2018	2017
Risk-free interest rate	2.84%	2.03%
Expected volatility	84.4%	62.9%
Expected term (in years)	5.31	6.08
Expected dividend yield	0.0%	0.0%

The weighted-average assumptions used in the Black-Scholes option pricing model to determine the fair value of the non-employee stock option grants were as follows:

	Year Ended December 31,	
	2018	2017
Risk-free interest rate	2.57%	1.29%
Expected volatility	88.3%	62.3%
Expected term (in years)	6.08	6.08
Expected dividend yield	0.0%	0.0%

**Risk-free Interest Rate.** The risk-free interest rate assumption is based on observed interest rates appropriate for the expected term of the stock option grants.

**Expected Volatility.** Due to the Company's limited operating history and lack of company-specific historical or implied volatility, the expected volatility assumption is based on historical volatilities of a peer group of similar companies whose share prices are publicly available. The peer group was developed based on companies in the biotechnology and medical device industries.

**Expected Term.** The expected term represents the period of time that options are expected to be outstanding. Because the Company does not have historical exercise behavior, through December 31, 2018 it determined the expected life assumption using the simplified method, which is an average of the contractual term of the option and its vesting period.

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**Expected Dividend Yield.** The expected dividend yield assumption is based on the fact that the Company has never paid cash dividends and has no present intention to pay cash dividends.

On October 1, 2018, the Compensation Committee of the Board of Directors approved a repricing (the “Repricing”) of 3,807,779 stock options (the “Options”) granted prior to September 1, 2018 pursuant to our 2013 Equity Incentive Plan and our 2012 Equity Incentive Plan to executive officers, employees and consultants of the Company. The Options had exercise prices between \$0.75628 and \$9.97 per share, which were reduced to \$0.568 per share (the closing price of the Company’s common stock on The Nasdaq Capital Market on October 1, 2018). The number of shares, vesting schedules and expiration period of the Options were not altered. The impact to the Company’s financial statements in 2018 was immaterial.

## 12. INCOME TAXES

For the years ended December 31, 2018 and 2017, the Company did not record a current or deferred income tax expense or benefit due to current and historical losses incurred by the Company.

The components of loss before income taxes were as follows:

	As of December 31,	
	2018	2017
	(in thousands)	
U.S.	\$(8,503)	\$(26,275)
Foreign	(140)	(140)
Total	<u>\$(8,643)</u>	<u>\$(26,415)</u>

A reconciliation of income tax expense (benefit) computed at the statutory federal income tax rate to income taxes as reflected in the financial statements is as follows:

	As of December 31,	
	2018	2017
Federal income tax (benefit) at statutory rate	21.1%	33.7%
(Increase) decrease income tax benefit resulting from:		
State income tax benefit, net of federal benefit	22.5%	0.0%
Permanent differences	54.4%	(2.6)%
Net Operating Loss Limitation	0.0%	0.0%
Federal Tax Rate change	0%	(47.2)%
R&D Credit Limitation	0.9%	0.0%
Change in valuation allowance	(98.5)%	14.6%
Other	-0.4%	1.5%
Income tax expense (benefit)	<u>0.0%</u>	<u>0.0%</u>

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Deferred taxes are recognized for temporary differences between the basis of assets and liabilities for financial statement and income tax purposes. The significant components of the Company's deferred tax assets and liabilities are comprised of the following:

	As of December 31,	
	2018	2017
	(in thousands)	
Deferred tax assets:		
Net operating loss carryforwards	\$ 24,941	\$ 18,540
Depreciation and amortization	4,878	4,121
Accrued expenses	141	1,484
Capitalized start-up costs	9,143	7,942
R&D credits	312	243
Other	1,155	808
Deferred tax assets before valuation allowance	40,570	33,138
Valuation allowance	(40,570)	(33,138)
	<u>—</u>	<u>—</u>
Deferred tax liabilities		
IPR&D	—	—
Change in accounting method	—	—
Net deferred tax assets	<u>\$ —</u>	<u>\$ —</u>

The Company has evaluated the positive and negative evidence bearing upon the realizability of its deferred tax assets. As of December 31, 2018 and 2017, based on the Company's history of operating losses, the Company has concluded that it is not more likely than not that the benefit of its deferred tax assets will be realized. Accordingly, the Company has provided a full valuation allowance for deferred tax assets as of December 31, 2018 and 2017. The valuation allowance decreased by \$7.4 million during the year ended December 31, 2018, due primarily to net operating losses generated and capitalized expenses. The valuation allowance decreased \$1.0 million during the year ended December 31, 2017, due primarily to net operating losses generated, net of the impact of a federal tax rate change of \$11.5 million. In addition, the reduction in net operating losses were related to Section 382 limits as a result in a change in ownership.

As of December 31, 2018 and 2017, the Company had U.S. federal NOL carryforwards of \$67 million and \$43.9 million respectively, which may be available to offset future income tax liabilities and expire at various dates through 2037. As of December 31, 2018 and 2017, the Company also had U.S. state NOL carryforwards of \$66.9 million and \$43.6 million respectively, which may be available to offset future income tax liabilities and expire at various dates through 2037. At December 31, 2018 and 2017, the Company also had \$26.2 and \$26.1 respectively, of foreign NOL carryforwards which may be available to offset future income tax liabilities, which carryforwards do not expire. Utilization of the NOL and research and development credit carryforwards may be subject to a substantial annual limitation due to ownership change limitations that have occurred or that could occur in the future, as required by Section 382 and Section 383 of the Code, as well as similar state and foreign provisions. These ownership changes may limit the amount of NOL and research and development credit carryforwards that can be utilized annually to offset future taxable income and tax, respectively. In general, an "ownership change" as defined by Section 382 of the Code results from a transaction or series of transactions over a three-year period resulting in an ownership change of more than 50 percentage points of the outstanding stock of a company by certain stockholders. The Company has completed a study to assess whether an ownership change has occurred or whether there have been multiple ownership changes since its formation. The results of this study indicated that the Company experienced ownership changes as defined by Section 382 of the Code. The Company has not recorded NOLs that, as a result of these restrictions, from the 2016 ownership change, will expire unused. Accordingly, the Company has recorded NOL carryforwards net of these limitations, which are approximately \$52.9 million.



## TAX REFORM

On December 22, 2017 the Tax Cuts and Jobs Act (the “TCJA”) was signed into United States law. The TCJA includes a number of changes to existing tax law, including, among other things, a permanent reduction in the federal corporate income tax rate from 34% to 21%, effective as of January 1, 2018, as well as limitation of the deduction for net operating losses to 80% of annual taxable income and elimination of net operating loss carrybacks, in each case, for losses arising in taxable years beginning after December 31, 2017 (though any such net operating losses may be carried forward indefinitely). The tax rate change resulted in (i) a reduction in the gross amount of the Company’s deferred tax assets recorded as of December 31, 2017, without an impact on the net amount of its deferred tax assets, which are recorded with a full valuation allowance, and (ii) no income tax expense or benefit being recognized as of the enactment date of the TCJA.

The staff of the Securities and Exchange Commission issued Staff Accounting Bulletin No. 118 to address the application of U.S. GAAP in situations when a registrant does not have the necessary information available, prepared or analyzed (including computations) in reasonable detail to complete the accounting for certain income tax effects of the TCJA. In connection with the initial analysis of the impact of the TCJA, the Company remeasured its deferred tax assets and liabilities based on the rates at which they are expected to reverse in the future, which is generally 21%. The remeasurement of the Company’s deferred tax assets and liabilities was offset by a corresponding change in the valuation allowance for the year ended December 31, 2017. As a result, there was no impact to the Company’s consolidated statements of operations and comprehensive loss as a result of the reduction in tax rates. The other provisions of the TCJA did not have a material impact on the Company’s consolidated financial statements. The Company’s final determination of the TCJA impact and the remeasurement of its deferred assets and liabilities was completed prior to the deadline of one year from the enactment of the TCJA. For the year ended December 31, 2018, there were no material changes to the analysis originally performed as of December 31, 2017.

The changes in the Company’s unrecognized tax benefits are summarized as follows:

	As of December 31,	
	2018	2017
	(in thousands)	
Unrecognized tax benefit, beginning of year	\$ 303	\$ 562
Increase (decrease) related to current year positions	—	(123)
Federal rate revision	—	(136)
Unrecognized tax benefit, end of year	<u>\$ 303</u>	<u>\$ 303</u>

As of December 31, 2018 and 2017, the total amount of unrecognized tax benefits was \$0.3 million and \$0.3 million, respectively which, if recognized, would favorably affect the effective income tax rate in future periods. Note that liabilities for unrecognized tax benefits have been recorded to the extent that they do not exceed the Company’s available losses that are not limited as a result of ownership changes that have occurred under Section 382 of the Code. Reductions to unrecognized tax benefits for limitations on the utilization of net operating losses due to ownership changes occurring during the year has been reflected in the table as reductions based on tax positions related to the current year. The Company accrues interest and penalties related to unrecognized tax benefits as a component of its provision for income taxes. No accrued interest and penalties related to the Company’s unrecognized tax benefits has been accrued as of December 31, 2018 and 2017. The Company believes that it is reasonably possible that none of its unrecognized tax benefits, may be recognized at the end of 2018. The Company or one of its subsidiaries files income tax returns in the United States and various states and Israel. The Company is subject to U.S. federal, state and local income tax examinations by tax authorities for years 2001 through present. Carryforward attributes that were generated in earlier periods remain subject to examination to the extent the year in which they were used or will be used remains open for examination. The tax years which remain subject to examination by tax authorities in Israel, as of December 31, 2018, include years 2014 through the present.

### 13. EMPLOYEE BENEFITS

The Company has a defined contribution 401(k) plan for employees who are at least 21 years of age. Employees are eligible to participate in the plan beginning on the first day of the calendar quarter following their date of hire. Under the terms of the plan, employees may make voluntary contributions as a percent of compensation. No matching contributions have been made by the Company since the adoption of the 401(k) plan.

### 14. RELATED PARTIES

#### **Purpose, Co.**

In June 2012, the Company entered into an agreement with Purpose, Co. to amend its previous agreements. In the previous agreements, Purpose, Co. granted the Company a perpetual license to its patents related to its exogenous tissue processor which is used in the development of the Company's products. In exchange, the Company granted Purpose, Co. a perpetual license to all of the Company's biotechnology and biomaterial for use in Japan. The agreement provides for Purpose, Co. to manufacture and sell machinery to the Company for cost until the Company's products become commercially viable. The Company has also agreed to pay royalties on any third-party revenue generated using Purpose, Co.'s licensed technology.

Under the June 2012 amendment, the Company received exclusive rights to all of Purpose, Co.'s technology related to the exogenous tissue processor, continued supply of exogenous tissue processors during the Company's clinical trials, and rights to manufacture the exogenous tissue processors at any location the Company chooses. In exchange for such consideration, the Company named Purpose, Co. the sole manufacturer of equipment and also clarified the geographic territories of the exclusive license that Purpose Co. was granted for use of the Company's technology. Also, the Company agreed to reimburse Purpose, Co. for \$0.3 million of development costs on a next generation tissue processor. Refer to the discussion under Note 7, *Tissue Processor Sub-License*.

In May 2016, the Company acquired the development and commercialization rights to NeoCart for the Japanese market from Purpose, Co. Under the terms of the amended agreement, the Company assumes sole responsibility for and rights to the development and commercialization of NeoCart in Japan. In exchange for the transfer of development and commercialization rights, the Company will pay a success-based milestone to Purpose upon conditional approval of NeoCart in Japan, as well as commercial milestones and a low single digit royalty on Japanese sales of NeoCart, upon full approval, if any, in Japan.

The amounts that have been paid to Purpose, Co. under this agreement were \$0.1 and \$0.1 million for the years ended December 31, 2018 and 2017, respectively.

#### **Board of Director Affiliates**

Affiliates of certain members of the Company's Board of Directors participated in the Private Placement as described in Note 8.

### 15. SUBSEQUENT EVENTS

*Restructuring*—Effective January 23, 2019, the Board of Directors of the Company approved a restructuring plan involving reductions in headcount as part of a plan to reduce operating costs following the Company's decision to discontinue the development of NeoCart. The positions eliminated together represent approximately 65% of the Company's workforce, including the Company's Chief Medical Officer and Chief Business Officer. The Company expects to substantially complete the initial restructuring efforts and record a one-time charge for severance and related expenses of approximately \$1.4 million in the first quarter of 2019.

*Additional Restructuring*—On March 14, 2019, the Board of Directors approved a further restructuring of the Company that terminated all but one of the remaining employees. The effective date of the restructuring is

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March 22, 2019. In connection with this additional restructuring, the Company intends to engage, Mr. Adam Gridley, its Chief Executive Officer, Mr. Stephen Kennedy, its Chief Operating Officer, along with up to four additional employees as consultants to assist with the continuing evaluation of strategic alternatives. The Company expects to substantially complete the second restructuring and record an additional one-time charge for severance and related expenses of approximately \$2.2 million also in the first quarter of 2019.

*Warrant Amendments*—In the first quarter of 2019, The Company and certain holders of the warrants issued in 2016 (the “Participating 2016 Holders”) entered into a Warrant Amendment and Exercise Agreement (the “2016 Exercise Agreement”) pursuant to which the Company agreed to reduce the exercise price of the warrants held by such Participating 2016 Holders from \$2.25 to \$0.01 per share (the “2016 Reduced Exercise Price”) in consideration for the exercise of the warrants held by such Participating 2016 Holders in full at the 2016 Reduced Exercise Price for cash. In connection with the exercise of the warrants by the Participating 2016 Holders, the Company received aggregate gross proceeds of approximately \$0.1 million. After the full exercise of the warrants held by the Participating 2016 Holders, warrants issued in 2016 to purchase approximately 508,714 shares of the Company’s Common Stock are outstanding.

Also in the first quarter of 2019, the Company reduced the exercise price of the warrants issued in 2018 from \$0.70 to \$0.01 per share (the “2018 Reduced Exercise Price”) and all of the holders of these warrants (the “Participating 2018 Holders”) entered into a Warrant Exercise Agreement (the “2018 Exercise Agreement”) pursuant to which in consideration for the 2018 Reduced Exercise Price, the Participating 2018 Holders agreed to exercise the warrants held by such Participating 2018 Holders in full at the 2018 Reduced Exercise Price for cash. In connection with the exercise of the warrants by the Participating 2018 Holders, the Company received aggregate gross proceeds of approximately \$0.2 million.

**HISTOGENICS CORPORATION**  
**CONSOLIDATED BALANCE SHEETS**  
(in thousands, except share and per share data)

	March 31, 2019 (Unaudited)	December 31, 2018
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 7,376	\$ 15,542
Prepaid expenses and other current assets	764	858
Total current assets	<u>8,140</u>	<u>16,400</u>
Property and equipment, net	135	141
Other assets, long-term	6,426	750
Restricted cash	137	137
Total assets	<u>\$ 14,838</u>	<u>\$ 17,428</u>
<b>LIABILITIES AND STOCKHOLDERS' DEFICIT</b>		
Current liabilities:		
Accounts payable	\$ 1,100	\$ 1,590
Accrued expenses	99	1,000
Accrued lease liability—current portion	1,118	—
Current portion of deferred rent	—	45
Current portion of deferred lease incentive	—	238
Total current liabilities:	<u>2,317</u>	<u>2,873</u>
Accrued expenses due to Intrexon Corporation	1,125	1,125
Accrued lease liability—long-term	6,918	—
Deferred revenue	10,000	10,000
Deferred rent, net of current portion	—	351
Deferred lease incentive, net of current portion	—	1,025
Warrant liability	10	2,512
Total liabilities	<u>20,370</u>	<u>17,886</u>
Commitments and contingencies (Note 5)		
Convertible preferred stock and stockholders' deficit:		
Convertible preferred stock, \$0.01 par value; 30,000 shares authorized, 400 shares issued and outstanding at March 31, 2019 and December 31, 2018	—	—
Common stock, \$0.01 par value; 100,000,000 shares authorized, 94,599,601 and 62,025,398 shares issued and outstanding at March 31, 2019 and December 31, 2018, respectively	839	513
Additional paid-in capital	219,874	215,859
Accumulated deficit	<u>(226,245)</u>	<u>(216,830)</u>
Total stockholders' deficit	<u>(5,532)</u>	<u>(458)</u>
Total liabilities and stockholders' deficit	<u>\$ 14,838</u>	<u>\$ 17,428</u>

*See accompanying notes to unaudited consolidated financial statements.*

**HISTOGENICS CORPORATION**  
**CONSOLIDATED STATEMENTS OF OPERATIONS**  
**(unaudited)**  
**(in thousands, except share and per share data)**

	<b>Three Months Ended March 31,</b>	
	<b>2019</b>	<b>2018</b>
Revenue	\$ —	\$ —
Operating expenses:		
Research and development	1,583	3,286
General and administrative	2,929	2,807
Restructuring	2,789	—
Loss on asset impairment	750	—
Total operating expenses	<u>8,051</u>	<u>6,093</u>
Loss from operations	(8,051)	(6,093)
Other income (expense):		
Interest income, net	48	37
Other expense, net	(5)	(24)
Change in fair value of warrant liability	(1,407)	(8,753)
Total other income (expense), net	<u>(1,364)</u>	<u>(8,740)</u>
Net loss	<u>\$ (9,415)</u>	<u>\$ (14,833)</u>
Comprehensive loss	<u>\$ (9,415)</u>	<u>\$ (14,833)</u>
Net loss attributable to common stockholders—basic and diluted	<u>\$ (9,394)</u>	<u>\$ (14,370)</u>
Net loss per common share—basic and diluted	<u>\$ (0.12)</u>	<u>\$ (0.52)</u>
Weighted-average shares used to compute net loss per common share—basic and diluted	<u>80,484,113</u>	<u>27,670,118</u>

*See accompanying notes to unaudited consolidated financial statements.*

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**HISTOGENICS CORPORATION**  
**CONSOLIDATED STATEMENTS OF CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' DEFICIT**  
**(unaudited)**  
**(in thousands, except share and per share amounts)**

	Series A Convertible Preferred Stock \$0.01 Par Value		Common Stock \$0.01 Par Value		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount			
Balance at December 31, 2018	400	\$ —	62,025,398	\$ 513	\$215,859	\$ (216,830)	\$ (458)
Stock-based compensation expense	—	—	—	—	107	—	107
Exercise of warrants	—	—	32,574,203	326	3,908	—	4,234
Net loss	—	—	—	—	—	(9,415)	(9,415)
Balance at March 31, 2019	<u>400</u>	<u>\$ —</u>	<u>94,599,601</u>	<u>\$ 839</u>	<u>\$219,874</u>	<u>\$ (226,245)</u>	<u>(5,532)</u>
Balance at December 31, 2017	4,605	\$ —	24,571,029	\$ 159	\$196,760	\$ (208,187)	\$ (11,268)
Stock-based compensation expense	—	—	—	—	403	—	403
Exercise of common stock options	—	—	919	—	2	—	2
Issuance of common stock—net	—	—	2,691,494	27	5,842	—	5,869
Fees related to issuance of common stock	—	—	—	—	(243)	—	(243)
Conversion of convertible preferred stock	(3,204)	—	1,423,970	—	—	—	—
Net loss	—	—	—	—	—	(14,833)	(14,833)
Balance at March 31, 2018	<u>1,401</u>	<u>\$ —</u>	<u>28,687,412</u>	<u>\$ 186</u>	<u>\$202,764</u>	<u>\$ (223,020)</u>	<u>\$ (20,070)</u>

*See accompanying notes to unaudited consolidated financial statements*

HSGX Q1-3

**HISTOGENICS CORPORATION**  
**CONSOLIDATED STATEMENTS OF CASH FLOWS**  
**(unaudited)**  
**(in thousands)**

	<b>Three Months Ended March 31,</b>	
	<b>2019</b>	<b>2018</b>
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>		
Net loss	\$ (9,415)	\$(14,833)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Depreciation	6	172
Loss on asset impairment	750	—
Deferred rent and lease incentive	—	853
Stock-based compensation	107	403
Change in fair value of warrant liability	1,407	8,753
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	94	(664)
Other assets and accrued lease obligations, net	(49)	(375)
Accounts payable	(491)	586
Accrued expenses	(901)	(1,609)
Deferred revenue	—	10,000
Net cash provided by (used in) operating activities	<u>(8,492)</u>	<u>3,286</u>
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>		
Purchases of property and equipment	—	(1,255)
Proceeds from maturities of marketable securities	—	900
Net cash used in investing activities	<u>—</u>	<u>(355)</u>
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>		
Repayments on equipment term loan	—	(133)
Net proceeds from issuance of common stock	—	5,732
Expenses incurred for at-the-market sales agreement of common stock	—	(106)
Proceeds from exercise of warrants	326	—
Proceeds from exercise of stock options	—	2
Net cash provided by financing activities	<u>326</u>	<u>5,495</u>
Net increase (decrease) in cash and cash equivalents and restricted cash	<u>(8,166)</u>	<u>8,426</u>
Cash and cash equivalents and restricted cash—Beginning of period	15,679	7,218
Cash and cash equivalents and restricted cash—End of period	<u>\$ 7,513</u>	<u>\$ 15,644</u>
<b>Reconciliation of cash, cash equivalents and restricted cash reported within the consolidated balance sheets:</b>		
Cash and cash equivalents	\$ 7,376	\$ 15,507
Restricted cash	137	137
Total cash, cash equivalents, and restricted cash at the end of period	<u>\$ 7,513</u>	<u>\$ 15,644</u>
<b>Supplemental cash flow disclosures from investing and financing activities:</b>		
Right-of-use assets and lease liability recorded upon adoption of ASC 842	\$ 6,635	\$ —
Purchases of property and equipment in accounts payable and accrued expenses	\$ —	\$ 905
Public offering costs in accounts payable	\$ —	\$ 106

*See accompanying notes to unaudited consolidated financial statements*

**HISTOGENICS CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**  
**(unaudited)**

**1. NATURE OF BUSINESS**

**Organization**

Histogenics Corporation (the “Company”) was incorporated under the laws of the Commonwealth of Massachusetts on June 28, 2000 and has its principal operations in Waltham, Massachusetts. In 2006, the Company’s board of directors approved a corporate reorganization pursuant to which the Company incorporated as a Delaware corporation. The Company historically focused on the development of restorative cell therapies (“RCTs”). RCTs refer to a new class of products that are designed to offer patients rapid-onset pain relief and restored function through the repair of damaged or worn tissue. The Company’s lead product, NeoCart<sup>®</sup>, is an innovative cell therapy designed to treat tissue injury in the field of orthopedics, specifically cartilage damage in the knee. In the third quarter of 2018, the Company announced that its Phase 3 clinical trial of NeoCart did not meet the primary endpoint in the Phase 3 clinical trial. Histogenics subsequently initiated a dialogue with the United States Food and Drug Administration (“FDA”) to discuss the regulatory path forward for NeoCart with a goal of determining whether the FDA would accept a submission of a Biologics License Application (“BLA”) for NeoCart without data from an additional Phase 3 clinical trial. In December 2018, the Company received final feedback from the FDA indicating the need for an additional Phase 3 clinical trial prior to the FDA’s acceptance of a NeoCart BLA submission. However, considering the time and funding required to conduct such a trial, the Company discontinued the development of NeoCart and is not planning to submit a BLA.

In connection with the decision to discontinue the development of NeoCart, the Company’s board of directors engaged a financial advisory firm to help explore its available strategic alternatives, including possible mergers and business combinations, a sale of part or all of its assets, and collaboration and licensing arrangements. On April 8, 2019, the Company and Ocugen, Inc. (“Ocugen”) announced entering into the Merger Agreement. Upon the terms and subject to the satisfaction of the conditions described in the Merger Agreement, including approval of the transaction by our stockholders and Ocugen’s stockholders, a wholly-owned subsidiary of the Company will be merged with and into Ocugen, with Ocugen surviving the Merger as a wholly-owned subsidiary of the Company.

The proposed Merger is structured as a stock-for-stock transaction whereby all of Ocugen’s outstanding shares of common stock and securities convertible into or exercisable for Ocugen’s common stock will be converted into the right to receive the Company’s common stock and securities convertible into or exercisable for the Company’s common stock. Under the exchange ratio formula in the Merger Agreement, the former Ocugen equity holders immediately before the Merger are expected to own approximately 90% of the outstanding capital stock of Histogenics, and the stockholders of Histogenics immediately before the Merger are expected to own approximately 10% of the outstanding capital stock of Histogenics subject to certain adjustments as described in the Merger Agreement. These adjustments include additional potential ownership based on Histogenics’ cash at the closing of the Merger (the “Closing”) after taking into account, among other things as set forth in the Merger Agreement, any Ocugen convertible notes that are not converted into equity at the Closing and proceeds from any Divestiture Transactions (as defined in the Merger Agreement), and may result in up to an additional 5% of the outstanding capital stock of Histogenics. The exchange ratio formula includes Ocugen’s outstanding stock options and warrants and Histogenics’ outstanding stock options, warrants and Series A Convertible Preferred Stock.

At the effective time of the Merger (the “Effective Time”), the Company’s board of directors is expected to consist solely of members designated by Ocugen. Following the Closing, Shankar Musunuri is expected to serve as Histogenics’ Chairman of the Board and Chief Executive Officer and Susan L. Drexler is expected to serve as the Company’s Interim Chief Financial Officer. Also at the Effective Time, the Company will effect a name change to “Ocugen, Inc.” and it is anticipated that trading for Ocugen’s securities will be listed on The Nasdaq Capital Market under the symbol “OCGN.”



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The Merger Agreement contains customary representations, warranties and covenants made by the Company and Ocugen, including covenants relating to obtaining the requisite approvals of the stockholders of the Company and Ocugen, indemnification of directors and officers, and the Company's and Ocugen's conduct of their respective businesses between the date of signing of the Merger Agreement and the Closing.

In connection with the Merger, the Company will prepare and file with the U.S. Securities and Exchange Commission ("SEC") a registration statement on Form S-4 that will contain a prospectus and a proxy statement, and will seek the approval of the Company's stockholders with respect to certain actions, including the following (collectively, the "Histogenics Stockholder Matters"):

- the Merger Agreement, including the issuance of shares of Histogenics common stock to the Ocugen's stockholders in connection with the transactions contemplated by the Merger Agreement;
- the amendment of Histogenics' restated certificate of incorporation to effect a reverse split of all outstanding shares of the Company's common stock at a reverse stock split ratio as mutually agreed to by Histogenics and Ocugen; and
- the change of control of the Company resulting from the Merger pursuant to pertinent Nasdaq rules.

The Closing is subject to satisfaction or waiver of certain conditions including, among other things, (i) the required approvals by the parties' stockholders, (ii) the accuracy of the representations and warranties, subject to certain materiality qualifications, (iii) compliance by the parties with their respective covenants, (iv) no law or order preventing the Merger and related transactions, and (v) the listing of the Shares on The Nasdaq Capital Market.

The Merger Agreement contains certain termination rights for both Histogenics and Ocugen, and further provides that, upon termination of the Merger Agreement under specified circumstances, Histogenics may be required to pay to Ocugen a termination fee of \$0.6 million or Ocugen may be required to pay to Histogenics a termination fee of \$0.7 million, and in other circumstances each party may be required to reimburse the other party's expenses incurred, up to a maximum of \$0.3 million.

In connection with the execution of the Merger Agreement, the executive officers and directors of the Company entered into voting agreements with Ocugen and Histogenics relating to the Merger covering less than one percent of the outstanding capital stock of Histogenics, as of date of the Merger Agreement (the "Histogenics Voting Agreements"). The Histogenics Voting Agreements provide, among other things, that the stockholders who are parties to the Histogenics Voting Agreements will vote all of the shares held by them in favor of Histogenics Stockholder Matters and against any competing acquisition proposals. The Histogenics Voting Agreements also place certain restrictions on the transfer of the shares of Histogenics held by the respective signatories thereto.

In connection with the execution of the Merger Agreement, certain officers, directors, stockholders and noteholders of Ocugen entered into voting agreements with Histogenics and Ocugen covering approximately 68% of the outstanding capital stock of Ocugen as of date of the Merger Agreement (the "Ocugen Voting Agreements"). The Ocugen Voting Agreements provide, among other things, that the officers, stockholders and investors party to the Ocugen Voting Agreements will vote all of the shares of Ocugen held by them in favor of the adoption of the Merger Agreement, the approval of the Merger and the other transactions contemplated by the Merger Agreement and against any competing acquisition proposals. The Ocugen Voting Agreements also place certain restrictions on the transfer of the shares of Ocugen held by the respective signatories thereto.

Concurrently with the execution of the Merger Agreement, the officers and directors of Histogenics and the officers, directors and certain stockholders of Ocugen entered into lock-up agreements, pursuant to which they accepted certain restrictions on transfers of any shares of Histogenics' common stock for the 180-day period following the Effective Time.

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Although the Company has entered into the Merger Agreement and intends to consummate the proposed Merger, there is no assurance that it will be able to successfully consummate the proposed Merger on a timely basis, or at all. If, for any reason, the proposed Merger is not completed, Histogenics will reconsider its strategic alternatives and could pursue one or more of the following courses of action:

- **Pursue potential collaborative, partnering or other strategic arrangements for our NeoCart assets, including a sale or other divestiture.** Although Histogenics has discontinued further development of the NeoCart program and does not currently have any plans to resume the development of NeoCart, the Company continues to seek potential collaborative, partnering or other strategic arrangements for the NeoCart assets, including a sale or other divestiture of such assets.
- **Pursue another strategic transaction like the proposed Merger.** The Company's board of directors may elect to pursue an alternative strategy, one of which may be a strategic transaction similar to the proposed Merger.
- **Dissolve and liquidate the Company's assets.** If, for any reason, the proposed Merger is not consummated and the Company is unable to identify and complete an alternative strategic transaction like the Merger or potential collaborative, partnering or other strategic arrangements for the NeoCart assets, the Company may be required to dissolve and liquidate its assets. In such case, Histogenics would be required to pay all of its debts and contractual obligations, and to set aside certain reserves for potential future claims, and there can be no assurances as to the amount or timing of available cash left to distribute to stockholders after paying debts and other obligations and setting aside funds for reserves.

Since its inception, the Company has devoted substantially all of its efforts to product development, recruiting management and technical staff, raising capital, starting up production and building infrastructure and has not yet generated product revenues. Expenses have primarily been for research and development and related administrative costs.

The Company is subject to a number of risks including the successful development of therapeutics, the ability to obtain adequate financing, the ability to obtain FDA approval and reimbursement for any products we may develop, protection of intellectual property, fluctuations in operating results, dependence on key personnel and collaborative partners, rapid technological changes inherent in the target markets of any products the Company may develop, the introduction of substitute products and competition from larger companies.

### **Liquidity**

The consolidated financial statements have been prepared on a going-concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. As shown in the accompanying consolidated financial statements, the Company has incurred losses and cash flow deficits from operations since inception, resulting in an accumulated deficit at March 31, 2019 of \$226.2 million. The Company has financed operations to date primarily through public and private placements of equity securities, and borrowings under debt agreements. The Company anticipates that it will continue to incur net losses for the foreseeable future. The Company believes that its existing cash, cash equivalents and marketable securities will only be sufficient to fund its projected cash needs into the middle of 2019. Accordingly, these factors, among others, raise substantial doubt about the Company's ability to continue as a going concern and its ability to complete the proposed merger with Ocugen. If Histogenics needs to raise additional capital to complete the merger, the Company would need to raise additional capital through debt or equity financing or other strategic transactions. However, any such financing may not be on favorable terms or available to the Company. The failure of the Company to obtain sufficient funds on commercially acceptable terms when needed will have a material adverse effect on the Company's business, results of operations and financial condition. The forecast of cash resources is forward-looking information that involves risks and uncertainties, and the actual amount of our expenses could vary materially and adversely as a result of a number of factors. The Company has based its

estimates on assumptions that may prove to be wrong, and the Company's expenses could prove to be significantly higher than it currently anticipates.

### **Basis of Accounting**

The consolidated financial statements are unaudited and have been prepared in conformity with accounting principles generally accepted in the United States of America ("GAAP"). However, they do not include all of the information and footnotes required by GAAP for complete financial statements. These interim consolidated financial statements, in the opinion of the Company's management, reflect all normal recurring adjustments necessary for a fair presentation of the Company's financial position and results of operations for the interim periods ended March 31, 2019 and 2018. The results of operations for the interim periods are not necessarily indicative of the results of operations to be expected for the full year. These interim financial statements should be read in conjunction with the audited financial statements as of and for the year ended December 31, 2018, and the notes thereto, which are included in the Company's Annual Report on Form 10-K, filed with the Securities and Exchange Commission (the "SEC") on March 22, 2019.

The consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries, ProChon and Histogenics Securities Corporation. All significant intercompany accounts and transactions are eliminated in consolidation.

## **2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

During the three months ended March 31, 2019, there have been no material changes to the significant accounting policies described in the Company's audited financial statements as of and for the year ended December 31, 2018, and the notes thereto, which are included in the Annual Report on Form 10-K, except as noted below.

### **Recently Adopted Accounting Standards - Leases**

The Company adopted Financial Accounting Standards Board Accounting Standards Update No. 2016-02, Leases (Topic 842) on January 1, 2019, using the alternative modified transition method, which requires a cumulative-effect adjustment, if any, to the opening balance of retained earnings to be recognized on the date of adoption with no restatement of prior periods not restated. There was no cumulative-effect adjustment recorded on January 1, 2019. Please see Note 5 – Commitments and Contingencies for a description of the Company's Leases and related impact on the financial statements.

The Company elected the following practical expedients when assessing the transition impact of the new standard from both the lessee and lessor perspective and did not: (i) reassess whether any expired or existing contracts as of January 1, 2019, are or contain leases; (ii) reassess the lease classification for any expired or existing leases as of January 1, 2019; (iii) reassess initial direct costs for any existing leases as of January 1, 2019; and (iv) reassess whether land easements meet the definition of a lease. The primary impact was the balance sheet recognition of right-of-use ("ROU") assets which is included in Other assets and lease liabilities for operating leases as a lessee.

### **Fair Value Measurements**

The carrying amounts reported in the Company's consolidated financial statements for cash and cash equivalents, accounts payable, and accrued liabilities approximate their respective fair values because of the short-term nature of these accounts.

Fair value is defined as the price that would be received if selling an asset or paid to transfer a liability in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date.

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Additionally, from time to time, the Company may be required to record at fair value other assets on a nonrecurring basis, such as assets held for sale and certain other assets. These nonrecurring fair value adjustments typically involve the application of lower-of-cost-or-market accounting or write-downs of individual assets.

The fair value hierarchy gives the highest priority to unadjusted quoted prices in active markets for identical assets (Level 1), and the lowest priority to unobservable inputs (Level 3). The Company's financial assets are classified within the fair value hierarchy based on the lowest level of inputs that is significant to the fair value measurement. The three levels of the fair value hierarchy, and their applicability to the Company's financial assets, are described below.

*Level 1* : Unadjusted quoted prices in active markets that are accessible at the measurement date of identical, unrestricted assets.

*Level 2* : Quoted prices for similar assets, or inputs that are observable, either directly or indirectly, for substantially the full term through corroboration with observable market data. Level 2 includes investments valued at quoted prices adjusted for legal or contractual restrictions specific to the security.

*Level 3* : Pricing inputs are unobservable for the assets. Level 3 assets include private investments that are supported by little or no market activity. Level 3 valuations are for instruments that are not traded in active markets or are subject to transfer restrictions and may be adjusted to reflect illiquidity and/or non-transferability, with such adjustment generally based on available market evidence. In the absence of such evidence, management's best estimate is used.

An adjustment to the pricing method used within either Level 1 or Level 2 inputs could generate a fair value measurement that effectively falls in a lower level in the hierarchy. The Company had no material re-measurements of fair value with respect to financial assets and liabilities, during the periods presented, other than those assets and liabilities that are measured at fair value on a recurring basis. At March 31, 2019, the only assets or liabilities classified as Level 3 were the outstanding warrants issued in connection with the private placement transaction which closed on September 29, 2016. At December 31, 2018 the Company's only assets or liabilities classified as level 3 were the warrants issued in connection with the September 2016 private placement and the October 2018 underwritten public offering. Transfers are calculated using values as of the transfer date. There were no transfers between Levels 1, 2 and 3 during the three months ended March 31, 2019 and the twelve months ended December 31, 2018.

The fair value of the warrants issued in connection with the September 2016 private placement was determined using a Monte Carlo simulation model. This model incorporated several assumptions at each valuation date including: the price of the Company's common stock on the date of valuation, the historical volatility of the price of the Company's common stock, the remaining contractual term of the warrant and estimates of the probability of a fundamental transaction occurring. The fair value of the warrants issued in connection with the October 2018 underwritten public offering was determined using the Black Scholes model. See Note 6, Capital Stock, for further discussion of the private placement and underwritten public offering.

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The Company's financial instruments as of March 31, 2019 and December 31, 2018 consisted primarily of cash and cash equivalents and warrant liability. As of March 31, 2019, and December 31, 2018, the Company's financial assets recognized at fair value consisted of the following:

<u>Description</u>	<u>Total</u>	<u>Quoted prices in active markets (Level 1)</u>	<u>Significant other observable inputs (Level 2)</u>	<u>Significant unobservable inputs (Level 3)</u>
(in thousands)				
<b>March 31, 2019</b>				
<b>Assets:</b>				
Cash Equivalents				
Money market funds	<u>\$4,747</u>	<u>\$ 4,747</u>	<u>\$ —</u>	<u>\$ —</u>
<b>Liabilities:</b>				
Warrant liability	<u>\$ 10</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 10</u>
<b>December 31, 2018</b>				
<b>Assets:</b>				
Cash Equivalents				
Money market funds	<u>\$9,711</u>	<u>\$ 9,711</u>	<u>\$ —</u>	<u>\$ —</u>
<b>Liabilities:</b>				
Warrant liability	<u>\$2,512</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 2,512</u>

The following table provides a reconciliation of all liabilities measured at fair value using Level 3 significant unobservable inputs:

	<u>March 31, 2019</u>
	(in thousands)
Beginning balance, December 31, 2018	\$ 2,512
Exercise of warrants	(1,095)
Change in fair value of warrant liability	(1,407)
Ending balance	<u>\$ 10</u>

### **Cash and Cash Equivalents**

The Company considers all highly liquid securities with original maturities of three months or less from the date of purchase to be cash equivalents. Cash and cash equivalents are comprised of funds in money market accounts. In addition, the Company has recorded restricted cash of \$0.1 million as of March 31, 2019 and December 31, 2018. Restricted cash consists of a security deposit related to a lease obligation.

### **Revenue Recognition**

In May 2014, the Financial Accounting Standards Board (the "FASB") issued a new standard related to revenue recognition, Accounting Standard Update ("ASU") No. 2014-09, Revenue from Contracts with Customers. This new accounting standard will replace most current U.S. GAAP guidance on this topic and eliminate most industry-specific guidance. It provides a unified model to determine when and how revenue is recognized. The core principle is that an entity should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration for which the entity expects to be entitled in exchange for those goods or services. Entities may adopt the new standard either retrospectively to all periods presented in the financial statements (the full retrospective method) or as a cumulative-effect adjustment as of the date of adoption (modified retrospective method) in the year of adoption without applying to comparative years'

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financial statements. Further, in August 2015, the FASB issued ASU No. 2015-14, Revenue from Contracts with Customers: Deferral of the Effective Date, to defer the effective adoption date by one year to December 15, 2017 for annual reporting periods beginning after that date and permitted early adoption of the standard, but not before fiscal years beginning after the original effective date of December 15, 2016. The Company elected to early adopt the guidance in 2017 using the modified retrospective method. There was no cumulative impact due to the adoption of this standard.

Revenue is recognized when, or as, performance obligations are satisfied, which occurs when control of the promised products or services is transferred to customers. Revenue is measured as the amount of consideration the Company expects to receive in exchange for transferring products or services to a customer ("transaction price"). To the extent that the transaction price includes variable consideration, the Company estimates the amount of variable consideration that should be included in the transaction price utilizing the most likely amount method. Variable consideration is included in the transaction price if, in the Company's judgment, it is probable that a significant future reversal of cumulative revenue under the contract will not occur. Estimates of variable consideration and determination of whether to include estimated amounts in the transaction price are based largely on an assessment of the Company's anticipated performance and all information (historical, current and forecasted) that is reasonably available.

If the contract contains a single performance obligation, the entire transaction price is allocated to the single performance obligation. Contracts that contain multiple performance obligations require an allocation of the transaction price to each performance obligation based on a relative standalone selling price basis unless the transaction price is variable and meets the criteria to be allocated entirely to a performance obligation or to a distinct service that forms part of a single performance obligation. The Company currently generates revenue primarily through collaborative research, development and commercialization agreements. The terms of these agreements may contain multiple promises which may include: (i) licenses to the Company's technology; (ii) services related to the transfer and update of know-how; and (iii) manufacturing supply services. Payments to the Company under these arrangements typically include one or more of the following: non-refundable upfront license fees; milestone payments; royalties on future product sales; and fees for manufacturing supply services. None of the Company's contracts as of March 31, 2019 contained a significant financing component.

The Company assesses the promises to determine if they are distinct performance obligations. Once the performance obligations are determined, the transaction price is allocated based on a relative standalone selling price basis. Milestone payments and royalties are typically considered variable consideration at the outset of the contract and are recognized in the transaction price either upon occurrence or when the constraint of a probable reversal is no longer applicable.

### *Collaboration Revenue*

While no revenue has been recognized as of March 31, 2018, the Company has collaboration and license agreements with strategic partners for the development and commercialization of product candidates. The collaboration and license agreements are within the scope of Accounting Standards Codification (ASC 606) Revenue from Contracts with Customers.

In determining the appropriate amount of revenue to be recognized as it fulfills its obligations under the agreements, the Company performs the following steps: (i) identification of the promised goods or services in the contract; (ii) determination of whether the promised goods or services are performance obligations including whether they are distinct in the context of the contract; (iii) measurement of the transaction price, including the constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations; and (v) recognition of revenue when (or as) the Company satisfies each performance obligation. As part of the accounting for the arrangement, the Company must develop assumptions that require judgment to determine the stand-alone selling price for each performance obligation identified in the contract. The Company uses key assumptions to determine the stand-alone selling price, which may include market conditions, reimbursement rates for personnel costs, development timelines and probabilities of regulatory success.

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*Licenses of intellectual property:* If the license to the Company's intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, the Company recognizes revenues from non-refundable, up-front fees allocated to the license when the license is transferred to the customer and the customer is able to use and benefit from the license. For licenses that are bundled with other promises, the Company utilizes judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue from non-refundable, up-front fees. The Company evaluates the measure of progress each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition.

*Manufacturing Supply Services:* If the promise to supply products for clinical and/or commercial development are determined to be distinct from the other performance obligations identified in the arrangement, the Company recognizes revenues from the fees allocated to the supply when or as the supply is transferred to the customer, generally upon delivery to the customer. If the promise to supply products for clinical and/or commercial development are not determined to be distinct from the other performance obligations identified in the arrangement, the Company utilizes judgement to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue , including amounts from non-refundable, up-front fees. The Company evaluates the measure of progress each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition.

*Milestone Payments:* At the inception of each arrangement that includes developmental and regulatory milestone payments, the Company evaluates whether the achievement of each milestone specifically relates to the Company's efforts to satisfy a performance obligation or transfer a distinct good or service within a performance obligation. If the achievement of a milestone is considered a direct result of the Company's efforts to satisfy a performance obligation or transfer a distinct good or service and the receipt of the payment is based upon the achievement of the milestone, the associated milestone value is allocated to that distinct good or service and revenue is recognized in the period in which the milestone is achieved. If the milestone payment is not specifically related to the Company's effort to satisfy a performance obligation or transfer a distinct good or service, the Company evaluates the milestone to determine whether the milestone is considered probable of being reached and estimates the amount to be included in the transaction price using either the most likely amount or the expected value method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price to be allocated. At the end of each subsequent reporting period, the Company re-evaluates the probability of achievement of such development milestones and any related constraint, and if necessary, adjusts its estimate of the overall allocation. Any such adjustments are recorded on a cumulative catch-up basis, which would affect license, collaboration and other revenues and earnings in the period of adjustment.

*Royalties:* For arrangements that include sales-based or usage-based royalties, including milestone payments based on the level of sales, and the license is deemed to be the predominant item to which the royalties relate, the Company will recognize revenue at the later of: (i) when the related sales occur; or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied).

### **License and Collaboration Arrangements**

#### ***MEDINET Co., Ltd.***

In December 2017, the Company entered into a License and Commercialization Agreement (the "License Agreement") with MEDINET Co., Ltd. ("MEDINET") to grant MEDINET a license under certain patents, patent applications, know-how, and technology to develop and commercialize certain therapeutic products to replace or repair damaged, worn, or defective cartilage in humans and non-human animals.

In exchange for the license, MEDINET agreed to pay the Company an upfront cash payment of \$10.0 million which the Company received in January 2018. As of March 31, 2019, the contract with MEDINET was wholly

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unperformed and all revenue under the License Agreement has been deferred and has not been recognized. As of March 31, 2019, the aggregate amount of the transaction price allocated to remaining performance obligations was \$10.0 million. Because the License Agreement was not terminated as of March 31, 2019, the authoritative accounting literature requires that the \$10.0 million of deferred revenue remain a liability on the Company's balance sheet. The Company anticipates that MEDINET will terminate the License Agreement in 2019 resulting in the recognition of the \$10 million of deferred revenue in the period of termination.

MEDINET also agreed to pay the Company tiered royalties, at percentages ranging from the low single digits to low double digits, of net sales of MEDINET products governed by the License Agreement. Over the life of the License Agreement, the Company is eligible to receive up to ¥330 million (\$2.9 million as of March 31, 2019) in development milestone payments, \$1.0 million and ¥720 million (\$7.4 million as of March 31, 2019) in regulatory payments and up to an aggregate of ¥7,300 million (\$64.1 million as of March 31, 2019) for the achievement of certain commercial milestones related to the sales of MEDINET products governed by the License Agreement.

As a condition of the License Agreement, the Company agreed to supply NeoCart for MEDINET's planned Phase 3 clinical trial in Japan. The Company assessed its promised goods and services under the License Agreement to determine if they are distinct. Due to the unique nature of the clinical manufacturing services to be provided by the Company, there are currently no other third-party vendors from which MEDINET can obtain such supply. The Company expected to be the only vendor capable of providing the manufacturing services for a period of at least one to two years, which is approximately the estimated length of time for the Japanese clinical trial period. After this point, if the Company were to transfer to a third-party its technology and know-how related to the manufacturing services, the third-party vendor would be capable of providing the commercial manufacturing services, and therefore MEDINET would be able to choose whether to utilize the Company for such services or another vendor. The Company determined that MEDINET's option to obtain commercial manufacturing services does not represent a material right, as the fees charged to MEDINET by the Company are expected to approximate the fair market value for manufacturing services. As noted, with the assistance of the Company, third-party vendors could have the capability to perform commercial manufacturing services by this time, and the Company expects the contract value to approximate the market price. Due to MEDINET's limitations in obtaining the clinical manufacturing services from a third-party, as well as MEDINET's limited ability to obtain the benefits of the licensed intellectual property without the clinical manufacturing services, the licensed intellectual property and clinical manufacturing services are determined to be a combined performance obligation. Based on this assessment, the Company determined that the promised goods and services do not have standalone value and are highly interrelated. Accordingly, the promised goods and services represent one performance obligation.

Based on the assessment of the combined performance obligation, the Company determined that the predominant promise in the arrangement is the transfer of the license and associated manufacturing know-how expected to occur over the length of the clinical trial. The Company determined that MEDINET will be simultaneously receiving and consuming the benefits of the Company's performance related to the supply of the clinical trial. Therefore, the revenue associated with the combined performance obligation will be recognized over time.

In determining the correct measure of progress to use when recognizing revenue over time, the Company assessed whether an input- or output- based measure of progress would be appropriate. The Company determined that an output-based measure of progress would be appropriate to use when recognizing revenue associated with the combined performance obligation and intended to recognize revenue under the License Agreement as the clinical manufacturing services were performed.

Revenue was to be recognized using the output method over the length of the clinical trial enrollment, as the clinical manufacturing services were delivered, over the estimated service period. Upon the conclusion of the clinical manufacturing period, the Company would have expected other third-party vendors to have the capabilities to provide similar services. At this point, the license would effectively become a distinct performance



obligation, with no remaining undelivered obligations. Therefore, the Company determined that the up-front payment associated with the licensed intellectual property should be fully recognized by the conclusion of the clinical manufacturing service period.

At contract inception, the Company determined that the \$10.0 million non-refundable upfront amount constituted the entirety of the consideration to be included in the transaction price as the development, regulatory, and commercial milestones represent variable consideration and were fully constrained. As part of its evaluation of the constraint, the Company considered numerous factors, including that receipt of the milestones is outside the control of the Company and contingent upon success in future clinical trials and the licensees' efforts. Any consideration related to sales-based milestones (including royalties) will be recognized when the related sales occur. The Company re-evaluates the transaction price in each reporting period and as uncertain events are resolved or other changes in circumstances occur. The Company also determined that consideration associated with the clinical trials, which are payable by MEDINET on per-patient basis represent variable consideration, will be included in the transaction price upon occurrence, or once the associated clinical manufacturing service(s) for the patient are concluded.

The Company incurred cost of \$0.9 million related to the License Agreement with MEDINET. \$0.8 million was recorded as an asset that was to be expensed proportionally over the performance service period. However, given the Company's decision to discontinue the development of NeoCart and terminate its manufacturing operations, the Company concluded that the asset was impaired and a decision was made to write down the value of this asset to \$0 in the first quarter of 2019. This impairment resulted in a charge to the income statement of \$0.8 million.

### **Stock-Based Compensation**

The Company accounts for stock options and restricted stock based on their grant date fair value and recognizes compensation expense on a straight-line basis over their vesting period. The Company estimates the fair value of stock options as of the date of grant using the Black-Scholes option pricing model, with the exception of stock options that include a market condition, and restricted stock based on the fair value of the underlying common stock as of the date of grant or the value of the services provided, whichever is more readily determinable. The Company, in conjunction with adoption of ASU 2016-09- Stock Compensation: Improvements to Employee Share-Based Payment Accounting has elected to estimate forfeitures at the time of grant, and revise those estimates in subsequent periods if actual forfeitures differ from its estimates. The Company uses historical data to estimate pre-vesting option forfeitures and records stock-based compensation expense only for those awards that are expected to vest. To the extent that actual forfeitures differ from the Company's estimates, the differences are recorded as a cumulative adjustment in the period the estimates were revised. Stock-based compensation expense is classified as research and development or general and administrative based on the grantee's respective compensation classification.

For stock option grants with vesting triggered by the achievement of performance-based milestones, the expense is recorded over the remaining service period after the point when the achievement of the milestone is probable or the performance condition has been achieved. For stock option grants with both performance-based milestones and market conditions, expense is recorded over the derived service period after the point when the achievement of the performance-based milestone is probable or the performance condition has been achieved. For stock option grants with market conditions, the expense is calculated using the Monte Carlo model based on the grant date fair value of the option and is recorded on a straight line basis over the requisite service period, which represents the derived service period and accelerated when the market condition is satisfied. The Company did not issue awards with market conditions during the three months ended March 31, 2019. The Company accounts for stock options and restricted stock awards to non-employees using the fair value approach. Stock options and restricted stock awards to non-employees are subject to periodic revaluation over their vesting terms.

### **Warrant Accounting**

As noted in Note 6, Capital Stock, the Company classifies a warrant to purchase shares of its common stock as a liability on its consolidated balance sheet if the warrant is a free-standing financial instrument that may require the Company to transfer consideration upon exercise. Each warrant of this type is initially recorded at fair value on date of grant using the Monte Carlo simulation model net of issuance costs, and is subsequently re-measured to fair value at each subsequent balance sheet date. Changes in fair value of the warrant are recognized as a component of other income (expense), net in the consolidated statement of operations and comprehensive loss. The Company will continue to adjust the liability for changes in fair value until the earlier of the exercise or expiration of the warrant.

### **Recent Accounting Pronouncements**

In November 2018, the FASB issued ASU No. 2018-18, Collaborative Arrangements (Topic 808): Clarifying the Interaction between Topic 808 and Topic 606. The amendments in this update provide guidance on whether certain transactions between collaborative arrangement participants should be accounted for with revenue under Topic 606. The guidance also provides more comparability in the presentation of revenue for certain transactions between collaborative arrangement participants. For public business entities, the amendments in this update are effective for fiscal years and interim periods within those fiscal years, beginning after December 15, 2019. Early adoption is permitted, including adoption in any interim period, for public business entities for periods for which financial statements have not yet been issued. The Company is currently evaluating the impact that the adoption of this guidance will have on the Company's consolidated financial statements and related disclosures.

In August 2018, the FASB issued ASU No. 2018-13, Fair Value Measurement (Topic 820): Changes to the Disclosure Requirements for Fair Value Measurement. The amendments in this update modify the disclosure requirements on fair value measurements based on the concepts in the Concepts Statement, including the consideration of costs and benefits. The amendments in this update are effective for all entities for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2019 with early adoption permitted upon issuance of this Update. The Company is currently evaluating the impact that the adoption of this guidance will have on the Company's consolidated financial statements and related disclosures.

In August 2018, the SEC adopted the final rule under SEC Release No. 33-10532, Disclosure Update and Simplification. This final rule amends certain disclosure requirements that are redundant, duplicative, overlapping, outdated or superseded. In addition, the amendments expand the disclosure requirements on the analysis of stockholders' equity for interim financial statements. Under the amendments, an analysis of changes in each caption of stockholders' equity presented in the balance sheet must be provided in a note or separate statement. The analysis should present a reconciliation of the beginning balance to the ending balance of each period for which a statement of comprehensive income is required to be filed. This final rule is effective for the Company for all filings made on or after November 5, 2018. The SEC staff clarified that the first presentation of the changes in shareholders' equity may be included in the first Form 10-Q for the quarter that begins after the effective date of the amendments. The adoption of the final rule did not have a material impact on the Company's consolidated financial statements.

In June 2018, the FASB issued ASU No. 2018-07, Compensation-Stock Compensation (Topic 718): Improvements to Nonemployee Share- Based Payment Accounting. This update is to simplify the aspects of accounting for nonemployee share-based payment transactions for acquiring goods or services from nonemployees. The amendments in this update are effective for fiscal years beginning after December 15, 2018, including interim periods within that year. The Company has concluded that this guidance has no material impact on the Company's consolidated financial statements and related disclosures.

### **3. LOSS PER COMMON SHARE**

The Company computes basic and diluted loss per share using a methodology that gives effect to the impact of outstanding participating securities (the "two-class method"). For the three months ended March 31, 2019 and

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2018, there was dilution attributed to the weighted-average shares outstanding in the calculation of diluted loss per share.

	Three Months Ended March 31,	
	2019	2018
(In thousands, except share and per share data)		
Numerator:		
Net loss	\$ (9,415)	\$ (14,833)
Net loss attributable to Series A Preferred Stock (a)	(21)	(463)
Income attributable to common stockholders—basic and diluted	<u>\$ (9,394)</u>	<u>\$ (14,370)</u>
Denominator:		
Weighted-average number of common shares used in loss per share—basic and diluted	<u>80,484,113</u>	<u>27,670,118</u>
Loss per share - basic and diluted	<u>\$ (0.12)</u>	<u>\$ (0.52)</u>

(a) The Series A Preferred Stock participates in income and losses.

The following potentially dilutive securities have been excluded from the computation of diluted weighted-average shares outstanding, as they would be anti-dilutive (in common stock equivalent shares):

	Three Months Ended March 31,	
	2019	2018
Unvested restricted stock and options to purchase common stock	1,803,167	3,101,143
Series A Preferred Stock unconverted	177,996	622,987
Warrants exercisable into common stock	571,025	13,633,070

## 4. PROPERTY AND EQUIPMENT

Property and equipment consisted of the following:

	March 31,	December 31,
	2019	2018
(in thousands)		
Office equipment	\$ 233	\$ 266
Laboratory equipment	4,536	4,561
Leasehold improvements	5,383	5,504
Software	96	96
Total property and equipment	10,248	10,427
Less: accumulated depreciation	(10,113)	(10,286)
Property and equipment, net	<u>\$ 135</u>	<u>\$ 141</u>

Depreciation expense related to property and equipment amounted to less than \$0.1 million and \$0.2 million for the three months ended March 31, 2019 and 2018, respectively.

## 5. COMMITMENTS AND CONTINGENCIES

### Leases

The Company leases its office and research facilities in Waltham and Lexington, Massachusetts under non-cancellable operating leases. The Lexington, Massachusetts facility lease expires in June 2023. The

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Waltham, Massachusetts facility lease was extended in April 2017. The effective date of the extension is January 2018. Under the terms of the extension, the lease will expire in December 2024 with one extension term of five years. Terms of the agreements generally provide for an initial rent-free period and future rent escalation and provide that in addition to minimum lease rental payments, the Company is responsible for a pro-rata share of common area operating expenses. Rent expense under operating lease agreements amounted to approximately \$0.4 million for each of the three months ended March 31, 2019 and 2018.

In evaluating any potential accounting for leases, the Company determines if an arrangement contains a lease at inception. For arrangements where the Company is the lessee, operating leases are included in other assets, net; other accrued liabilities; and other long-term liabilities on the Consolidated Balance Sheet. Operating lease ROU assets and operating lease liabilities are recognized based on the present value of the future minimum lease payments over the lease term at the commencement date. ROU assets also include any initial direct costs incurred and any lease payments made at or before the lease commencement date, less lease incentives received. The Company uses its incremental borrowing rate based on the information available at the commencement date in determining the lease liabilities as the Company's leases generally do not provide an implicit rate. Lease terms may include options to extend or terminate when the Company is reasonably certain that the option will be exercised. Lease expense is recognized on a straight-line basis over the lease term. The Company also has lease arrangements with lease and non-lease components. The Company elected the practical expedient not to separate non-lease components from lease components for the Company's real estate leases.

Operating lease expense was \$0.4 million for the three months ended March 31, 2019. Variable executory cost was \$0.3 million for the three months ended March 31, 2019. The following table contains supplemental cash flow information related to operating leases as of March 31, 2019.

	<b>(in thousands)</b>
Cash paid within operating cash flows	\$ 459
Right-of-use assets recognized in exchange for new lease obligations	—

The following table contains supplemental balance sheet information related to operating leases, as of March 31, 2019.

	<b>(in thousands)</b>
Other assets, net (Right-of-use assets)	\$ 6,426
Accrued lease liability, current	1,118
Accrued lease liability, long-term	6,918
Total lease liabilities	<u>\$ 8,036</u>
Weighted average remaining lease term	5.3 years
Weighted average discount rate	10%

The Company deemed restructurings in the first quarter of 2019 to be a triggering event that necessitated an evaluation of a potential impairment to the ROU asset related to the Company's operating leases. Based on the analysis performed no impairment was necessary.

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Maturities of the Company's operating lease liabilities as of March 31, 2019 are summarized in the table below.

<u>Year</u>	<u>Amount</u> <u>(in thousands)</u>
2019	\$ 1,385
2020	1,892
2021	1,941
2022	1,991
2023	1,729
2024 and after	1,460
Total lease payments	10,398
Less: imputed interest	(2,362)
Total operating lease liabilities	<u>\$ 8,036</u>

### **License Agreements**

From time to time, the Company enters into various licensing agreements whereby the Company may use certain technologies in conjunction with its product research and development. Licensing agreements and the Company's commitments under the agreements are as follows:

#### *Hydrogel License*

In May 2005, the Company entered into an exclusive license agreement with Angiotech Pharmaceuticals (US), Inc. for the use of certain patents, patent applications, and knowledge related to the manufacture and use of a hydrogel material in conjunction with NeoCart and certain other products ("Hydrogel License Agreement"). As of March 31, 2019, the Company has paid an aggregate \$3.2 million in commercialization milestones under the terms of the Hydrogel License Agreement, which have been expensed to research and development.

Under the terms of the Hydrogel License Agreement, the Company's future commitments include:

- A one-time \$3.0 million payment upon approval of an eligible product by the FDA; and
- Single digit royalties on the net sales of NeoCart and certain other future products.

#### *Tissue Regeneration License*

In April 2001, the Company entered into an exclusive license agreement with The Board of Trustees of the Leland Stanford Junior University ("Stanford University") for the use of certain technology to develop, manufacture and sell licensed products in the field of growth and regeneration of cartilage ("Tissue Regeneration License Agreement"). The term of the Tissue Regeneration License Agreement extends to the expiration date of Stanford University's last to expire domestic or foreign patents. As of March 31, 2019, the Company has paid an aggregate \$0.8 million in patent reimbursement costs, royalty fees, and commercialization milestone payments under the terms of the Tissue Regeneration License Agreement, which have been recorded to research and development expense.

Under the terms of the Tissue Regeneration License Agreement, the Company's future commitments include:

- A one-time \$0.3 million payment upon approval of an eligible product by the FDA;
- An annual minimum non-refundable royalty fee of \$10 thousand for the life of the license that may be used to offset up to 50% of the earned royalty below; and
- Low single digit royalties on net sales.

### *Tissue Processor Sub-License*

In December 2005, the Company entered into an exclusive agreement to sub-license certain technology from Purpose, Co. (“Purpose”), which is owned by a stockholder of the Company (“Sub-License Agreement”). Purpose entered into the original license agreement (“Original Agreement”) with Brigham and Women’s Hospital, Inc. (“Brigham and Women’s”) in August 2001. The Original Agreement shall remain in effect for the term of the licensed patents owned by Brigham and Women’s unless extended or terminated as provided for in the agreement. The technology is to be used to develop, manufacture, use and sell licensed products that cultivate cell or tissue development. The Sub-License Agreement extends to the expiration date of the last to expire domestic or foreign patents covered by the agreement. As of March 31, 2019, the Company has paid an aggregate \$0.7 million in royalty and sub-license payments under the terms of the Sub-License Agreement.

The Sub-License Agreement was amended and restated in June 2012. Under the amended and restated agreement, the Company made Purpose the sole supplier of equipment the Company uses in its manufacturing processes and granted Purpose distribution rights of the Company’s products for certain territories. In exchange, Purpose allowed for the use of its technology (owned or licensed) and manufactured and serviced exogenous tissue processors used by the Company. Under the terms of the agreement, as amended, Purpose granted the Company: (a) exclusive rights to all of Purpose’s technology (owned or licensed) related to the exogenous tissue processors, (b) continued supply of exogenous tissue processors during the Company’s clinical trials, and (c) rights to manufacture the exogenous tissue processors at any location the Company chooses. In exchange for such consideration, the Company granted Purpose an exclusive license in Japan for the use of all of the Company’s technology and made a payment of \$0.3 million to reimburse Purpose for development costs on a next generation tissue processor.

In May 2016, the Original Agreement was amended whereby the Company acquired the development and commercialization rights to NeoCart for the Japanese market from Purpose. Under the terms of the amended agreement, the Company assumes sole responsibility for and rights to the development and commercialization of NeoCart in Japan. In exchange for the transfer of development and commercialization rights, the Company will pay a success-based milestone to Purpose upon conditional approval of NeoCart in Japan, as well as commercial milestones and a low single digit royalty on Japanese sales of NeoCart, upon full approval, if any, in Japan.

In addition to the above, the Company’s future commitments under the terms of the Original Agreement and Sub-License Agreement include:

- A minimum non-refundable annual royalty fee of \$20 thousand, for the life of the license;
- An additional, non-refundable annual royalty fee of \$30 thousand from 2016 through 2019;
- \$10.2 million in potential milestone payments; and
- Low single digit royalties on net sales of a licensed product.

## **6. CAPITAL STOCK**

In October 2018, the Company closed an underwritten public offering of 26,155,000 shares of its common stock and warrants to purchase up to 19,616,250 shares of common stock, at a combined purchase price of \$0.65 per share of common stock and accompanying warrant. The gross proceeds to the Company from this offering were \$17.0 million, before deducting underwriting discounts and commissions, and offering expenses payable by the Company. The warrants were exercisable immediately upon issuance at a price of \$0.70 per share of common stock and have a term of five years commencing on the date of issuance. The exercise price of the warrants was subject to adjustment upon the occurrence of specific events, including stock dividends, stock splits, combinations and reclassifications of the Company’s Common Stock. In the event of certain fundamental transactions of the Company, a warrant holder may have demanded redemption of its warrant for cash in accordance with a Black-Scholes option pricing model. A fundamental transaction was defined as a merger, sale

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of assets, sale of the Company, recapitalization of stock and a sale of stock whereby any owner after the transaction would own greater than 50% of the outstanding common stock in the Company. The Company determined the warrants were classified as a liability on the consolidated balance sheet because of the provision whereby in a fundamental transaction (as described above), the holder could have elected to receive either the amount they were entitled to on an as-if-exercised basis or an amount based on the Black-Scholes value of the warrants at the time of the fundamental transaction. At the issuance date, the warrants were recorded at the fair value of \$8.4 million.

In three months ended March 31, 2019, the Company reduced the exercise price of the warrants issued in 2018 from \$0.70 to \$0.01 per share (the “2018 Reduced Exercise Price”) and all of the holders of these warrants (the “Participating 2018 Holders”) entered into a Warrant Exercise Agreement (the “2018 Exercise Agreement”) pursuant to which, in consideration for the 2018 Reduced Exercise Price, the Participating 2018 Holders agreed to exercise the warrants held by such Participating 2018 Holders in full at the 2018 Reduced Exercise Price for cash. In connection with the exercise of the warrants by the Participating 2018 Holders, the Company received aggregate gross proceeds of approximately \$0.2 million.

In March 2018, the Company entered into an equity distribution agreement (“ATM Agreement”) with Canaccord Genuity Inc. (“Canaccord”), pursuant to which the Company may, from time to time, sell shares of its common stock having an aggregate offering price of up to up to \$10.0 million (the “Shares”) through Canaccord, as sales agent. The Shares will be offered and sold by the Company pursuant to its previously filed and currently effective Registration Statement on Form S-3 (Reg. No. 333-216741) (the “Registration Statement”). The Shares may only be offered and sold by means of a prospectus, including a prospectus supplement, forming part of the effective Registration Statement. Sales of the common stock, if any, will be made at market prices by methods deemed to be an “at the market offering” as defined in Rule 415 promulgated under the Securities Act of 1933, as amended (the “Securities Act”), including sales made directly on The Nasdaq Capital Market, on any other existing trading market for the common stock, or to or through a market maker other than on an exchange. There were no sales of common stock under the ATM Agreement during the three months ended March 31, 2019 and March 31, 2018.

In January 2018, the Company completed an underwritten registered direct offering of 2,691,494 shares of common stock at a price of \$2.35 per share. The total net proceeds of the offering were \$5.7 million after deducting underwriter’s discounts and commissions, and expenses related to the offering.

In September 2016, the Company closed the private placement contemplated by the securities purchase agreement (the “Purchase Agreement”), dated September 15, 2016, between the Company and certain institutional and accredited investors in which the Company received gross proceeds of \$30.0 million (the “Private Placement”). The net proceeds after deducting placement agent fees and other transaction-related expenses was \$27.6 million. At the closing, the Company issued 2,596,059 shares of the Company’s common stock at a per share price of \$2.25 and 24,158.8693 shares of the Company’s newly-created Series A Convertible Preferred Stock (“Series A Preferred Stock”), which are convertible into approximately 10,737,275 shares of common stock. As of March 31, 2019, there were 400.4910 shares of Series A Preferred Stock outstanding, which remain convertible into 177,996 shares of the Company’s common stock. As part of the Private Placement, the investors received warrants to purchase up to 13,333,334 shares of the Company’s common stock at an exercise price of \$2.25 per share. The placement agent for the Private Placement, H.C. Wainwright & Co. LLC (“HCW”), and certain of its affiliates were also granted warrants to purchase 133,333 shares of the Company’s common stock at an exercise price of \$2.25 per share in exchange for the services provided by HCW. The placement agent warrants were considered a financing cost of the Company and included in warrant expense within the consolidated statements of operations.

The warrants include a cashless-exercise feature that may be exercised solely in the event there is no effective registration statement, or no current prospectus available for, the resale of the shares of common stock underlying the warrants as of the six-month anniversary of the closing of the Private Placement. Upon a fundamental transaction, the holders of the warrant may require the Company to purchase any unexercised warrants in an

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amount equal to the Black-Scholes value of the option. A fundamental transaction is defined as a merger, sale of assets, sale of the Company, recapitalization of stock and a sale of stock whereby any owner after the transaction would own greater than 50% of the outstanding common stock in the Company. The warrants became exercisable following approval of the Private Placement by our stockholders in the fourth quarter of 2016 and expire five years after the date of such stockholder approval. The Company determined the warrants are classified as a liability on the consolidated balance sheet because they contain a provision whereby in a fundamental transaction (as described above), the holder can elect to receive either the amount they are entitled to on an as-if-exercised basis or an amount based on the Black-Scholes value of the warrants at the time of the fundamental transaction. At the issuance date, the warrants were recorded at the fair value of \$30.7 million.

Concurrent with the closing of the Private Placement, the Company's Certificate of Incorporation was amended by the filing of a Certificate of Designation to create the Series A Preferred Stock. The Series A Preferred Stock has a par value of \$0.01 and each share is convertible into 444.44 shares of common stock, at a conversion price of \$2.25 per share, at the option of the holder. The Series A Preferred Stock has no voting rights and is only entitled to dividends as declared on an as-converted basis. The Series A Preferred Stock contains no liquidation preferences or redemption rights and shares in distributions of the Company on an as-converted basis with the common stock.

As part of the Private Placement, affiliates of certain members of the Company's Board of Directors purchased an aggregate of 283,046 shares of common stock, an aggregate of 2,563,1439 shares of Series A Preferred Stock and received warrants to purchase up to 1,422,221 shares of common stock at an exercise price of \$2.25 per share in the Private Placement. These amounts are included in the amounts noted above.

In the three months ended March 31, 2019, the Company and certain holders of the warrants issued in 2016 (the "Participating 2016 Holders") entered into a Warrant Amendment and Exercise Agreement (the "2016 Exercise Agreement") pursuant to which the Company agreed to reduce the exercise price of the warrants held by such Participating 2016 Holders from \$2.25 to \$0.01 per share (the "2016 Reduced Exercise Price") in consideration for the exercise of the warrants held by such Participating 2016 Holders in full at the 2016 Reduced Exercise Price for cash. In connection with the exercise of the warrants by the Participating 2016 Holders, the Company received aggregate gross proceeds of approximately \$0.1 million. After the full exercise of the warrants held by the Participating 2016 Holders, warrants issued in 2016 to purchase approximately 508,714 shares of the Company's Common Stock are outstanding.

## 7. WARRANTS

The Company has warrants to purchase its common stock outstanding as of March 31, 2019, as follows:

<u>Issued</u>	<u>Classification</u>	<u>Warrants Outstanding</u>	<u>Exercise Price</u>	<u>Expiration</u>
September 2016	Liability	508,714	\$ 2.25	November 2021
March 2015	Equity	3,699	9.75	March 2025
July 2014	Equity	6,566	7.99	July 2024
July 2012	Equity	52,046	0.01	July 2022



**8. STOCK-BASED COMPENSATION**

Stock option activity under the Company's 2012 Equity Incentive Plan (the "2012 Plan") and 2013 Equity Incentive Plan (the "2013 Plan") for the three months ended March 31, 2019 is summarized as follows:

	Number of Options	Weighted- Average Exercise Price	Weighted- Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2018	3,339,471	\$ 1.03	8.1	\$ —
Cancelled	(1,536,304)	0.57	—	—
Outstanding at March 31, 2019	<u>1,803,167</u>	<u>\$ 1.03</u>	<u>7.2</u>	<u>\$ —</u>
Vested and expected to vest at March 31, 2019	<u>1,766,323</u>	<u>\$ 1.41</u>	<u>7.2</u>	<u>\$ —</u>
Exercisable at March 31, 2019	<u>1,723,797</u>	<u>\$ 1.37</u>	<u>7.1</u>	<u>\$ —</u>

As of March 31, 2019, the weighted average grant date fair value of vested options and options outstanding was \$1.82.

**Stock-Based Compensation Expense**

The Company did not grant any stock options to employees during the three ended March 31, 2019 but did grant stock options to employees during the three months ended March 31, 2018. The Company estimates the fair value of stock options as of the date of grant using the Black-Scholes option pricing model and restricted stock based on the stock price, with the exception of those stock options that included a market condition. The Company estimates the fair value of stock options that include a market condition using a Monte-Carlo model. Stock options and restricted stock issued to non-board member, non-employees are accounted for using the fair value approach and are subject to periodic revaluation over their vesting terms.

Stock-based compensation expense amounted to \$0.1 million and \$0.4 million for the three months ended March 31, 2019 and 2018, respectively.

The allocation of stock-based compensation for all options granted and restricted stock awards is as follows:

	Three Months Ended March 31,	
	2019	2018
	(in thousands)	
Research and development	\$ (38)	\$ 96
General and administrative	145	307
Total stock-based compensation expense	<u>\$ 107</u>	<u>\$ 403</u>

The weighted-average assumptions used in the Black-Scholes option pricing model to determine the fair value of the employee stock option grants and non-employee stock options grants for the three months ended March 31, 2018 were as follows:

	Three Months Ended March 31, 2018	
	Employees	Non-employees
Risk-free interest rate	2.70%	1.97%
Expected volatility	88.2%	74.0%
Expected term (in years)	6.08	6.08
Expected dividend yield	0.0%	0.0%

## 9. INCOME TAXES

Deferred tax assets and deferred tax liabilities are recognized based on temporary differences between the financial reporting and tax basis of assets and liabilities using statutory rates. A valuation allowance is recorded against deferred tax assets if it is more likely than not that some or all of the deferred tax assets will not be realized. Due to the uncertainty surrounding the realization of the favorable tax attributes in future tax returns, the Company has recorded a full valuation allowance against the Company's otherwise recognizable net deferred tax assets. The Company recorded no income tax expense or benefit during the three months ended March 31, 2019 and 2018, due to a full valuation allowance recognized against its deferred tax assets.

### TAX REFORM

On December 22, 2017, the Tax Cuts and Jobs Act (the "TCJA") was signed into United States law. The TCJA includes a number of changes to existing tax law, including, among other things, a permanent reduction in the federal corporate income tax rate from 34% to 21%, effective as of January 1, 2018, as well as limitation of the deduction for net operating losses to 80% of annual taxable income and elimination of net operating loss carrybacks, in each case, for losses arising in taxable years beginning after December 31, 2017 (though any such net operating losses may be carried forward indefinitely). The tax rate change resulted in (i) a reduction in the gross amount of the Company's deferred tax assets recorded as of December 31, 2017, without an impact on the net amount of its deferred tax assets, which are recorded with a full valuation allowance, and (ii) no income tax expense or benefit being recognized as of the enactment date of the TCJA.

The staff of the Securities and Exchange Commission issued Staff Accounting Bulletin No. 118 to address the application of U.S. GAAP in situations when a registrant does not have the necessary information available, prepared or analyzed (including computations) in reasonable detail to complete the accounting for certain income tax effects of the TCJA. In connection with the initial analysis of the impact of the TCJA, the Company remeasured its deferred tax assets and liabilities based on the rates at which they are expected to reverse in the future, which is generally 21%.

## 10. RELATED PARTIES

### Purpose, Co.

In June 2012, the Company entered into an agreement with Purpose to amend its previous agreements. In the previous agreements, Purpose granted the Company a perpetual license to its patents related to its exogenous tissue processor which is used in the development of the Company's products. In exchange, the Company granted Purpose a perpetual license to all of the Company's biotechnology and biomaterial for use in Japan. The agreement provided for Purpose to manufacture and sell machinery to the Company for cost until the Company's products become commercially viable. The Company also agreed to pay royalties on any third-party revenue generated using Purpose's licensed technology.

Under the June 2012 amendment, the Company received exclusive rights to all of Purpose's technology related to the exogenous tissue processor, continued supply of exogenous tissue processors during the Company's clinical trials, and rights to manufacture the exogenous tissue processors at any location the Company chooses. In exchange for such consideration, the Company named Purpose the sole manufacturer of equipment and also clarified the geographic territories of the exclusive license that Purpose was granted for use of the Company's technology. In addition, the Company agreed to reimburse Purpose for \$0.3 million of development costs on a next generation tissue processor. Refer to the discussion under Note 5, Commitments and Contingencies—License Agreements—*Tissue Processor Sub-License*.

In May 2016, the Company acquired the development and commercialization rights to NeoCart for the Japanese market from Purpose. Under the terms of the amended agreement, the Company assumes sole responsibility for and rights to the development and commercialization of NeoCart in Japan. In exchange for the transfer of

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development and commercialization rights, the Company will pay a success-based milestone to Purpose upon conditional approval of NeoCart in Japan, as well as commercial milestones and a low single digit royalty on Japanese sales of NeoCart, upon full approval, if any, in Japan.

The Company paid Purpose \$0.1 million in each of the three months ended March 31, 2019 and 2018.

### **11. RESTRUCTURING**

In connection with the aforementioned restructuring plans implemented in January 2019 and March 2019, the Company severed substantially all of its employees before March 31, 2019. The Company incurred a restructuring charge of approximately \$2.8 million, of which \$0.1 million remains unpaid at March 31, 2019. The restructuring charges were comprised solely of employee severance packages which included salary, healthcare benefits and guaranteed bonuses.

### **12. SUBSEQUENT EVENTS**

On April 8, 2019, the Company and Ocugen announced entering into the Merger Agreement. Upon the terms and subject to the satisfaction of the conditions described in the Merger Agreement, including approval of the transaction by the Company's stockholders and Ocugen's stockholders, a wholly-owned subsidiary of the Company will be merged with and into Ocugen, with Ocugen surviving the Merger as a wholly-owned subsidiary of the Company. The proposed Merger is structured as a stock-for-stock transaction whereby all of Ocugen's outstanding shares of common stock and securities convertible into or exercisable for Ocugen's common stock will be converted into the right to receive the Company's common stock and securities convertible into or exercisable for the Company's common stock. Under the exchange ratio formula in the Merger Agreement, the former Ocugen equity holders immediately before the Merger are expected to own approximately 90% of the outstanding capital stock of Histogenics, and the stockholders of Histogenics immediately before the Merger are expected to own approximately 10% of the outstanding capital stock of Histogenics, subject to certain adjustments as described in the Merger Agreement. If the proposed Merger is not completed and the Merger Agreement is terminated under certain circumstances, Histogenics or Ocugen may be required to pay the other party a termination fee of up to 600,000 or \$700,000, respectively. Even if a termination fee is not payable in connection with a termination of the Merger Agreement, each of Histogenics and Ocugen will have incurred significant fees and expenses, which must be paid whether or not the Merger is completed. See Note 1, Nature of Business and Management's Discussion and Analysis of Financial Condition and Results of Operations, for further discussion of the Merger.

On April 30, 2019, the Company terminated its property lease in Waltham, Massachusetts and made a payment of \$1.3 million to the landlord in connection with the termination. The Company expects to record a \$0.5 million loss in connection with the settlement of the lease obligations in the second quarter of 2019.

On May 8, 2019, the Company entered into an agreement with the landlord to terminate its property lease Lexington, Massachusetts effective as of June 30, 2019. In connection with the termination of this lease, the Company paid the landlord \$0.3 million and agreed that the landlord shall retain the full amount of the security deposit of \$0.1 million. In the event these premises are leased to a new tenant prior to June 30, 2019, the Company's obligation to pay base rent, operating expenses and any other obligations due under the lease shall terminate as of the commencement of such new lease and such date shall be deemed to be the termination date.

On May 8, 2019, the Company entered into an asset purchase agreement with Medavate Corp., a Colorado corporation (the "Asset Purchase Agreement"), pursuant to which the Company has agreed to sell substantially all of its assets relating to its NeoCart program, including, without limitation, intellectual property, business and license agreements and clinical trial data (the "Assets") in return for a cash payment of \$6.5 million. The closing of the sale of the Assets is subject to and conditioned upon the consummation of the planned merger with Ocugen following a vote of the Company's stockholders approving such transaction as contemplated by the Merger Agreement made and entered as of April 5, 2019, by and among the Company, Restore Merger Sub, Inc. and Ocugen, Inc.

**OCUGEN, INC.**  
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**Condensed Consolidated Financial Statements (Unaudited)**

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<a href="#">Condensed Consolidated Statements of Operations and Comprehensive Loss for the Three Months Ended March 31, 2019 and 2018</a>	OCGN UNAUD-2
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OCGN AUD-1

## Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors of Ocugen, Inc.

### Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Ocugen, Inc. (the Company) as of December 31, 2018 and 2017, the related consolidated statements of operations and comprehensive loss, stockholders' equity (deficit) and cash flows for the years then ended, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2018 and 2017, and the results of its operations and its cash flows for the years then ended in conformity with U.S. generally accepted accounting principles.

### The Company's Ability to Continue as a Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company has suffered recurring losses from operations, has a working capital deficiency, and has stated that substantial doubt exists about the Company's ability to continue as a going concern. Management's evaluation of the events and conditions and management's plans regarding these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

### Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB and in accordance with auditing standards generally accepted in the United States of America. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2018.

Philadelphia, Pennsylvania  
June 14, 2019

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**OCUGEN, INC.**  
**CONSOLIDATED BALANCE SHEETS**

	<u>December 31,</u>	
	<u>2018</u>	<u>2017</u>
<b>Assets</b>		
Current Assets		
Cash and cash equivalents	\$ 1,628,136	\$ 6,201,540
Prepaid expenses and other current assets	313,499	111,638
Total Current Assets	1,941,635	6,313,178
Property and equipment, net	245,788	154,181
Restricted cash	150,477	100,032
Other assets	116,333	62,130
<b>Total Assets</b>	<u>\$ 2,454,233</u>	<u>\$ 6,629,521</u>
<b>Liabilities and Stockholders' (Deficit) Equity</b>		
Current Liabilities		
Accounts payable	\$ 3,277,525	\$ 156,694
Accrued expenses	1,402,750	890,187
Short term debt, net	7,483,847	—
Derivative liabilities	1,741,222	—
Capital lease obligation	20,442	—
Deferred grant proceeds	183,800	183,800
Total Current Liabilities	14,109,586	1,230,681
Non-Current Liabilities		
Deferred rent	3,739	2,199
Capital lease obligation, less current portion	33,720	—
Long term debt, net	1,016,727	961,654
Total Non-Current Liabilities	1,054,186	963,853
Total Liabilities	15,163,772	2,194,534
Stockholders' (Deficit) Equity		
Common stock, \$0.001 par value, 20,000,000 authorized at December 31, 2018 and 2017; 10,347,418 issued and outstanding at December 31, 2018 and 2017	10,347	10,347
Accumulated other comprehensive income	451	—
Additional paid-in capital	18,516,857	17,442,170
Accumulated deficit	(31,237,194)	(13,017,530)
Total Stockholders' (Deficit) Equity	(12,709,539)	4,434,987
<b>Total Liabilities and Stockholders' (Deficit) Equity</b>	<u>\$ 2,454,233</u>	<u>\$ 6,629,521</u>

See accompanying notes to financial statements.

## OCUGEN, INC.

## CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

	Year ended December 31,	
	2018	2017
<b>Operating Expenses</b>		
Research and development	\$ 10,321,397	\$ 4,927,511
General and administrative	5,819,111	2,862,013
<b>Total Operating Expenses</b>	<u>16,140,508</u>	<u>7,789,524</u>
<b>Loss from Operations</b>	<u>(16,140,508)</u>	<u>(7,789,524)</u>
<b>Other Income (Expense)</b>		
Change in fair value of derivative liabilities	1,664,689	—
Interest income	19,213	31,148
Interest expense	(3,750,630)	(55,827)
Other expense	(12,428)	(1,277)
<b>Total Other Expense</b>	<u>(2,079,156)</u>	<u>(25,956)</u>
<b>Net Loss</b>	<u>\$ (18,219,664)</u>	<u>\$ (7,815,480)</u>
Foreign currency translation adjustment	451	—
<b>Comprehensive Loss</b>	<u>\$ (18,219,213)</u>	<u>\$ (7,815,480)</u>
<b>Net loss per share of common stock, basic and diluted</b>	<u>\$ (1.76)</u>	<u>\$ (0.82)</u>
<b>Basic and diluted weighted average shares outstanding</b>	10,347,418	9,483,504

See accompanying notes to financial statements.

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**OCUGEN, INC.**  
**CONSOLIDATED STATEMENTS OF STOCKHOLDERS' (DEFICIT) EQUITY**  
**YEARS ENDED DECEMBER 31, 2018 AND 2017**

	Common Stock		Additional Paid in Capital	Other Comprehensive Income	Accumulated Deficit	Total
	Shares	Amount				
<b>Balance at December 31, 2016</b>	<b>8,277,879</b>	<b>\$ 8,278</b>	<b>\$ 9,244,228</b>	<b>\$ —</b>	<b>\$ (5,188,438)</b>	<b>\$ 4,064,068</b>
Cumulative effect adjustment upon adoption of ASU 2016-09	—	—	13,612	—	(13,612)	—
Issuance of common stock and warrants	2,069,539	2,069	7,497,931	—	—	7,500,000
Common stock issuance costs	—	—	(46,983)	—	—	(46,983)
Stock-based compensation expense	—	—	522,415	—	—	522,415
Warrants issued for services performed	—	—	210,967	—	—	210,967
Net loss	—	—	—	—	(7,815,480)	(7,815,480)
<b>Balance at December 31, 2017</b>	<b>10,347,418</b>	<b>10,347</b>	<b>17,442,170</b>	<b>—</b>	<b>(13,017,530)</b>	<b>4,434,987</b>
Stock-based compensation expense	—	—	1,074,687	—	—	1,074,687
Foreign currency translation adjustment	—	—	—	451	—	451
Net loss	—	—	—	—	(18,219,664)	(18,219,664)
<b>Balance at December 31, 2018</b>	<b>10,347,418</b>	<b>\$10,347</b>	<b>\$18,516,857</b>	<b>\$ 451</b>	<b>\$ (31,237,194)</b>	<b>\$ (12,709,539)</b>

See accompanying notes to financial statements.

OCGN AUD-5



**OCUGEN, INC.**  
**CONSOLIDATED STATEMENTS OF CASH FLOWS**

	<u>Year ended December 31,</u>	
	<u>2018</u>	<u>2017</u>
<b>Cash Flows from Operating Activities</b>		
Net loss	\$ (18,219,664)	\$ (7,815,480)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	49,623	15,816
Non-cash interest expense	3,750,630	55,827
Warrants issued for services performed	—	210,967
Change in fair value of derivative liability	(1,664,689)	—
Stock-based compensation expense	1,074,687	522,415
Changes in assets and liabilities:		
Prepaid expenses and other current assets	(201,861)	(111,638)
Other assets	(54,203)	(61,480)
Accounts payable and accrued expenses	3,633,394	861,048
Deferred rent	1,540	2,199
<b>Net Cash Used in Operating Activities</b>	<b>(11,630,543)</b>	<b>(6,320,326)</b>
<b>Cash Flows from Investing Activities</b>		
Purchases of property and equipment	(77,414)	(169,997)
<b>Net Cash Used in Investing Activities</b>	<b>(77,414)</b>	<b>(169,997)</b>
<b>Cash Flows from Financing Activities</b>		
Capital lease principal payments	(11,928)	—
Deferred financing costs	(103,925)	—
Proceeds from issuance of common stock and warrants, net of issuance costs	—	7,453,017
Proceeds from issuance of convertible debt	7,300,400	—
<b>Net Cash Provided by Financing Activities</b>	<b>7,184,547</b>	<b>7,453,017</b>
<b>Effect of changes in exchange rate on cash</b>	<b>451</b>	<b>—</b>
<b>Net (Decrease) / Increase in Cash, Cash Equivalents, and Restricted Cash</b>	<b>(4,522,959)</b>	<b>962,694</b>
<b>Cash, cash equivalents and restricted cash at beginning of period</b>	<b>6,301,572</b>	<b>5,338,878</b>
<b>Cash, cash equivalents and restricted cash at end of period</b>	<b>\$ 1,778,613</b>	<b>\$ 6,301,572</b>
<b>Supplemental Disclosure of Non-Cash Financing Activities</b>		
Purchase of fixed assets by entering into a capital lease	\$ 63,817	\$ —

See accompanying notes to financial statements.

**OCUGEN, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS  
FOR THE YEARS ENDED DECEMBER 31, 2018 AND 2017**

**NOTE 1—NATURE OF BUSINESS**

Ocugen, Inc. (the “Company”), located in Malvern Pennsylvania, is a clinical stage biopharmaceutical company focused on discovering, developing and commercializing a pipeline of innovative therapies to address rare and underserved eye diseases.

The Company is developing a modifier gene therapy platform which is based on the nuclear hormone receptor, or NHR, gene, *NR2E3*, using an adeno-associated virus vector for the treatment of *NR2E3* mutation-associated retinal degenerative diseases. The Company’s late stage program product candidate is OCU300, a small molecule therapeutic for patients with ocular graft-versus-host disease, or oGVHD. The Company is developing OCU310 for patients with dry eye disease, or DED. Both OCU300 and OCU310 are formulated using its proprietary nanoemulsion technology, OcuNanoE—Ocugen’s ONE Platform™, or OcuNanoE™.

The Company is also developing OCU200, a novel fusion protein for the treatment of wet age-related macular degeneration, or wet AMD, and OCU100 for the treatment of RP.

In January 2018, the Company formed Ocugen Limited, an Irish subsidiary, and purchased one share of common stock, representing 100% ownership, for €1 (Euro). Ocugen Limited will be used as the designated company for future European regulatory filings.

**GOING CONCERN**

The Company has incurred recurring losses and negative cash flows from operations since inception and has funded its operating losses through the sale of common stock, warrants to purchase common stock, the issuance of convertible notes, and debt. The Company incurred net losses of approximately \$18.2 million and \$7.8 million for the years ended December 31, 2018 and 2017, respectively, and had an accumulated deficit of \$31.2 million as of December 31, 2018. As of December 31, 2018, the Company had cash and cash equivalents of \$1.6 million and a working capital deficit of \$12.2 million.

The Company has a limited operating history and its prospects are subject to risks, expenses and uncertainties frequently encountered by companies in its industry. The Company intends to continue its research and development efforts for its product candidates, which will require significant funding. If the Company is unable to obtain additional financing in the future or research and development efforts require higher than anticipated capital, there may be a negative impact on the financial viability of the Company. The Company plans to increase working capital by raising additional capital through either private or public equity or debt financing. Such financing may not be available at all, or on terms which are favorable to the Company. While management of the Company believes that it has a plan to fund ongoing operations, its plan may not be successfully implemented. Failure to generate sufficient cash flows from operations, raise additional capital through one or more financings, or reduce certain discretionary spending could have a material adverse effect on the Company’s ability to achieve its intended business objectives.

As a result of these factors, together with the anticipated increase in spending that will be necessary to continue to develop the Company’s products, there is substantial doubt about the Company’s ability to continue as a going concern within one year after the date that these financial statements are issued. The financial statements do not contain any adjustments that might result from the resolution of any of the above uncertainties. The Company plans to continue raising additional funds to meet its operational goals until profitable.

## **NOTE 2—SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

### **BASIS OF PRESENTATION**

The accompanying financial statements of the Company were prepared in accordance with generally accepted accounting principles in the United States of America (“GAAP”).

Certain amounts in the consolidated financial statements and associated notes may not add due to rounding. All percentages have been calculated using unrounded amounts.

### **PRINCIPALS OF CONSOLIDATION**

The consolidated financial statements include the accounts of Ocugen, Inc. and its wholly owned subsidiary. All intercompany balances and transactions have been eliminated in consolidation.

### **FOREIGN CURRENCY TRANSLATION AND TRANSACTIONS**

The assets and liabilities of the Company’s foreign subsidiary are translated into U.S. dollars based on exchange rates in effect at the end of each period. Revenues and expenses are translated at average exchange rates during the periods. Currency transaction gains or losses are included in Other expenses. Gains or losses from balance sheet translation are included in Accumulated other comprehensive income.

### **USE OF ESTIMATES**

In preparing financial statements in conformity with GAAP, management is required to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported amounts of expenses during the reporting period. Due to inherent uncertainty involved in making estimates, actual results reported in future periods may be affected by changes in these estimates. On an ongoing basis, the Company evaluates its estimates and assumptions. These estimates and assumptions include estimating the fair value of equity securities in share-based payment arrangements.

### **CONCENTRATION OF CREDIT RISK**

Financial instruments that potentially subject the Company to concentrations of credit risk consist primarily of cash and cash equivalents. A financial institution in the United States that management believes to be of high credit quality holds the Company’s cash and cash equivalents. At times, such cash balances may be in excess of federal insurance limits.

### **CASH, CASH EQUIVALENTS, AND RESTRICTED CASH**

The Company considers all highly-liquid investments that have maturities of three months or less when acquired to be cash equivalents. Cash and cash equivalents include bank demand deposits, marketable securities with maturities of three months or less at purchase, and money market funds that invest primarily in certificates of deposit, commercial paper and United States government and United States government agency obligations. The Company’s restricted cash balance consists of cash held to collateralize a corporate credit card account.

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The following table provides a reconciliation of cash, cash equivalents, and restricted cash in the consolidated balance sheets to the total amount shown in the consolidated statements of cash flows:

	As of December 31,	
	2018	2017
Cash, cash equivalents and restricted cash reconciliation:		
Cash and cash equivalents	\$ 1,628,136	\$ 6,201,540
Restricted cash	150,477	100,032
Total cash, cash equivalents and restricted cash	<u>\$ 1,778,613</u>	<u>\$ 6,301,572</u>

## FAIR VALUE OF FINANCIAL INSTRUMENTS

The Company measures certain assets and liabilities at fair value, which is defined as the price that would be received to sell an asset or paid to transfer a liability (the exit price) in an orderly transaction between market participants at the measurement date. The FASB accounting guidance outlines a valuation framework and creates a fair value hierarchy in order to increase the consistency and comparability of fair value measurements and the related disclosures. In determining fair value, the Company uses quoted prices and observable inputs when available. Observable inputs are inputs that market participants would use in pricing the asset or liability based on market data obtained from independent sources. The fair value hierarchy is broken down into three levels based on the source of the inputs as follows:

- Level 1—Valuations based on unadjusted quoted prices in active markets for identical assets or liabilities.
- Level 2—Valuations based on observable inputs and quoted prices in active markets for similar assets and liabilities.
- Level 3—Valuations based on inputs that are unobservable and models that are significant to the overall fair value measurement.

At December 31, 2018 and 2017, the Company's financial instruments included cash and cash equivalents, restricted cash, accounts payable, debt, and derivatives (See section DERIVATIVE INSTRUMENTS). The carrying amounts reported in the Company's consolidated financial statements for cash and cash equivalents, restricted cash and accounts payable approximate their respective fair values because of the short-term nature of these instruments. The estimated fair value of the borrowing under the EB-5 Loan approximates its carrying value due to the nature of the loan and the similarity between the interest rate on the borrowings and prevailing interest rates.

## CONVERTIBLE DEBT

The Company analyzes its convertible debt instruments for embedded derivatives that may require bifurcation from the host and accounted for as derivatives. At the inception of each instrument, the Company performs an analysis of the embedded features requiring bifurcation and may elect, if eligible, to account for the entire debt instrument at fair value. If the fair value option were to be elected, any changes in fair value would be recognized in the accompanying statements of operations until the instrument is settled. The Company has not elected to account for its convertible debt at fair value.

## DERIVATIVE INSTRUMENTS

The Company issued certain convertible notes which contained embedded derivative instruments. In particular, some convertible notes contained a conversion feature and all notes contained a change in control feature. These features are not considered clearly and closely related to the debt host and therefore are considered embedded derivatives that must be bifurcated and accounted for separately from the debt host. Accordingly, the Company has recorded these potential payments as derivative financial liabilities.

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Derivative financial liabilities are initially recorded at fair value, with gains and losses arising for changes in fair value recognized in the consolidated statement of operations at each period end while such instruments are outstanding. The liability is being valued using a with and without model. See Note 8 for further discussion of the convertible notes and the embedded derivative liability.

### **LICENSE FEES**

License fees paid to acquire access to proprietary technology to be used in research and development activities are expensed to research and development unless it is determined that the technology is expected to have an alternative future use. During the years ended December 31, 2018 and 2017, there were no license fees capitalized.

### **PATENT COSTS**

All patent related costs incurred in connection with filing and prosecuting patent applications are expensed as incurred to research and development expense due to the uncertainty about the recovery of such expenditures.

### **RESEARCH AND DEVELOPMENT**

Research and development costs are expensed as incurred. Research and development expense consists of internal and external expenses. Internal expenses include employee compensation and certain overhead. External expenses include costs of development, clinical trials, patent costs, license fees and regulatory compliance costs incurred with research organizations and other third-party vendors.

The Company records costs for certain development activities, such as clinical trials, based on its evaluation of the progress to completion of specific tasks using data such as patient enrollment, clinical site activations, or information provided to the Company by its vendors on their actual costs incurred. Payments for these activities are based on the terms of the individual arrangements, which may differ from the pattern of costs incurred, and are reflected in the consolidated financial statements as Prepaid expenses and other current assets or Accrued expenses, as the case may be.

### **COSTS FOR COLLABORATIVE ARRANGEMENTS**

Costs incurred under collaborative arrangements include personnel costs, laboratory supplies and fees paid to third parties. These amounts are included in research and development expense in the accompanying consolidated statements of operations. The Company accounts for its license agreement with The Schepens Eye Research Institute under the guidance in ASC 808 *Collaborative Arrangements*.

### **PROPERTY AND EQUIPMENT**

Property and equipment is recorded at cost. Significant additions or improvements are capitalized, and expenditures for repairs and maintenance are charged to expense as incurred. Gains and losses on disposal of assets are included in the consolidated statements of operations. Depreciation is calculated using the straight-line method and is recognized over an expected useful life of 5 years for equipment and 7 years for furniture.

### **LONG-LIVED ASSETS**

Long-lived assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to future net cash flows expected to be generated. Impairment charges are recognized at the amount by which the carrying amount of an asset exceeds the fair value of the asset. Assets to be disposed of are reported at the lower of the carrying amount or the fair value less costs to sell. The Company has not recognized any impairment or disposition of long-lived assets.

## **STOCK-BASED COMPENSATION AND FAIR VALUE OF STOCK**

The Company accounts for its stock-based compensation awards in accordance with FASB Accounting Standards Codification (“ASC”) Topic 718, *Compensation-Stock Compensation* (“ASC 718”). ASC 718 requires all stock-based payments to employees, including grants of employee stock options and restricted stock units and modifications to existing agreements, to be recognized in the statements of operations based on their fair values. The Company uses the Black-Scholes option-pricing model to determine the fair value of options granted.

As there has been no public market for the Company’s common stock to date, the estimated fair value of its common stock has been determined by the Board of Directors as of the date of each option grant, with input from management, considering the Company’s most recently available third-party valuations of common stock and the Board of Directors’ assessment of additional objective and subjective factors that it believed were relevant and which may have changed from the date of the most recent valuation through the date of the grant. These third-party valuations were performed in accordance with the guidance outlined in the American Institute of Certified Public Accountants’ Accounting and Valuation Guide, Valuation of Privately-Held-Company Equity Securities Issued as Compensation. The Company’s common stock valuations were prepared using either a hybrid method, where the equity value in one or more of the scenarios is calculated using an option-pricing method, or a probability-weighted expected return method, or PWERM, where the fair value of common stock is estimated based upon an analysis of future values for the Company, assuming various outcomes. Under the PWERM, the estimated common stock value is based on the probability-weighted present value of expected future investment returns considering each of the possible outcomes available as well as the rights of each class of stock. The future value of the common stock under each outcome is discounted back to the valuation date at an appropriate risk-adjusted discount rate and probability weighted to arrive at an indication of value for the common stock.

In addition to considering the results of these third-party valuations, the Company’s Board of Directors considered various objective and subjective factors to determine the fair value of its common stock as of each grant date, which may be as of a date later than the most recent third-party valuation date, including the price per share of common stock issued in recent financing transactions with new third-party investors, the progress of the Company’s research and development programs, external market conditions affecting and trends within the biotechnology industry and the likelihood of achieving a liquidity event.

The Company’s stock-based awards are subject to service-based vesting conditions. Compensation expense related to awards to employees and directors with service-based vesting conditions is recognized on a straight-line basis based on the grant date fair value over the associated service period of the award, which is generally the vesting term.

Prior to the adoption of ASU No. 2018-07, *Improvements to Nonemployee Share-Based Payment Accounting* (“ASU 2018-07”) during the third quarter of 2018, stock-based payments to non-employees were measured at the fair value of the consideration received, or the fair value of the equity instruments issued, or liabilities incurred, whichever was more reliably measurable, and the fair value of stock-based payments to non-employees was re-measured at the end of each reporting period until the counterparty performance was completed, with any change therein recognized over the vesting period of the award and in the same manner as if the Company had paid cash instead of paying with or using equity-based instruments. The fair value of the stock-based payments to non-employees that were fully vested and non-forfeitable as of the grant date was measured and recognized at that date. Following the adoption of ASU 2018-07, stock-based payments to non-employees are now being measured based on the fair value of the equity instrument issued and compensation expense for non-employee stock awards is recognized over the requisite service period following the measurement of the fair value on the grant date over the vesting period of the award.

## **DEFERRED GRANT PROCEEDS**

In 2015, the Company entered into a grant agreement with the Colorado Office of Economic Development & International Trade (“OEDIT”) whose purpose was to accelerate the economic growth and

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improve and expand the development of advanced industries, facilitate the collaboration of advanced industry stakeholders, and further the development of new advanced industries products and services in Colorado. The Company received a total of \$183,800 during 2016 and 2015, representing the full amount of the grant, and has recorded this amount to deferred grant proceeds until such time that the obligations of the grant are satisfied and contingencies are resolved.

As a condition of the grant with OEDIT, the Company was required to maintain its headquarters in Colorado or have at least 50% of its employees working in Colorado through the research completion date of May 1, 2016 and throughout the 24-month period following the completion date. As of December 31, 2018, the Company maintained its headquarters outside of Colorado and had more than 50% of its employees working outside of Colorado. As such, at December 31, 2018 and 2017, the grant proceeds have been recorded as a current liability.

### **DEBT ISSUANCE COSTS**

Upon the issuance of debt, debt issuance costs are presented as a reduction to the related debt and are amortized to interest expense using the effective interest method over the approximate life of the indebtedness or on a straight-line basis when it approximates the effective interest method. Debt issuance costs are capitalized and presented as Prepaid expenses and other current assets if incurred prior to the debt being issued.

### **COSTS OF EQUITY TRANSACTIONS**

Incremental direct costs incurred to issue shares of the Company's common stock are recorded as a reduction of the related proceeds.

### **INCOME TAXES**

The Company is a Delaware C Corporation. The Company recognizes deferred tax assets and liabilities for temporary differences between the financial reporting basis and the tax basis of its assets and liabilities and the expected benefits of net operating loss carryforwards. The impact of changes in tax rates and laws on deferred taxes, if any, is applied during the years in which temporary differences are expected to be settled and is reflected in the financial statements in the period of enactment. The measurement of deferred tax assets is reduced, if necessary, if, based on the weight of the evidence, it is more likely than not that some, or all, of the deferred tax assets will not be realized. The Company's policy is to recognize interest and penalties accrued on any unrecognized tax benefits as a component of income tax expense. No interest or penalty expense was recognized during the periods presented.

The Company has assessed its uncertain tax positions and has concluded that it does not have any uncertain tax positions. The Company's conclusions regarding uncertain tax positions may be subject to review and adjustment at a later date based upon ongoing analysis of tax laws, regulations and interpretations thereof, as well as other factors. Generally, federal, state, and local authorities may examine the Company's tax returns for three years from the date of the filing and the current and prior three years remain subject to examination as of December 31, 2018.

### **BASIC AND DILUTED NET LOSS PER SHARE OF COMMON STOCK**

The Company computes basic net loss per share of common stock by dividing net loss applicable to common stockholders by the weighted-average number of shares of common stock outstanding during the period, excluding the dilutive effects of warrants to purchase common stock and stock options. The Company computes diluted net loss per share of common stock by dividing the net loss applicable to common stockholders by the sum of the weighted-average number of shares of common stock outstanding during the period plus the potential dilutive effects of its convertible promissory notes and warrants to purchase common stock and stock options outstanding during the period calculated in accordance with the treasury stock method, but such items are

excluded if their effect is anti-dilutive. Because the impact of these items is anti-dilutive during periods of net loss, there was no difference between the Company's basic and diluted net loss per share of common stock for the years ended December 31, 2018 and 2017.

## SEGMENT INFORMATION

Operating segments are defined as components of an enterprise about which separate discrete information is available for evaluation by the chief operating decision-maker, or decision-making group, in deciding how to allocate resources and in assessing performance. The Company views its operations and manages its business as one operating segment, which is developing innovative therapies that address rare and underserved eye diseases. As of December 31, 2018, substantially all of the Company's assets were located in the United States.

## NOTE 3—RECENT ACCOUNTING PRONOUNCEMENTS

In May 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2014-09, *Revenue from Contracts with Customers (Topic 606)*. This standard requires revenue recognition to depict the transfer of goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. ASU 2014-09 sets forth a new revenue recognition model that requires identifying the contract, identifying the performance obligations, determining the transaction price, allocating the transaction price to performance obligations, and recognizing the revenue upon satisfaction of performance obligations. In August 2015, the FASB modified the standard with ASU 2015-14, *Deferral of the Effective Date*. ASU 2014-09 is effective for annual reporting periods beginning after December 15, 2017, and interim periods within that reporting period. Nonpublic entities are required to apply the guidance in annual periods beginning after December 15, 2018 and in interim periods beginning after December 15, 2019. The Company adopted ASU 2014-09 in 2018, however, there is no impact as the Company does not generate revenue.

In February 2016, the FASB issued ASU 2016-02, *Leases (Topic 842)*. This guidance revises existing practice related to accounting for leases under ASC 840, *Leases* ("ASC 840") for both lessees and lessors. The new guidance in ASU 2016-02 requires lessees to recognize a right-of-use asset and a lease liability for nearly all leases (other than leases that meet the definition of a short-term lease). The lease liability will be equal to the present value of lease payments and the right-of-use asset will be based on the lease liability, subject to adjustment such as for initial direct costs. For income statement purposes, the new standard retains a dual model similar to ASC 840, requiring leases to be classified as either operating leases or capital leases. For lessees, operating leases will result in straight-line expense (similar to current accounting by lessees for operating leases under ASC 840) while capital leases will result in a front-loaded expense pattern (similar to current accounting by lessees for capital leases under ASC 840). ASU 2016-02 is effective for annual reporting periods beginning after December 15, 2018 and interim periods within that reporting period. Nonpublic entities are required to apply the guidance in annual periods beginning after December 15, 2019 and in interim periods beginning after December 15, 2020. Early application is permitted. In July 2018, the FASB issued ASU 2018-11 related to ASC 842. The update provides for another transition method in addition to the existing transition method of a modified retrospective approach by allowing entities to initially apply ASC 842 at the adoption date and recognize a cumulative-effect adjustment to the opening balance of accumulated deficit in the period of adoption. The Company is adopting as of January 1, 2019 and expects assets and a corresponding lease liability of approximately \$0.4 million to be recorded.

In August 2016, the FASB issued ASU 2016-15, *Statement of Cash Flows, Classification of Certain Cash Receipts and Cash Payments*, which reduces existing diversity in the classification of certain cash receipts and cash payments on the statements of cash flows. ASU 2016-15 is effective for fiscal years beginning after December 15, 2017, and interim periods within that reporting period. Early adoption is permitted. Nonpublic entities are required to apply the guidance in annual periods beginning after December 15, 2018 and in interim periods beginning after December 15, 2019. The Company adopted this standard on January 1, 2018 and it did not have an impact on its financial statements.



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In November 2016, the FASB issued ASU 2016-18, *Restricted Cash*. The guidance is intended to address the diversity that currently exists in the classification and presentation of changes in restricted cash on the statement of cash flows. The new standard requires that entities show the changes in the total of cash and cash equivalents, restricted cash and restricted cash equivalents on the statement of cash flows and no longer present transfers between cash and cash equivalents, restricted cash and restricted cash equivalents on the statement of cash flows. ASU 2016-18 is effective for fiscal years beginning after December 15, 2017, and interim periods within that reporting period. Nonpublic entities are required to apply the guidance in annual periods beginning after December 15, 2018 and in interim periods beginning after December 15, 2019. Early adoption is permitted. The Company adopted this standard on January 1, 2018 and retrospectively to all periods presented.

In May 2017, the FASB issued ASU 2017-09, *Compensation—Stock Compensation (Topic 718): Scope of Modification Accounting*, to clarify when to account for a change to the terms or conditions of a share-based payment award as a modification. Under the new guidance, modification accounting is required only if the fair value, the vesting conditions, or the classification of the award (as equity or liability) changes as a result of the change in terms or conditions. The guidance is effective prospectively for annual periods and interim periods within those annual periods, beginning after December 15, 2017 for all entities. The Company adopted this standard as of January 1, 2018. It did not have an impact on its financial statements.

In June 2018, the FASB issued ASU 2018-07 intended to reduce cost and complexity and to improve financial reporting for nonemployee share-based payments. Currently, the accounting requirements for nonemployee and employee share-based payment transactions are significantly different. This ASU expands the scope of Topic 718, *Compensation-Stock Compensation* (which currently only includes share-based payments to employees) to include share-based payments issued to nonemployees for goods or services. Consequently, the accounting for share-based payments to nonemployees and employees will be substantially aligned. This ASU supersedes Subtopic 505-50, *Equity-Based Payments to Nonemployees*. The amendments in this ASU are effective for annual periods and interim periods within those annual periods beginning after December 15, 2018, with early adoption permitted. Nonpublic entities are required to apply the guidance in annual periods beginning after December 15, 2019 and in interim periods beginning after December 15, 2020. Upon transition, the entity is required to measure these nonemployee awards at fair value as of the adoption date through a cumulative-effect adjustment to retained earnings as of the beginning of the fiscal year of adoption. The Company adopted as of July 1, 2018 and there was no impact. Early adoption is permitted to the extent ASC 606 has been adopted, which occurred in 2018.

### NOTE 4—NET LOSS PER SHARE OF COMMON STOCK

The following table sets forth the computation of basic and diluted earnings per share for the years ended December 31, 2018 and 2017:

	Year ended December 31,	
	2018	2017
Basic and diluted net loss per share of common stock:		
Net loss	<u>\$ (18,219,664)</u>	<u>\$ (7,815,480)</u>
Weighted average shares of common stock outstanding	<u>10,347,418</u>	<u>9,483,504</u>
Net loss per share of common stock—basic and diluted	<u>\$ (1.76)</u>	<u>\$ (0.82)</u>

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The following potentially dilutive securities outstanding at December 31, 2018 and 2017 have been excluded from the computation of diluted weighted average shares outstanding, as they would be antidilutive:

	December 31,	
	2018	2017
Stock options	1,319,900	966,000
Warrants	1,814,811	1,814,811
Total	3,134,711	2,780,811

In addition, the Company has convertible promissory notes that are currently anti-dilutive, however, the potential dilution is not determinable as the number of common shares to be issued upon conversion is variable based on the amount of the Qualified Financing.

### **NOTE 5—LICENSE AGREEMENTS**

#### **LICENSE AGREEMENT WITH UNIVERSITY OF COLORADO**

In March 2014, the Company entered into a patent license agreement with the University of Colorado (“University”), which granted the Company an exclusive license to develop and commercialize, and continue to secure patents for OCU100 and OCU200, including the ability to enforce any rights against infringement. Under the agreement, the Company assumed primary responsibility for preparing, filing and prosecuting broad patent claims for OCU100 and OCU200 for the University’s benefit. Further, the Company assumed primary responsibility for all patent activities, including all costs associated with the perfection and maintenance of the patents for OCU100 and OCU200.

In exchange for the licensed patents, the Company issued the University 180,000 shares of the Company’s common stock. The license agreement included an anti-dilution provision, requiring the issuance of additional shares to maintain a specified ownership interest until such time as the Company achieved a specified level of financing. Between the effective date of the agreement and December 31, 2016, the Company issued the University an additional 67,000 shares of the Company’s common stock. The anti-dilution provision was no longer effective per the terms of the agreement, as amended, after the Company’s Series A financing round closed in December 2016. The Company also reimbursed the University for \$26,179 of fees and costs previously incurred by the University. The aggregate fair value of the common stock issued was \$353,350 and the cost reimbursement was recognized as research and development expense in periods prior to 2017.

The agreement with the University, as amended in January 2017, obligates the Company to pay certain development and regulatory milestone fees of up to \$1.5 million, royalties in the low single digits on net sales and royalties ranging from the mid-teens to forty percent on sublicense income of OCU100 and OCU200.

The agreement with the University calls for minimum annual royalty payments of \$20,000, starting on the third anniversary of the agreement and on each annual anniversary thereafter, and after sales commence, increasing to a percentage rate in the mid-twenties of the previous year’s royalty payment paid to the University, through the term of the agreement. The Company paid \$20,000 during 2018 and 2017, as the minimum royalty is due annually beginning in 2017, and recognized such amounts as research and development expense. No additional royalties were paid or incurred during 2018 or 2017 as the Company has not achieved any milestones, net sales or sublicensing for OCU100 or OCU200. Future annual royalties will be recognized in the years they are earned, per the license agreement. The Company may cancel the license agreement at any time with 60 days’ written notice.

#### **LICENSE AGREEMENT WITH UNIVERSITY OF ILLINOIS**

In February 2016, the Company entered into a license agreement with the University of Illinois, Chicago (“UIC”), which granted the Company an exclusive license to develop, commercialize and continue to secure

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patents for OCU300 and OCU310. In connection with acquiring the license for OCU300 and OCU310, the Company was required to pay a signing fee of \$15,000, which was recognized as research and development expense.

The Company is required to pay royalties ranging from the low single digits to low teens to UIC based on net sales and sublicense revenues generated by OCU300 and OCU310. The Company is also required to pay minimum annual royalties to UIC, beginning with an annual payment of \$20,000 on the third anniversary of the effective date of the agreement, and increasing gradually to \$50,000 by the sixth anniversary and continuing through the term of the agreement. These minimum royalties will be recognized in the years in which they are earned. The Company is also obligated to pay UIC up to \$1.25 million upon the achievement of certain development and regulatory milestones.

The Company recognized \$18,333 of royalty expense related to this agreement during 2018. Additionally, the Company incurred \$250,000 in milestone payments during 2018 due to achieving a milestone associated with dosing the first patient in a Phase III clinical trial. The \$250,000 is in Accrued Expenses as of December 31, 2018. The Company has not achieved any other milestones, net sales or sublicensing for OCU300 or OCU310. The Company may cancel the license agreement at any time with 90 days' written notice.

### **LICENSE AGREEMENT WITH THE SCHEPENS EYE RESEARCH INSTITUTE**

In December 2017, the Company entered into a license agreement with The Schepens Eye Research Institute, ("SERI"), which granted the Company an exclusive license to develop, commercialize, and continue to secure patents for OCU400. This agreement is accounted for as a Collaborative Arrangement. In connection with acquiring the license, the Company was required to pay a license fee of \$125,000, which was recognized in 2017.

The Company was also required to reimburse SERI for all patent costs incurred prior to the effective date of the agreement, totaling \$39,681, and will be required to reimburse SERI for all future patent costs related to this licensed technology.

These license and patent fees were recognized as research and development expense in 2017.

The Company is obligated to pay SERI up to \$6.0 million upon the achievement of certain development and regulatory milestones. The Company is also obligated to pay SERI up to \$10.5 million upon the achievement of certain commercial milestones. The Company will also pay SERI royalties in the low single digits based on net sales, which will be credited against the annual license maintenance fees. The license agreement dictates that the Company will pay an annual license maintenance fee of \$25,000 for the first two years following expiration or termination of the Sponsored Research Agreement, and \$50,000 for each year thereafter. No license maintenance fees were paid or incurred during 2018. No milestones or royalties were paid or incurred during 2018, as the Company has not achieved any milestones, net sales or sublicensing under this agreement. The Company may cancel the license agreement at any time with 180 days' written notice.

In December 2017, the Company also entered into a Sponsored Research Agreement with SERI which is effective for two years. Pursuant to the terms of the agreement, the Company expects to make payments totaling approximately \$1.1 million for research services for OCU400 over the period beginning December 2017 and ending December 2019. The Company recognized approximately \$471,500 and \$22,000 as research and development expense in 2018 and 2017, respectively for work performed under this agreement.

**NOTE 6—BALANCE SHEET DETAIL**

Accrued Expenses are as follows:

	<u>December 31,</u>	
	<u>2018</u>	<u>2017</u>
Accrued Expenses:		
Research & Development	\$ 705,436	\$ 423,900
Clinical	469,473	154,610
Consulting	86,619	111,063
Employees	123,372	88,827
Legal	15,400	60,219
Other	2,450	51,568
Total	<u>\$ 1,402,750</u>	<u>\$ 890,187</u>

**NOTE 7—EQUITY TRANSACTIONS**FinancingsCommon Stock

The Company is authorized to issue up to 20,000,000 shares of common stock with a \$0.001 par value as of December 31, 2018. Each share of common stock entitles the holder to one vote. The shares of common stock are not subject to redemption and do not have any preference, conversion, exchange or pre-emptive rights. Pursuant to an Amended and Restated Stockholder's Agreement, dated as of May 25, 2017, certain holders of the Company's common stock are designated Series A stockholders (the "Series A Stockholders") and Series B stockholders (the "Series B Stockholders"). Both the Series A Stockholders and Series B Stockholders have board designation rights and consent rights with regard to certain transactions. In addition, the Series B Stockholders have consent rights with regard to certain corporate actions.

In May and June 2017, the Company raised \$7.5 million in connection with a common stock financing and issued 2,069,539 shares of common stock as well as warrants to purchase 103,476 shares of common stock. Each warrant allows the holder of the warrant to purchase common stock of the Company at a price of \$3.624 per share, was exercisable immediately upon issuance, and will expire on the earlier of the day prior to the first closing of a public common stock offering or the day prior to the first closing of any consolidation or merger of the Company such that the shareholders of the Company immediately prior to such transaction hold less than 50% of the resulting or surviving corporation's voting power immediately after such transaction or ten years from the date of issuance. The fair value of the warrants was estimated to be \$225,764 and was included in additional paid-in capital.

The proceeds of the Company's common stock financings are being used to provide liquidity for the Company to continue research and development on its products.

The warrants issued in the above-mentioned financings are accounted for as equity instruments. The Company estimated their fair value in the same manner as the Company's stock options using the Black-Scholes model, and the valuation assumptions are similar to those used in estimating the fair value of the Company's stock options.

Warrant Transactions

In addition to the above warrant transactions which were attached to stock purchase agreements, the Company had the following transactions:

In September 2017, the Company modified employment agreements for two employees, to issue warrants instead of restricted stock awards ("RSAs") upon the achievement of company milestones. The agreements

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previously called for issuance of 185,000 RSAs, contingent upon the Company achieving a certain IND milestone. As of the execution of the amendments, the IND milestone had not yet been met, however the amended employment agreements also included an amendment to the milestone definition so that the milestone would be considered already met by a previous Company IND achievement. Therefore, in September 2017, warrants to immediately purchase 185,000 shares of the Company's common stock were awarded to the employees. The estimated fair value of the warrants at the time of award was \$210,967. This amount was recognized as general and administrative expense and additional paid-in capital. The warrants became exercisable immediately at an exercise price of \$3.624 per share and will expire on the earlier of the day prior to the first closing of a public common stock offering or the day prior to the first closing of any consolidation or merger of the Company such that the shareholders of the Company immediately prior to such transaction hold less than 50% of the resulting or surviving corporation's voting power immediately after such transaction or ten years from the date of issuance.

The Company recognized the warrants described above as equity instruments.

The following is a summary of warrants outstanding and exercisable as of December 31, 2018 and grouped in accordance with their respective issuance dates:

<u>Issuance Date</u>	<u>Classification</u>	<u>Exercise Price</u>	<u>Expiration Date</u>	<u>Balance December 31, 2017</u>	<u>Warrants Issued</u>	<u>Warrants Exercised</u>	<u>Warrants Expired</u>	<u>Balance December 31, 2018</u>
Jan 2015	Equity	\$ 1.330	Jan 2025	300,000	—	—	—	300,000
Apr 2016	Equity	\$ 2.350	Apr 2026	319,330	—	—	—	319,330
Nov 2016	Equity	\$ 3.020	Nov 2026	16,556	—	—	—	16,556
Dec 2016	Equity	\$ 3.020	Dec 2026	120,000	—	—	—	120,000
Dec 2016	Equity	\$ 3.020	Dec 2026	66,224	—	—	—	66,224
Dec 2016	Equity	\$ 2.420	Dec 2026	4,225	—	—	—	4,225
Dec 2016	Equity	\$ 3.020	Dec 2026	500,000	—	—	—	500,000
Dec 2016	Equity	\$ 3.020	Dec 2026	200,000	—	—	—	200,000
May 2017	Equity	\$ 3.624	May 2027	6,898	—	—	—	6,898
Jun 2017	Equity	\$ 3.624	Jun 2027	96,578	—	—	—	96,578
Sep 2017	Equity	\$ 3.624	Sep 2027	185,000	—	—	—	185,000
				<u>1,814,811</u>	<u>—</u>	<u>—</u>	<u>—</u>	<u>1,814,811</u>

Warrants will expire on the earlier of the day prior to the first closing of a public common stock offering, the day prior to the first closing of any consolidation or merger of the Company such that the shareholders of the Company immediately prior to such transaction hold less than 50% of the resulting or surviving corporation's voting power immediately after such closing or transaction, or ten years from the date of issuance. The above table assumes the warrants expire ten years from the date of issuance.

### Stock Incentive Plan

In February 2014, the Company's Board of Directors adopted the Ocugen, Inc. 2014 Stock Option Plan ("Stock Option Plan"). The Stock Option Plan was established to provide additional incentive to current and prospective employees, consultants, and directors of the Company to enter into, or remain in, service or employment of the Company. The approval authorized issuance of 582,000 shares of the Company's common stock for the future issuance of stock options. In December 2015, November 2016, and September 2017, the Company's Board of Directors authorized increases of 100,000, 150,000, and 800,000 shares of the Company's common stock, respectively, to be issued under the Stock Option Plan, for a total number of options authorized at December 31, 2018 of 1,632,000. Certain option awards provide for accelerated vesting if there is a change of control, as defined in the Stock Option Plan.

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Option awards under the Stock Option Plan are granted with an exercise price at the estimated fair value of a share of stock at the date of grant. The awards generally vest over a period of up to three years and have up to ten-year contractual terms. At December 31, 2018, there were 1,319,900 options issued and there were an additional 312,100 that were available to be issued for future grants.

Information concerning options for the year ended December 31, 2018 is summarized as follows:

	<u>Shares</u>	<u>Exercise Price</u>	<u>Weighted-Average Remaining Contract Term (Years)</u>	<u>Aggregate Intrinsic Value</u>
Outstanding January 1, 2018	996,000	\$ 1.62	8.2	\$1,870,405
Granted	479,400	\$ 4.66		
Cancelled	(3,500)	\$ 1.26		
Forfeited	(122,000)	\$ 5.62		
Outstanding December 31, 2018	<u>1,319,900</u>	<u>\$ 2.84</u>	<u>7.9</u>	<u>\$4,801,696</u>
Exercisable at December 31, 2018	<u>762,333</u>	<u>\$ 1.21</u>	<u>6.8</u>	<u>\$4,020,221</u>

The aggregate intrinsic value is the sum of the amounts by which the fair value of the Company's common stock exceeded the exercise price of the options at December 31, 2018, for those options for which the fair value of common stock was in excess of the exercise price.

The weighted average fair value at the date of grant for options granted during the years ended December 31, 2018 and 2017 were \$3.82 and \$2.59 per share, respectively.

As of December 31, 2018, there was \$1,972,294 of total unrecognized compensation expense related to the unvested stock options, which is expected to be recognized over a weighted-average period of 1.9 years.

Included in the shares outstanding number at December 31, 2018 are 331,000 stock options granted to non-employees.

The Company recognized stock-based compensation expense as follows for the years ended December 31, 2018 and 2017:

	<u>Year ended December 31,</u>	
	<u>2018</u>	<u>2017</u>
Research and development	\$ 515,160	\$ 265,569
General and administrative	559,527	256,846
	<u>\$ 1,074,687</u>	<u>\$ 522,415</u>

The Company estimates the fair value of its option awards using the Black-Scholes option pricing model, which requires the input of subjective assumptions, including (i) the expected stock price volatility, (ii) the calculation of the expected term of the award, (iii) the risk-free interest rate, (iv) expected dividends and (v) the fair value of the Company's common stock.

- Due to the lack of substantial company-specific historical and implied volatility data of its common stock, the Company has based its estimate of expected volatility on the historical volatility of a group of similar public companies. When selecting these companies on which it has based its expected stock price volatility, the Company selected companies with comparable characteristics to it, including enterprise value, risk profiles, position within the industry and with historical share price information

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sufficient to meet the expected term of the stock-based awards. The Company will continue to apply this process until a sufficient amount of historical information regarding the volatility of its own stock price becomes available.

- The risk-free interest rates for periods within the expected term of the option are based on the United States Treasury securities with a maturity date commensurate with the expected term of the associated award.
- The expected term of the options granted to employees is derived from the “simplified” method as described in Staff Accounting Bulletin 107 relating to stock-based compensation. The expected term for options granted to non-employees is equal to the contractual term of the awards.
- The Company has never paid, and does not expect to pay, dividends in the foreseeable future.
- As the Company’s common stock has not historically been publicly traded, its board of directors periodically estimated the fair value of the Company’s common stock considering, among other things, contemporaneous valuations of its common stock prepared by an unrelated third-party valuation firm in accordance with the guidance provided by the American Institute of Certified Public Accountants 2013 Practice Aid, Valuation of Privately-Held-Company Equity Securities Issued as Compensation. The Company’s stock valuations were prepared using either a hybrid method, where the equity value in one or more of the scenarios is calculated using an option-pricing method, or a probability-weighted expected return method, or PWERM, where the fair value of common stock is estimated based upon an analysis of future values for the Company, assuming various outcomes. Under the PWERM, the common stock value is based on the probability-weighted present value of expected future investment returns considering each of the possible outcomes available as well as the rights of each class of stock. The future value of the common stock under each outcome is discounted back to the valuation date at an appropriate risk-adjusted discount rate and probability weighted to arrive at an indication of value for the common stock. In addition to considering the results of these third-party valuations, the Company’s Board of Directors considered various objective and subjective factors to determine the price of its common stock as of each grant date, which may be as of a date later than the most recent third-party valuation date, including the price per share of common stock issued in recent financing transactions with new third-party investors, the progress of the Company’s research and development programs, external market conditions affecting and trends within the biotechnology industry and the likelihood of achieving a liquidity event.

The assumptions used to calculate the fair value of stock options granted is as follows:

	Years ended December 31,	
	2018	2017
Weighted average common stock price	\$4.66	\$3.32
Expected dividend rate	0%	0%
Expected option term (years)	6.0 – 10.0	6.0 - 10.0
Weighted average expected stock price volatility	85%	99%
Risk-free interest rate	2.3 – 3.0%	1.8% - 2.4%

## **NOTE 8—DEBT**

### EB-5 LOAN

In September 2016, pursuant to the United States government’s Immigrant Investor Program, commonly known as the EB-5 program (the “EB-5 Program”), the Company entered into an arrangement to borrow up to \$10.0 million from EB5 Life Sciences, L.P. (the “Lender”) in \$0.5 million increments. Borrowings may be limited by the amount of funds raised by the Lender and are subject to certain job creation requirements by the Company. Borrowings are at a fixed interest rate of 4.0% and are to be utilized in the clinical development,

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manufacturing, and commercialization of the Company's products and for the general working capital needs of the Company. Outstanding borrowings pursuant to the EB-5 Program become due upon the seventh anniversary of the final disbursement. Amounts repaid cannot be re-borrowed.

In September 2016, \$0.5 million was borrowed by the Company followed by another borrowing of \$0.5 million in December 2016. Issuance costs for these borrowings totaled \$103,887. At December 31, 2018 and 2017, there is \$1.0 million of principal outstanding which has accrued interest of \$87,222 and \$46,990, respectively. As of December 31, 2018 and 2017, the Company believes the fair value of the EB-5 Note approximates its carrying value due to the nature of the loan and the similarity between the interest rate on the EB-5 Note and prevailing interest rates.

The EB-5 Note is secured by substantially all assets of the Company, except for any patents, patent applications, pending patents, patent license, patent sublicense, trademarks, and other intellectual property rights.

EB-5 debt at December 31, 2018, consisted of the following:

	<u>Principal</u>	<u>Unamortized Debt Issuance Costs</u>	<u>Long-Term Debt, net</u>
Balance as of January 1, 2017	\$1,006,004	\$ 100,177	\$ 905,827
Amortization	—	(14,841)	14,841
Accrued interest added to principal	40,986	—	40,986
Balance as of December 31, 2017	\$1,046,990	\$ 85,336	\$ 961,654
Amortization	—	(14,841)	14,841
Accrued interest added to principal	40,232	—	40,232
Balance as of December 31, 2018	\$1,087,222	\$ 70,495	\$1,016,727

Amortization expense for 2018 and 2017 amounted to \$14,841 and is included in interest expense. Amortization of debt issuance costs for the years ended December 31, 2019 through 2022 is \$14,841 per year.

### Convertible Notes

During the year ended December 31, 2018, the Company issued convertible promissory notes (the "Notes") to existing stockholders in the Company, including \$3.35 million to board members. At issuance, the following amounts were recorded:

<u>Note Issuance Date</u>	<u>Note Principal Amount</u>	<u>Fair Value of Conversion Feature</u>	<u>Fair Value of Change in Control Feature</u>	<u>Debt Issuance Costs</u>	<u>Carrying Amount of the Note</u>	<u>Maturity Date</u>
January 2018	\$ 5,000,000	\$ (2,579,074)	\$ (78,637)	\$ (35,969)	\$ 2,306,320	July 2019
June 2018	1,000,000	(714,041)	(10,175)	(3,000)	272,784	Dec. 2019
November 2018	1,150,400	—	(21,127)	(50,646)	1,078,627	May 2020
December 2018	150,000	—	(2,857)	(14,310)	132,833	May 2020
<b>Total</b>	<b>\$ 7,300,400</b>	<b>\$ (3,293,115)</b>	<b>\$ (112,796)</b>	<b>\$ (103,925)</b>	<b>\$ 3,790,564</b>	

The Notes accrue interest at a rate of 5% per annum and have scheduled maturity date on the eighteenth month anniversary of the date of the issuance of the Notes (the "Maturity Date"). If prior to the Maturity Date, there is a consummation of the sale of all or substantially all of the assets of the Company, change in control or event of default, the Notes becomes due and payable at an amount equal to 1.5 times the principal amount of the Notes together with all accrued interest (the "Change in Control Feature").



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With regards to the notes issued in January 2018 and June 2018, if the Company receives equity financing from the issuance of stock of the Company from an investor or group of investors in a transaction or series of related transactions resulting in gross proceeds to the Company of at least \$15.0 million (the “Financing Transaction”), including the conversion of these Notes, the principal amount and all interest accrued but not paid through the closing date of the equity financing shall automatically convert into the same class of equity securities as those issued in the equity financing at a price per share equal to a 30% discount to the lowest price per share being paid by investors in the equity financing (the “Conversion Feature”). In November 2018, the Company modified the gross proceeds requirement to \$10.0 million.

With regards to the notes issued in November 2018 and December 2018, if the Company receives equity financing from the issuance of stock of the Company from an investor or group of investors in a transaction or series of related transactions resulting in gross proceeds to the Company of at least \$4.0 million (the “Financing Transaction”), including the conversion of these Notes, the principal amount and all interest accrued but not paid through the closing date of the equity financing shall automatically convert into the same class of equity securities as those issued in the equity financing at a price per share equal to the lowest price per share being paid by investors in the equity financing.

The Company bifurcated the Conversion Feature for the January 2018 and June 2018 notes and classified it as a derivative liability because the Conversion Feature does not have a fixed conversion price and conversion will be settled in a variable number of common shares. There is no bifurcated conversion feature for the November 2018 and December 2018 notes as there is no discount to the lowest equity price triggering conversion.

The Company also bifurcated the Change in Control Feature for all of the notes because it was determined to be a redemption feature not clearly and closely related to the debt host. The fair value of both of these embedded features accounted for as a derivative liability is recorded as a discount on the Notes. The debt discount is accreted into interest expense over the expected time until conversion of the Notes. This accretion amounted to \$3,281,818 for the year ended December 31, 2018.

The fair value of the derivative liability for the embedded features was classified as a liability in the Company’s Consolidated Balance Sheet at issuance, with subsequent changes in fair value during the year ended December 31, 2018 recorded on the Company’s Consolidated Statements of Operations and Comprehensive Loss as Change in fair value of derivative liabilities.

	<b>Conversion feature</b>	<b>Change in Control feature</b>
Balance at January 1, 2018	\$ —	\$ —
Fair value at issuance—January notes	2,579,074	78,637
Fair value at issuance—June notes	714,041	10,175
Fair value at issuance—November notes	—	21,127
Fair value at issuance—December notes	—	2,857
Change in fair value of embedded derivatives	<u>(1,670,106)</u>	<u>5,417</u>
Balance at December 31, 2018	\$ 1,623,009	\$ 118,213

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For purposes of estimating the fair market value of the embedded features, the Company used a with and without model. The significant assumptions used in the valuation model are level 3 inputs and are as follows:

### Conversion feature – Crossover Triggered:

	At Issuance	January Notes	June Notes
Time until expected conversion (in years)		0.49	0.17
Probability of conversion		80%	75%

	At December 31, 2018	January Notes	June Notes
Time until expected conversion (in years)		0.02	0.02
Probability of conversion		60%	60%

### Conversion feature – IPO Triggered:

	At Issuance	January Notes	June Notes
Time until expected conversion (in years)		—	—
Probability of conversion		—	—

	At December 31, 2018	January Notes	June Notes
Time until expected conversion (in years)		0.33	0.33
Probability of conversion		20%	20%

### Change in Control feature:

	At Issuance	January Notes	June Notes	November Notes	December Notes
Time until expected conversion (in years)		1.24	0.83	0.47	0.38
Probability of conversion		3%	3%	3%	3%

	At December 31, 2018	January Notes	June Notes	November Notes	December Notes
Time until expected conversion (in years)		0.41	0.41	0.41	0.41
Probability of conversion		3%	3%	3%	3%

The Company considered several possible outcomes in the likelihood and timing of a qualified financing and/or a change in control occurring that would trigger conversion or redemption and believes the amounts disclosed above and utilized in the valuation are the best estimates of such amounts at each valuation date. The possible outcomes are impacted by the Company's current capital raising plans and its need for additional funding to continue its development efforts. These assumptions are updated each reporting period.

Debt issuance costs of \$103,925 incurred related to the issuance of the Notes were accounted for as debt discount and amortized over the period until expected conversion. This expense amounted to \$43,959 for the year ended December 31, 2018 and is included in interest expense.

## NOTE 9—COMMITMENTS

### OPERATING LEASES

The Company is obligated as lessee under several operating leases for facilities in Malvern, Pennsylvania and Boulder, Colorado. The Company changed its lab location, located in Malvern, Pennsylvania in February

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2018 and signed a one-year renewable lease agreement for a new lab, also located in Malvern, Pennsylvania, with monthly rent of approximately \$20,000. The lease was renewed in February 2019, with a monthly rent of \$16,000. The lease associated with the facility in Boulder, Colorado was terminated in July 2018.

The remaining lease terms range from one to five years with the last expiring in February 2022. Lease payments range from \$3,100 to \$20,333 per month. All of the leases contain renewal options. Rent expense under operating leases was approximately \$318,041 and \$90,000 for the years ended December 31, 2018 and 2017, respectively.

Future minimum lease payments for all leases, exclusive of taxes and other carrying charges, are approximately as follows:

<u>For the Years Ending December 31,</u>	<u>Amount</u>
2019	315,959
2020	147,555
2021	135,574
2022	22,707
<b>Total</b>	<b><u>\$ 621,795</u></b>

## CAPITAL LEASES

In June 2018, the Company leased a specialized research equipment under a lease classified as a capital lease. The leased equipment is amortized on a straight-line basis over 5 years. Total accumulated amortization related to the leased equipment is \$6,382 at December 31, 2018. The following is a schedule showing the future minimum lease payments under capital leases by years and the present value of the minimum lease payments as of December 31, 2018. The interest rate related to the lease obligation is 7.6 percent and the maturity date is July 2021.

Future minimum lease payments for all capital leases, exclusive of taxes and other carrying charges, are approximately as follows:

<u>For the Years Ending December 31,</u>	<u>Amount</u>
2019	23,856
2020	23,856
2021	11,930
<b>Total</b>	<b><u>\$ 59,642</u></b>
<b>Less: Amount representing interest</b>	<b><u>\$ 5,480</u></b>
<b>Present Value of Minimum Lease Payments</b>	<b><u>\$ 54,162</u></b>

**NOTE 10—INCOME TAXES**

Deferred taxes are recognized for temporary differences between the basis of assets and liabilities for financial statement and income tax purposes. The significant components of the Company's deferred tax assets are comprised of the following:

	<u>Year ended December 31,</u>	
	<u>2018</u>	<u>2017</u>
Deferred tax assets:		
Net operating loss carryforwards	\$ 6,864,360	\$ 2,600,496
Stock based compensation expense	993,234	835,476
Accrued expenses	35,645	25,496
Intellectual property, net	121,694	131,526
Research and development credit carryforward	548,399	26,888
Convertible debt	498,236	—
Total Deferred Tax Assets	<u>\$ 9,061,568</u>	<u>\$ 3,619,882</u>
Valuation Allowance	<u>(9,061,568)</u>	<u>(3,619,882)</u>
Deferred tax assets, net of allowance	<u>\$ —</u>	<u>\$ —</u>

As of December 31, 2018, the Company had U.S. federal net operating loss carryforwards of \$23,706,441, which may be available to offset future income tax liabilities and will expire beginning in 2033. As of December 31, 2018, the Company also had U.S. state net operating loss carryforwards of \$23,702,918 which may be available to offset future income tax liabilities and will expire beginning in 2034.

The Company has recorded a full valuation allowance against its net deferred tax assets as of December 31, 2018 and 2017, respectively, because the Company has determined that it is more likely than not that these assets will not be fully realized due to historic net operating losses incurred. The Company experienced a net change in valuation allowance of \$5,441,686 and \$1,626,168 in the years ended December 31, 2018 and 2017, respectively.

As of December 31, 2018, the Company had federal research and development tax credit carryforwards of \$548,399 available to reduce future tax liabilities which expire beginning in 2034.

	<u>Year ended</u>	
	<u>December 31,</u>	
	<u>2018</u>	<u>2017</u>
Federal income tax benefit at statutory rate	(21.0)%	(34.0)%
State and local tax, net of federal benefit	(7.6)%	(6.6)%
Permanent differences	0.8%	1.0%
R&D Credit	(2.1)%	0.0%
Impact of Tax Reform	0.0%	18.8%
Change in valuation allowance	<u>29.9%</u>	<u>20.8%</u>
Effective Income Tax rate	0.0%	0.0%

Under the provisions of the Internal Revenue Code, the net operating loss and tax credit carryforwards are subject to review and possible adjustment by the Internal Revenue Service and state tax authorities. Net operating loss and tax credit carryforwards may become subject to an annual limitation in the event of certain cumulative changes in the ownership interest of significant shareholders over a three-year period in excess of 50%, as defined under Sections 382 and 383 of the Internal Revenue Code, respectively, as well as similar state provisions. This could limit the amount of tax attributes that can be utilized annually to offset future taxable income or tax liabilities. The amount of the annual limitation is determined based on the value of the Company

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immediately prior to the ownership change. Subsequent ownership changes may further affect the limitation in future years. The Company has completed financing since its inception which may have resulted in a change in control as defined by Sections 382 and 383 of the Internal Revenue Code, or could result in a change in control in the future.

On December 22, 2017, the U.S. government enacted comprehensive tax legislation commonly referred to as the Tax Cuts and Jobs Act (the Tax Act). The Tax Act makes broad and complex changes to the U.S. tax code, including, but not limited to, reducing the U.S. federal corporate tax rate from 34% to 21%; eliminating the corporate alternative minimum tax (AMT) and changing how existing AMT credits can be realized; creating a new limitation on deductible interest expense; changing rules related to uses and limitations of net operating loss carryforwards created in tax years beginning after December 31, 2017; limitations on the deductibility of certain executive compensation; and changes to the calculation of the orphan drug credit.

With regard to the Tax Act's impact on the tax provision as it relates to the Company for the year ended December 31, 2017, the Company has recognized the impact of tax reform related to the revaluation of deferred tax assets and liabilities from 34% to 21% or a reduction of approximately \$1.5 million, which is offset by a reduction in the valuation allowance.

The Company files tax returns as prescribed by the tax laws of the jurisdictions in which it operates. In the normal course of business, the Company is subject to examination by federal and state jurisdictions, where applicable. The Company's tax years are still open under status from 2015 to present. All open years may be examined to the extent that tax credit or net operating loss carryforward are used in future periods. The Company will recognize interest and penalties related to uncertain tax positions in income tax expense. As of December 31, 2018, the Company had no accrued interest or penalties related to uncertain tax positions and no amounts have been recognized in the Company's consolidated statements of operations.

### **NOTE 11—DEFINED CONTRIBUTION PLAN**

On April 1, 2017, the Company adopted the Ocugen, Inc. 401(k) Plan. The Plan provides for a safe harbor Company matching contribution of 100% of the first 3% of a participant's contribution plus 50% of the amount of the participant's contribution that exceeds 3% but does not exceed 5%. The Plan also allows for discretionary profit-sharing contributions. In 2018 and 2017, the Company contributed matching contributions of approximately \$102,000 and \$42,000 to the Plan, of which approximately \$66,500 and \$24,000 were recognized as research and development expense and approximately \$35,500 and \$18,000 were recognized as general and administrative expense, respectively.

### **NOTE 12—RESTRICTED CASH**

In May 2017, the Company opened a corporate credit card account for use by employees for travel and other business-related expenses. To secure this credit account, the Company placed \$100,000 into a collateral savings account with its financial institution and recorded the \$100,000 as Restricted Cash on its Balance Sheet. The account earns 0.05% interest, which is deposited monthly into the collateral account and increases the Restricted Cash asset accordingly. The collateral account will remain restricted until the Company either closes the credit account or meets other revenue and/or cash balance criteria, as defined by the financial institution.

In January 2018, the Company opened a new corporate credit card account for use by employees for travel and other business-related expenses. To secure this credit account, the Company placed \$150,000 into a collateral savings account with its financial institution and recorded the \$150,000 as Restricted Cash on its Balance Sheet. The account earns 0.25% interest, which is deposited monthly into the collateral account and increases the Restricted Cash asset accordingly. The collateral account will remain restricted until the Company either closes the credit account or meets other revenue and/or cash balance criteria, as defined by the financial institution.

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In February 2018, the Company closed the corporate credit card account which had been opened in May 2017. As a result, the collateral savings account related to the credit account was closed and the \$100,000 balance plus accrued interest was released to cash.

**NOTE 13—PROPERTY AND EQUIPMENT, NET**

Property and equipment, net is as follows as of December 31, 2018:

	<u>Gross Carrying Amount</u>	<u>Accumulated Depreciation</u>	<u>Net Fixed Assets</u>
Scientific equipment	\$130,132	\$ 35,471	\$ 94,661
Office Furniture & Equip	117,280	23,588	93,692
Assets under Capital Lease.	63,817	6,382	57,435
Total	\$311,229	\$ 65,441	\$245,788

Property and equipment, net is as follows as of December 31, 2017:

	<u>Gross Carrying Amount</u>	<u>Accumulated Depreciation</u>	<u>Net Fixed Assets</u>
Scientific equipment	\$125,246	\$ 9,816	\$ 115,430
Office Furniture & Equip.	44,751	6,000	38,751
Total	\$169,997	\$ 15,816	\$154,181

The Company recognized \$49,623 and \$15,816 of depreciation expense, including expense related to assets under capital lease, for the years ended December 31, 2018 and 2017, respectively.

**NOTE 14—SUBSEQUENT EVENTS**Convertible Notes

In January and February 2019, the Company issued convertible promissory notes totaling \$1,450,000 with an annual interest rate of 5%. These notes had a redemption feature upon a change in control, but also had a conversion feature similar to the January 2018 and June 2018 notes. If the Company receives equity financing from the issuance of stock of the Company from an investor or group of investors in a transaction or series of related transactions resulting in gross proceeds to the Company of at least \$10.0 million, including the conversion of these Notes, the principal amount and all interest accrued but not paid through the closing date of the equity financing shall automatically convert into the same class of equity securities as those issued in the equity financing at a price per share equal to a 15% discount to the lowest price per share being paid by investors in the equity financing.

In April 2019, the Company entered into a subscription agreement with existing investors for the sale of 168,068 shares of common stock for \$1,000,000, or \$5.95 per share. This capital raise triggered the conversion features on the \$7,300,400 of convertible debt described in Note 8 above, as well as, the \$1,450,000 convertible promissory notes issued in January and February 2019. With regards to the January 2018, June 2018, January 2019, and February 2019 notes, the triggers for conversion met were an equity financing and \$10.0 million of gross proceeds from an investor or group of investors. With regards to the November 2018 and December 2018 notes, the triggers met were an equity financing and \$4.0 million of gross proceeds from an investor or group of investors.

The notes converted with a discount of 30%, which is consistent with the notes issued in January 2018 and June 2018, however, differs from the 0% discount on the November 2018 and December 2018 notes and the 15%

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on the January 2019 and February 2019 notes. This modification occurred at the time of conversion. The Company issued 2,195,157 shares of common stock on the date of conversion to extinguish the debt. Certain aspects of the accounting for the conversion have not been finalized.

Subsequently, in April 2019 the Company issued a convertible note in the amount of \$900,000, which was converted into equity on May 16, 2019 upon agreement between the Company and the other party. The Company issued 152,521 shares of common stock at the conversion date to extinguish the debt.

### Proposed Merger

In April 2019, the Company and Histogenics Corporation (“Histogenics”) entered into a Merger Agreement. Upon the terms and subject to the satisfaction of the conditions described in the Merger Agreement, including approval of the transaction by the Company’s stockholders and Histogenics’ stockholders, a wholly-owned subsidiary of Histogenics will be merged with and into Ocugen, with Ocugen surviving the Merger as a wholly-owned subsidiary of Histogenics. The proposed Merger is structured as a stock-for-stock transaction whereby all of Ocugen’s outstanding shares of common stock and securities convertible into or exercisable for Ocugen’s common stock will be converted into the right to receive Histogenics’ common stock and securities convertible into or exercisable for Histogenics’ common stock. Under the exchange ratio formula in the Merger Agreement, as amended on June 13, 2019, the former Ocugen equity holders immediately before the Merger are expected to own approximately 86.24% of the outstanding capital stock of Histogenics, and the stockholders of Histogenics immediately before the Merger are expected to own approximately 13.76% of the outstanding capital stock of Histogenics, including the Initial Shares but excluding the Additional Shares issued in the Financing SPA (as such terms are defined below). If the proposed Merger is not completed and the Merger Agreement is terminated under certain circumstances, Histogenics or Ocugen may be required to pay the other party a termination fee of up to \$600,000 or \$700,000, respectively. Even if a termination fee is not payable in connection with a termination of the Merger Agreement, each of Histogenics and Ocugen will have incurred significant fees and expenses, which must be paid whether or not the Merger is completed.

### Securities Purchase Agreement and Bridge Loan

In June 2019, the Company and Histogenics entered into a Securities Purchase Agreement with several investors (the “Financing SPA”), pursuant to which, among other things, the Company agreed to issue immediately prior to the Merger 4,574,272 common shares to the investors (the “Initial Shares”), and 4,574,272 common shares into escrow (the “Additional Shares”) on behalf of the investors, and Histogenics agreed to issue after the Merger, warrants to purchase common shares of Histogenics, in exchange for \$25.0 million. In May 2019, the Company entered into a Bridge Loan with certain of the investors to advance \$2.1 million of the \$25.0 million. The Bridge Loan is securitized against the intellectual property of the Company. If the proposed Merger is completed, immediately prior to the Effective Time, the Company will offset \$2.4 million from the remaining amount to be received from the investors under the Financing SPA and the Bridge Loan will be deemed to have been repaid and cancelled. If the proposed Merger is not completed, the Company may be required to pay the note holders \$2.4 million.

Management has evaluated subsequent events through June 14, 2019, the date the financial statements were available to be issued. Adjustments or additional disclosures, if any, have been included in these financial statements.

**OCUGEN, INC.**  
**CONDENSED CONSOLIDATED BALANCE SHEETS**

	March 31, 2019 <u>(Unaudited)</u>	December 31, 2018 <u></u>
<b>Assets</b>		
Current Assets		
Cash and cash equivalents	\$ 308,717	\$ 1,628,136
Prepaid expenses and other current assets	313,945	313,499
<b>Total Current Assets</b>	<u>622,662</u>	<u>1,941,635</u>
Property and equipment, net	243,832	245,788
Restricted cash	150,625	150,477
Other assets	564,408	116,333
<b>Total Assets</b>	<u>\$ 1,581,527</u>	<u>\$ 2,454,233</u>
<b>Liabilities and Stockholders' (Deficit) Equity</b>		
Current Liabilities		
Accounts payable	\$ 5,382,564	\$ 3,277,525
Accrued expenses	998,370	1,402,750
Short term debt, net	9,042,346	7,483,847
Derivative liabilities	3,002,756	1,741,222
Operating lease obligations	260,906	—
Financing lease obligation	20,833	20,442
Deferred grant proceeds	183,800	183,800
<b>Total Current Liabilities</b>	<u>18,891,575</u>	<u>14,109,586</u>
Non-Current Liabilities		
Deferred rent	—	3,739
Operating lease obligations, less current portion	238,377	—
Financing lease obligation, less current portion	28,363	33,720
Long term debt, net	1,030,437	1,016,727
<b>Total Non-Current Liabilities</b>	<u>1,297,177</u>	<u>1,054,186</u>
<b>Total Liabilities</b>	<u>20,188,752</u>	<u>15,163,772</u>
<b>Stockholders' (Deficit) Equity</b>		
Common stock, \$0.001 par value, 20,000,000 authorized at March 31, 2019 and December 31, 2018, 10,347,418 issued and outstanding at March 31, 2019 and December 31, 2018	10,347	10,347
Accumulated other comprehensive income	169	451
Additional paid-in capital	18,932,059	18,516,857
Accumulated deficit	<u>(37,549,800)</u>	<u>(31,237,194)</u>
<b>Total Stockholders' (Deficit) Equity</b>	<u>(18,607,225)</u>	<u>(12,709,539)</u>
<b>Total Liabilities and Stockholders' (Deficit) Equity</b>	<u>\$ 1,581,527</u>	<u>\$ 2,454,233</u>

See accompanying notes to condensed consolidated financial statements.



**OCUGEN, INC.**  
**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND**  
**COMPREHENSIVE LOSS**  
**(Unaudited)**

	<b>Three months ended March 31,</b>	
	<b>2019</b>	<b>2018</b>
<b>Operating Expenses</b>		
Research and development	\$ 3,793,022	\$ 3,012,389
General and administrative	1,048,020	982,046
<b>Total Operating Expenses</b>	<u>4,841,042</u>	<u>3,994,435</u>
<b>Loss from Operations</b>	(4,841,042)	(3,994,435)
<b>Other Income (Expense)</b>		
Change in fair value of derivative liabilities	(776,273)	(245,102)
Interest income	594	7,431
Interest expense	(695,469)	(798,514)
Other expense	(416)	(8,406)
<b>Total Other Expense</b>	<u>(1,471,564)</u>	<u>(1,044,591)</u>
<b>Net Loss</b>	<u>\$ (6,312,606)</u>	<u>\$ (5,039,026)</u>
<b>Other Comprehensive Income</b>		
Foreign currency translation adjustment	(282)	(34)
<b>Comprehensive Loss</b>	<u>\$ (6,312,888)</u>	<u>\$ (5,039,060)</u>
<b>Net loss per share of common stock, basic and diluted</b>	\$ (0.61)	\$ (0.49)
<b>Basic and diluted weighted average shares outstanding</b>	10,347,418	10,347,418

See accompanying notes to condensed consolidated financial statements.

OCGN UNAUD-2

## OCUGEN, INC.

## CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' (DEFICIT) EQUITY

(Unaudited)

	Common Stock		Additional Paid in Capital	Other Comprehensive Income	Accumulated Deficit	Total
	Shares	Amount				
<b>Balance at December 31, 2018</b>	<b>10,347,418</b>	<b>\$10,347</b>	<b>\$18,516,857</b>	<b>\$ 451</b>	<b>\$(31,237,194)</b>	<b>\$(12,709,539)</b>
Stock-based compensation expense	—	—	415,202	—	—	415,202
Foreign currency translation adjustment	—	—	—	(282)	—	(282)
Net Loss	—	—	—	—	(6,312,606)	(6,312,606)
<b>Balance at March 31, 2019</b>	<b>10,347,418</b>	<b>\$10,347</b>	<b>\$18,932,059</b>	<b>\$ 169</b>	<b>\$(37,549,800)</b>	<b>\$(18,607,225)</b>

	Common Stock		Additional Paid in Capital	Other Comprehensive Income	Accumulated Deficit	Total
	Shares	Amount				
<b>Balance at December 31, 2017</b>	<b>10,347,418</b>	<b>\$10,347</b>	<b>\$17,442,170</b>	<b>\$ —</b>	<b>\$(13,017,530)</b>	<b>\$ 4,434,987</b>
Stock-based compensation expense	—	—	258,682	—	—	258,682
Foreign currency translation adjustment	—	—	—	(34)	—	(34)
Net Loss	—	—	—	—	(5,039,026)	(5,039,026)
<b>Balance at March 31, 2018</b>	<b>10,347,418</b>	<b>\$10,347</b>	<b>\$17,700,852</b>	<b>\$ (34)</b>	<b>\$(18,056,556)</b>	<b>\$ (345,391)</b>

See accompanying notes to condensed consolidated financial statements.

OCGN UNAUD-3

**OCUGEN, INC.**  
**CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS**  
**(Unaudited)**

	Three months ended	
	March 31,	
	2019	2018
<b>Cash Flows from Operating Activities</b>		
Net loss	\$ (6,312,606)	\$ (5,039,026)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	14,604	9,646
Non-cash interest expense	695,469	798,514
Change in fair value of derivative liability	776,273	245,102
Stock-based compensation expense	415,202	258,682
Changes in assets and liabilities:		
Prepaid expenses and other current assets	(445)	(179,143)
Other assets	47,372	(5,333)
Accounts payable and accrued expenses	1,700,659	1,118,423
Deferred rent	(3,739)	550
<b>Net Cash Used in Operating Activities</b>	<u>(2,667,211)</u>	<u>(2,792,584)</u>
<b>Cash Flows from Investing Activities</b>		
Purchase of property and equipment	(10,581)	(53,774)
<b>Net Cash Used in Investing Activities</b>	<u>(10,581)</u>	<u>(53,774)</u>
<b>Cash Flows from Financing Activities</b>		
Financing lease principal payments	(5,964)	—
Deferred financing costs	(85,233)	(35,969)
Proceeds from convertible debt	1,450,000	5,000,000
<b>Net Cash Provided by Financing Activities</b>	<u>1,358,803</u>	<u>4,964,031</u>
<b>Effect of changes in exchange rate on cash</b>	(282)	(34)
<b>Net (Decrease) / Increase in Cash, Cash Equivalents and Restricted Cash</b>	<u>(1,319,271)</u>	<u>2,117,639</u>
<b>Cash, cash equivalents and restricted cash at beginning of period</b>	<u>1,778,613</u>	<u>6,301,572</u>
<b>Cash, cash equivalents and restricted cash at end of period</b>	<u>\$ 459,342</u>	<u>\$ 8,419,211</u>

See accompanying notes to condensed consolidated financial statements.

**OCUGEN, INC.**

**NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS  
FOR THE THREE MONTHS ENDED MARCH 31, 2019 AND 2018  
(Unaudited)**

**NOTE 1—NATURE OF BUSINESS**

Ocugen, Inc. (the “Company”), located in Malvern Pennsylvania, is a clinical stage biopharmaceutical company focused on discovering, developing and commercializing a pipeline of innovative therapies to address rare and underserved eye diseases.

The Company is developing a modifier gene therapy platform which is based on the nuclear hormone receptor, or NHR, gene, *NR2E3*, using an adeno-associated virus vector for the treatment of *NR2E3* mutation associated retinal degenerative diseases. The Company’s late stage program product candidate is OCU300, a small molecule therapeutic for patients with ocular graft-versus-host disease, or oGVHD. The Company is developing OCU310 for patients with dry eye disease, or DED. Both OCU300 and OCU310 are formulated using its proprietary nanoemulsion technology, OcuNanoE—Ocugen’s ONE Platform™, or OcuNanoE™.

The Company is also developing OCU200, a novel fusion protein for the treatment of wet age-related macular degeneration, or wet AMD, and OCU100 for the treatment of RP.

In January 2018, the Company formed Ocugen Limited, an Irish subsidiary, and purchased one share of common stock, representing 100% ownership, for €1 (Euro). Ocugen Limited will be used as the designated company for future European regulatory filings.

**GOING CONCERN**

The Company has incurred recurring losses and negative cash flows from operations since inception and has funded its operating losses through the sale of common stock, warrants to purchase common stock, the issuance of convertible notes, and debt. The Company incurred net losses of approximately \$6.3 million and \$5.0 million for the three months ended March 31, 2019 and 2018, respectively, and had an accumulated deficit of \$37.5 million as of March 31, 2019. As of March 31, 2019, the Company had cash and cash equivalents of \$0.3 million and a working capital deficit of \$18.3 million.

The Company has a limited operating history and its prospects are subject to risks, expenses and uncertainties frequently encountered by companies in its industry. The Company intends to continue its research and development efforts for its product candidates, which will require significant funding. If the Company is unable to obtain additional financing in the future or research and development efforts require higher than anticipated capital, there may be a negative impact on the financial viability of the Company. The Company plans to increase working capital by raising additional capital through either private or public equity or debt financing. Such financing may not be available at all, or on terms which are favorable to the Company. While management of the Company believes that it has a plan to fund ongoing operations, its plan may not be successfully implemented. Failure to generate sufficient cash flows from operations, raise additional capital through one or more financings, or reduce certain discretionary spending could have a material adverse effect on the Company’s ability to achieve its intended business objectives.

As a result of these factors, together with the anticipated increase in spending that will be necessary to continue to develop the Company’s products, there is substantial doubt about the Company’s ability to continue as a going concern within one year after the date that these unaudited condensed consolidated financial statements are issued. The unaudited condensed consolidated financial statements do not contain any adjustments that might result from the resolution of any of the above uncertainties. The Company plans to continue raising additional funds to meet its operational goals until profitable.

## **NOTE 2—SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

### **BASIS OF PRESENTATION**

The accompanying unaudited condensed consolidated financial statements included herein have been prepared in conformity with accounting principles generally accepted in the United States (“GAAP”) and under the rules and regulations of the United States Securities and Exchange Commission (“SEC”) for interim reporting. The accompanying unaudited condensed consolidated financial statements include all adjustments, consisting of normal recurring adjustments, which are necessary to present fairly the Company’s financial position, results of operations, and cash flows. The unaudited condensed consolidated results of operations are not necessarily indicative of the results that may occur for the full fiscal year. Certain information and note disclosures normally included in the financial statements prepared in accordance with GAAP have been condensed or omitted under the SEC’s rules and regulations. These unaudited condensed consolidated financial statements should be read in conjunction with the audited financial statements and accompanying notes thereto for the years ended December 31, 2018. The balance sheet data as of December 31, 2018 was derived from the Company’s audited financial statements for the year ended December 31, 2018.

The Company’s significant accounting policies have not changed substantially from those previously described in the consolidated financial statements for the year ended December 31, 2018, except for the adoption of ASU 2016-02, *Leases (Topic 842)*. The following are updates to certain policies described in Note 2 to the Company’s consolidated financial statements for the year ended December 31, 2018.

Certain amounts in the unaudited condensed consolidated financial statements and associated notes may not add due to rounding. All percentages have been calculated using unrounded amounts.

### **PRINCIPALS OF CONSOLIDATION**

The unaudited condensed consolidated financial statements include the accounts of Ocugen, Inc. and its wholly owned subsidiary. All intercompany balances and transactions have been eliminated in consolidation.

### **FOREIGN CURRENCY TRANSLATION AND TRANSACTIONS**

The assets and liabilities of the Company’s foreign subsidiary are translated into U.S. dollars based on exchange rates in effect at the end of each period. Revenues and expenses are translated at average exchange rates during the periods. Currency transaction gains or losses are included in Other expenses. Gains or losses from balance sheet translation are included in Accumulated other comprehensive income.

### **USE OF ESTIMATES**

In preparing unaudited condensed consolidated financial statements in conformity with GAAP, management is required to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported amounts of expenses during the reporting period. Due to inherent uncertainty involved in making estimates, actual results reported in future periods may be affected by changes in these estimates. On an ongoing basis, the Company evaluates its estimates and assumptions. These estimates and assumptions include valuing equity securities in share-based payment arrangements and valuation of the embedded conversion feature on the convertible promissory notes.

### **CASH, CASH EQUIVALENTS, AND RESTRICTED CASH**

The Company considers all highly-liquid investments that have maturities of three months or less when acquired to be cash equivalents. Cash and cash equivalents include bank demand deposits, marketable securities with maturities of three months or less at purchase, and money market funds that invest primarily in certificates of deposit, commercial paper and United States government and United States government agency obligations. The Company’s restricted cash balance consists of cash held to collateralize a corporate credit card account.

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The following table provides a reconciliation of cash, cash equivalents, and restricted cash in the consolidated balance sheets to the total amount shown in the condensed consolidated statements of cash flows:

	As of March 31,	
	2019	2018
Cash, cash equivalents and restricted cash reconciliation:		
Cash and cash equivalents	\$ 308,717	\$ 8,269,146
Restricted cash	150,625	150,065
Total cash, cash equivalents and restricted cash	<u>\$ 459,342</u>	<u>\$ 8,419,211</u>

### NOTE 3—RECENT ACCOUNTING PRONOUNCEMENTS

#### RECENTLY ADOPTED ACCOUNTING STANDARDS

In February 2016, the FASB issued ASU No. 2016-02 Leases (ASC 842). In July 2018, the FASB issued ASU No. 2018-10, “Codification Improvements to Topic 842, Leases” (ASU 2018-10), which provides narrow amendments to clarify how to apply certain aspects of the new lease standard, and ASU No. 2018-11, “Leases (Topic 842)—Targeted Improvements” (ASU 2018-11), which addressed implementation issues related to the new lease standard. These and certain other lease-related ASUs have generally been codified in ASC 842. ASC 842 supersedes the lease accounting requirements in Accounting Standards Codification Topic 840, Leases (ASC 840). ASC 842 establishes a right-of-use model that requires a lessee to record a right-of-use (“ROU”) asset and a lease liability on the balance sheet for all leases. Under ASC 842, leases are classified as either finance or operating, with classification affecting the pattern of expense recognition in the income statement. The standard also requires disclosures to help investors and other financial statement users better understand the amount, timing and uncertainty of cash flows arising from leases. ASU 2016-02 is effective for annual reporting periods beginning after December 15, 2018 and interim periods within that reporting period. Nonpublic entities are required to apply the guidance in annual periods beginning after December 15, 2019 and in interim periods beginning after December 15, 2020. The Company adopted ASC 842 on January 1, 2019 using the effective date transition method. Prior period results continue to be presented under ASC 840 based on the accounting standards originally in effect for such periods.

The Company has elected certain practical expedients permitted under the transition guidance within ASC 842 to leases that commenced before January 1, 2019, including the package of practical expedients. The election of the package of practical expedients resulted in the Company not reassessing prior conclusions under ASC 840 related to lease identification, lease classification and initial direct costs for expired and existing leases prior to January 1, 2019. The Company did not elect the practical expedient to not record short-term leases on its consolidated balance sheet. The adoption of ASU 2016-02 did not have a significant impact on the Company’s consolidated results of operations or cash flows. Upon adoption, the Company recognized a ROU asset and lease liability of \$0.4 million and \$0.4 million, respectively. See Note 8.

**NOTE 4—NET LOSS PER SHARE OF COMMON STOCK**

The following table sets forth the computation of basic and diluted earnings per share for the three months ended March 31, 2019 and 2018:

	Three months ended March 31,	
	2019	2018
Basic and diluted net loss per share of common stock:		
Net loss	<u>\$ (6,312,606)</u>	<u>\$ (5,039,026)</u>
Weighted average shares of common stock outstanding	<u>10,347,418</u>	<u>10,347,418</u>
Net loss per share of common stock—basic and diluted	<u>\$ (0.61)</u>	<u>\$ (0.49)</u>

The following potentially dilutive securities outstanding at March 31, 2019 and 2018 have been excluded from the computation of diluted weighted average shares outstanding, as they would be antidilutive:

	Three months ended March 31,	
	2019	2018
Stock options	1,281,367	1,000,000
Warrants	1,814,811	1,814,811
Total	<u>3,096,178</u>	<u>2,814,811</u>

In addition, the Company has convertible promissory notes that are currently anti-dilutive, however, the potential dilution is not determinable as the number of common shares to be issued upon conversion is variable based on the amount of the Qualified Financing.

**NOTE 5—LICENSE AGREEMENTS****LICENSE AGREEMENT WITH UNIVERSITY OF COLORADO**

In March 2014, the Company entered into a patent license agreement with the University of Colorado (“University”), which granted the Company an exclusive license to develop and commercialize, and continue to secure patents for OCU100 and OCU200, including the ability to enforce any rights against infringement. Under the agreement, the Company assumed primary responsibility for preparing, filing and prosecuting broad patent claims for OCU100 and OCU200 for the University’s benefit. Further, the Company assumed primary responsibility for all patent activities, including all costs associated with the perfection and maintenance of the patents for OCU100 and OCU200.

In exchange for the licensed patents, the Company issued the University 180,000 shares of the Company’s common stock. The license agreement included an anti-dilution provision, requiring the issuance of additional shares to maintain a specified ownership interest until such time as the Company achieved a specified level of financing. Between the effective date of the agreement and December 31, 2016, the Company issued the University an additional 67,000 shares of the Company’s common stock. The anti-dilution provision was no longer effective per the terms of the agreement, as amended, after the Company’s Series A financing round closed in December 2016. The Company also reimbursed the University for \$26,179 of fees and costs previously incurred by the University.

The agreement with the University, as amended in January 2017, obligates the Company to pay certain development and regulatory milestone fees of up to \$1.5 million, royalties in the low single digits on net sales and royalties ranging from the mid-teens to forty percent on sublicense income of OCU100 and OCU200.

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The agreement with the University calls for minimum annual royalty payments of \$20,000, starting on the third anniversary of the agreement and on each annual anniversary thereafter, and after sales commence, increasing to a percentage rate in the mid-twenties of the previous year's royalty payment paid to the University, through the term of the agreement. The Company paid \$20,000 during 2018 and will pay \$20,000 in 2019 as the minimum royalty is due annually beginning in 2017 and recognized such amount as research and development expense. No additional royalties were paid or incurred during 2018 or the three months ended March 31, 2019 as the Company has not achieved any milestones, net sales or sublicensing for OCU100 or OCU200. Future annual royalties will be recognized in the years they are earned, per the license agreement. The Company may cancel the license agreement at any time with 60 days' written notice.

### **LICENSE AGREEMENT WITH UNIVERSITY OF ILLINOIS**

In February 2016, the Company entered into a license agreement with the University of Illinois, Chicago ("UIC"), which granted the Company an exclusive license to develop, commercialize and continue to secure patents for OCU300 and OCU310. In connection with acquiring the license for OCU300 and OCU310, the Company was required to pay a signing fee of \$15,000, which was recognized as research and development expense.

The Company is required to pay royalties ranging from the low single digits to low teens to UIC based on net sales and sublicense revenues generated by OCU300 and OCU310. The Company is also required to pay minimum annual royalties to UIC, beginning with an annual payment of \$20,000 on the third anniversary of the effective date of the agreement, and increasing gradually to \$50,000 by the sixth anniversary and continuing through the term of the agreement. These minimum royalties will be recognized over the annual period to which they relate. The Company is also obligated to pay UIC up to \$1.25 million upon the achievement of certain development and regulatory milestones.

The Company recognized \$5,833 and \$3,333 of royalty expense related to this agreement during the three months ended March 31, 2019 and March 31, 2018, respectively. Additionally, during 2018, the Company incurred \$250,000 in milestone payments due to achieving a milestone associated with dosing the first patient in a Phase 3 clinical trial. The \$250,000 is in Accrued Expenses as of March 31, 2019 and December 31, 2018. The Company has not achieved any other milestones, net sales or sublicensing for OCU300 or OCU310. The Company may cancel the license agreement at any time with 90 days' written notice.

### **LICENSE AGREEMENT WITH THE SCHEPENS EYE RESEARCH INSTITUTE**

In December 2017, the Company entered into a license agreement with The Schepens Eye Research Institute, ("SERI"), which granted the Company an exclusive license to develop, commercialize, and continue to secure patents for OCU400. This agreement is accounted for as a Collaborative Arrangement. In connection with acquiring the license, the Company was required to pay a license fee of \$125,000, which was recognized in 2017.

The Company was also required to reimburse SERI for all patent costs incurred prior to the effective date of the agreement, totaling \$39,681, and will be required to reimburse SERI for all future patent costs related to this licensed technology.

These license and patent fees were recognized as research and development expense in 2017.

The Company is obligated to pay SERI up to \$6.0 million upon the achievement of certain development and regulatory milestones. The Company is also obligated to pay SERI up to \$10.5 million upon the achievement of certain commercial milestones. The Company will also pay SERI royalties in the low single digits based on net sales, which will be credited against the annual license maintenance fees. The license agreement dictates that the Company will pay an annual license maintenance fee of \$25,000 for the first two years following expiration or termination of the Sponsored Research Agreement, and \$50,000 for each year thereafter. No license maintenance



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fees were paid during the three months ended March 31, 2019 or in 2018. No milestones or royalties were paid or incurred through March 31, 2019, as the Company has not achieved any milestones, net sales or sublicensing under this agreement. The Company may cancel the license agreement at any time with 180 days' written notice.

In December 2017, the Company also entered into a Sponsored Research Agreement with SERI which is effective for two years. Pursuant to the terms of the agreement, the Company expects to make payments of approximately \$1.1 million for research services for OCU400 over the period beginning December 2017 and ending December 2019. The Company recognized approximately \$159,250 and \$145,600 as research and development expense in the three months ended March 31, 2019 and March 31, 2018, respectively for work performed under this agreement.

### **NOTE 6—BALANCE SHEET DETAIL**

Accrued Expenses are as follows:

	<u>March 31,</u> <u>2019</u>	<u>December 31,</u> <u>2018</u>
Accrued expenses:		
Research & Development	\$ 456,757	\$ 705,436
Clinical	234,973	469,473
Consulting	72,333	86,619
Employees	223,920	123,372
Legal	10,387	15,400
Other	—	2,450
Total	<u>\$ 998,370</u>	<u>\$ 1,402,750</u>

### **NOTE 7—DEBT**

#### *EB-5 LOAN*

In September 2016, pursuant to the U.S. government's Immigrant Investor Program, commonly known as the EB-5 program (the "EB-5 Program"), the Company entered into an arrangement to borrow up to \$10.0 million from EB5 Life Sciences, L.P. (the "Lender") in \$0.5 million increments. Borrowing may be limited by the amount of funds raised by the Lender and are subject to certain job creation requirements by the Company. Borrowings are at a fixed interest rate of 4.0% and are to be utilized in the clinical development, manufacturing, and commercialization of the Company's products and for the general working capital needs of the Company. Outstanding borrowings pursuant to the EB-5 Program become due upon the seventh anniversary of the final disbursement. Amounts repaid cannot be re-borrowed.

In September 2016, \$0.5 million was borrowed by the Company followed by another borrowing of \$0.5 million in December 2016. Issuance costs for these borrowings totaled \$103,887. At March 31, 2019, there is \$1.0 million of principal outstanding which has accrued interest of approximately \$10,000 during the three months ended March 31, 2019 and 2018, respectively. As of March 31, 2019, total accrued interest is approximately \$97,000. As of March 31, 2019 and December 31, 2018, the Company believes the fair value of the EB-5 Note approximates its carrying value due to the nature of the loan and the similarity between the interest rate on the Note and prevailing interest rates.

The EB-5 Note is secured by substantially all assets of the Company, except for any patents, patent applications, pending patents, patent license, patent sublicense, trademarks, and other intellectual property rights.

Amortization expense amounted to approximately \$3,710 for the three months ended March 31, 2019 and March 31, 2018, and is included in interest expense.

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### Convertible Notes

During the year ended December 31, 2018, the Company issued convertible promissory notes (the “Notes”) to existing stockholders in the Company, including \$3.35 million to board members. At issuance, the following amounts were recorded:

<u>Note Issuance Date</u>	<u>Note Principal Amount</u>	<u>Fair Value of Conversion Feature</u>	<u>Fair Value of Change in Control Feature</u>	<u>Debt Issuance Costs</u>	<u>Carrying Amount of the Note</u>	<u>Maturity Date</u>
January 2018	\$ 5,000,000	\$ (2,579,074)	\$ (78,637)	\$ (35,969)	\$ 2,306,320	July 2019
June 2018	1,000,000	(714,041)	(10,175)	(3,000)	272,784	Dec. 2019
November 2018	1,150,400	—	(21,127)	(50,646)	1,078,627	May 2020
December 2018	150,000	—	(2,857)	(14,310)	132,833	May 2020
<b>Total</b>	<b>\$ 7,300,400</b>	<b>\$ (3,293,115)</b>	<b>\$ (112,796)</b>	<b>\$ (103,925)</b>	<b>\$ 3,790,564</b>	

During the three months ended March 31, 2019, the Company issued convertible promissory notes (the “Notes”) to existing stockholders in the Company, including \$0.1 million to a board member. At issuance, the following amounts were recorded:

<u>Note Issuance Date</u>	<u>Note Principal Amount</u>	<u>Fair Value of Conversion Feature</u>	<u>Fair Value of Change in Control Feature</u>	<u>Debt Issuance Costs</u>	<u>Carrying Amount of the Note</u>	<u>Maturity Date</u>
January 2019	\$ 450,000	\$ (172,227)	\$ (10,655)	\$ (29,358)	\$ 237,760	May 2020
February 2019	1,000,000	(284,448)	(17,931)	(55,875)	641,746	June 2020
<b>Total</b>	<b>\$ 1,450,000</b>	<b>\$ (456,675)</b>	<b>\$ (28,586)</b>	<b>\$ (85,233)</b>	<b>\$ 879,506</b>	

All Notes accrue interest at a rate of 5% per annum and have scheduled maturity date on the eighteenth month anniversary of the date of the issuance of the Notes (the Maturity Date”). If prior to the Maturity Date, there is a consummation of the sale of all or substantially all of the assets of the Company, change in control or event of default, the Notes becomes due and payable at an amount equal to 1.5 times the principal amount of the Notes together with all accrued interest (the “Change in Control Feature”).

With regards to the notes issued in January 2018 and June 2018, if the Company receives equity financing from the issuance of stock of the Company from an investor or group of investors in a transaction or series of related transactions resulting in gross proceeds to the Company of at least \$15.0 million (the “Financing Transaction”), including the conversion of these Notes, the principal amount and all interest accrued but not paid through the closing date of the equity financing shall automatically convert into the same class of equity securities as those issued in the equity financing at a price per share equal to a 30% discount to the lowest price per share being paid by investors in the equity financing (the “Conversion Feature”).

With regards to the notes issued in November 2018 and December 2018 notes, if the Company receives equity financing from the issuance of stock of the Company from an investor or group of investors in a transaction or series of related transactions resulting in gross proceeds to the Company of at least \$4.0 million (the “Financing Transaction”), including the conversion of these Notes, the principal amount and all interest accrued but not paid through the closing date of the equity financing shall automatically convert into the same class of equity securities as those issued in the equity financing at a price per share equal to the lowest price per share being paid by investors in the equity financing.

With regards to the notes issued in January 2019 and February 2019, if the Company receives equity financing from the issuance of stock of the Company from an investor or group of investors in a transaction or

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series of related transactions resulting in gross proceeds to the Company of at least \$10.0 million (the “Financing Transaction”), including the conversion of these Notes, the principal amount and all interest accrued but not paid through the closing date of the equity financing shall automatically convert into the same class of equity securities as those issued in the equity financing at a price per share equal to a 15% discount to the lowest price per share being paid by investors in the equity financing (the “Conversion Feature”).

The Company bifurcated the Conversion Feature for the January 2018, June 2018, January 2019, and February 2019 notes and classified it as a derivative liability because the Conversion Feature does not have a fixed conversion price and conversion will be settled in a variable number of common shares. There is no bifurcated conversion feature for the November 2018 and December 2018 notes as there is no discount to the lowest equity price triggering conversion.

The Company also bifurcated the Change in Control Feature for all of the notes because it was determined to be a redemption feature not clearly and closely related to the debt host. The fair value of both of these embedded features accounted for as a derivative liability is recorded as a discount on the Notes. The debt discount is accreted into interest expense over the expected time until conversion of the Notes. This accretion amounted to \$465,186 and \$730,556 in the three months ending March 31, 2019 and March 31, 2018, respectively.

The fair value of the derivative liability for the embedded features was classified as a liability in the Company’s Consolidated Balance Sheets at issuance, with subsequent changes in fair value during the three months ended March 31, 2019 recorded on the Company’s Condensed Consolidated Statements of Operations and Comprehensive Loss as Change in fair value of derivative liabilities.

	Conversion feature	Change in Control feature
Balance at January 1, 2019	\$ 1,623,009	\$ 118,213
Fair value at issuance — January 2019 notes	172,227	10,655
Fair value at issuance — February 2019 notes	284,448	17,931
Change in fair value of embedded derivatives	768,805	7,468
Balance at March 31, 2019	\$ 2,848,489	\$ 154,267

For purposes of estimating the fair market value of the embedded features, the Company used a with and without model. The significant assumptions used in the valuation model are level 3 inputs and are as follows:

### Conversion feature – Crossover Triggered:

	Jan 2018 Notes	Jun 2018 Notes	Nov 2018 Notes	Dec 2018 Notes	Jan 2019 Notes	Feb 2019 Notes
<b>At Issuance</b>						
Time until expected conversion (in years)	0.49	0.17	—	—	.02	.02
Probability of conversion	80%	75%	—	—	60%	60%
<b>At December 31, 2018</b>						
Time until expected conversion (in years)	0.02	0.02	—	—	—	—
Probability of conversion	60%	60%	—	—	—	—
<b>At March 31, 2019</b>						
Time until expected conversion (in years)	0.02	0.02	—	—	0.02	0.02
Probability of conversion	0%	0%	—	—	0%	0%

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**Conversion feature – IPO Triggered / Reverse Merger Triggered:**

	Jan 2018 Notes	Jun 2018 Notes	Nov 2018 Notes	Dec 2018 Notes	Jan 2019 Notes	Feb 2019 Notes
<b>At Issuance</b>						
Time until expected conversion (in years)	—	—	—	—	0.25	0.18
Probability of conversion	—	—	—	—	20%	20%
<b>At December 31, 2018</b>						
Time until expected conversion (in years)	0.33	0.33	—	—	—	—
Probability of conversion	20%	20%	—	—	—	—
<b>At March 31, 2019</b>						
Time until expected conversion (in years)	0.08	0.08	—	—	0.08	0.08
Probability of conversion	80%	80%	—	—	80%	80%

**Change in Control feature:**

	Jan 2018 Notes	Jun 2018 Notes	Nov 2018 Notes	Dec 2018 Notes	Jan 2019 Notes	Feb 2019 Notes
<b>At Issuance</b>						
Time until expected conversion (in years)	1.24	0.83	0.47	0.38	0.33	0.33
Probability of conversion	3%	3%	3%	3%	3%	3%
<b>At December 31, 2018</b>						
Time until expected conversion (in years)	0.41	0.41	0.41	0.41	—	—
Probability of conversion	3%	3%	3%	3%	—	—
<b>At March 31, 2019</b>						
Time until expected conversion (in years)	0.17	0.17	0.17	0.17	0.17	0.17
Probability of conversion	3%	3%	3%	3%	3%	3%

The Company considered several possible outcomes in the likelihood and timing of a qualified financing and/or a change in control occurring that would trigger conversion or redemption and believes the amounts disclosed above and utilized in the valuation are the best estimates of such amounts at each valuation date. The possible outcomes are impacted by the Company's current capital raising plans and its need for additional funding to continue its development efforts. These assumptions are updated each reporting period.

Debt issuance costs incurred related to the issuance of the January 2019 and February 2019 notes were \$85,233 and accounted for as debt discount and amortized over the period until expected conversion. This expense amounted to \$114,389 and \$11,999 for the three months ended March 31, 2019 and March 31, 2018, respectively, and is included in interest expense.

**NOTE 8—COMMITMENTS**

**OPERATING LEASES**

The Company determines if an arrangement is a lease at inception. This determination generally depends on whether the arrangement conveys to the Company the right to control the use of an explicitly or implicitly

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identified fixed asset for a period of time in exchange for consideration. Control of an underlying asset is conveyed to the Company if the Company obtains the rights to direct the use of and to obtain substantially all of the economic benefits from using the underlying asset. The Company has lease agreements which include lease and non-lease components, which the Company has elected to account for as a single lease component for all classes of underlying assets. Lease expense for variable lease components are recognized when the obligation is probable.

Operating leases are included in Other assets and Lease obligations on the Company's consolidated balance sheets. Operating lease ROU assets and liabilities are recognized at commencement date based on the present value of lease payments over the lease term. Operating lease payments are recognized as lease expense on a straight-line basis over the lease term. The Company primarily leases buildings (real estate) which are classified as operating leases. ASC 842 requires a lessee to discount its unpaid lease payments using the interest rate implicit in the lease or, if that rate cannot be readily determined, its incremental borrowing rate. As an implicit interest rate is not readily determinable in the Company's leases, the incremental borrowing rate is used based on the information available at commencement date in determining the present value of lease payments.

The lease term for all of the Company's leases includes the non-cancellable period of the lease plus any additional periods covered by either a Company option to extend (or not to terminate) the lease that the Company is reasonably certain to exercise, or an option to extend (or not to terminate) the lease controlled by the lessor. Options for lease renewals have been excluded from the lease term (and lease liability) for the majority of the Company's leases as the reasonably certain threshold is not met.

Lease payments included in the measurement of the lease liability are comprised of fixed payments, variable payments that depend on index or rate, and amounts probable to be payable under the exercise of the Company option to purchase the underlying asset if reasonably certain.

Variable lease payments not dependent on a rate or index associated with the Company's leases are recognized when the event, activity, or circumstance in the lease agreement on which those payments are assessed as probable. Variable lease payments are presented as operating expenses in the Company's income statement in the same line item as expense arising from fixed lease payments.

The Company has commitments under operating leases for certain facilities used in its operations. The Company's leases have initial lease terms ranging from one to five years. Certain lease agreements contain provisions for future rent increases.

The components of lease expense were as follows:

	<b>Three Months Ended March 31, 2019</b>
Operating lease cost	\$ 73,273
Variable lease cost	15,848
<b>Total lease cost</b>	<b>\$ 89,121</b>

Supplemental balance sheet information related to leases was as follows:

	<b>March 31, 2019</b>
Right of use assets, net	\$ 498,075
Current Lease obligations	260,906
Non-current Lease obligations	238,377
<b>Total lease liabilities</b>	<b>\$ 499,283</b>

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Supplemental cash flow information and other information related to leases was as follows:

	<b>Three Months Ended March 31, 2019</b>
Cash paid for amounts included in measurement of liabilities:	
Operating cash flows from operating leases	\$ 89,121
Right-of-use assets obtained in exchange for new operating liabilities	\$ 134,974
Weighted-average remaining lease terms—operating leases (years)	2.3
Weighted-average discount rate—operating leases	7.6%

Future minimum operating minimum lease payments for all leases, exclusive of taxes and other carrying charges, are approximately as follows:

<b>For the Years Ending December 31,</b>	<b>Amount</b>
2019	240,155
2020	147,555
2021	135,574
2022	22,707
<b>Total</b>	<b>\$ 545,991</b>

The Company does not have any leases that have not yet commenced which are significant.

### **FINANCING LEASES**

In June 2018, The Company leased a specialized research equipment under a lease classified as a financing lease. The leased equipment is amortized on a straight-line basis over 5 years. Total accumulated amortization related to the leased equipment is \$9,573 at December 31, 2018, of which \$3,191 was recognized in the three months ended March 31, 2019. The following is a schedule showing the future minimum lease payments under financing leases by years and the present value of the minimum lease payments as of March 31, 2019. The interest rate related to the lease obligation is 7.6 percent and the maturity date is July 2021.

Future minimum lease payments for all financing leases, exclusive of taxes and other carrying charges, are approximately as follows:

<b>For the Years Ending December 31,</b>	<b>Amount</b>
2019	17,892
2020	23,857
2021	11,928
<b>Total</b>	<b>\$ 53,677</b>
<b>Less: Amount representing interest</b>	<b>\$ 4,481</b>
<b>Present Value of Minimum Lease Payments</b>	<b>\$ 49,196</b>

### **NOTE 9—RESTRICTED CASH**

In May 2017, the Company opened a corporate credit card account for use by employees for travel and other business-related expenses. To secure this credit account, the Company placed \$100,000 into a collateral savings account with its financial institution and recorded the \$100,000 as Restricted Cash on its Balance Sheet. The

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account earns 0.05% interest, which is deposited monthly into the collateral account and increases the Restricted Cash asset accordingly. The collateral account will remain restricted until the Company either closes the credit account or meets other revenue and/or cash balance criteria, as defined by the financial institution.

In January 2018, the Company opened a new corporate credit card account for use by employees for travel and other business-related expenses. To secure this credit account, the Company placed \$150,000 into a collateral savings account with its financial institution and recorded the \$150,000 as Restricted Cash on its Balance Sheet. The account earns 0.25% interest, which is deposited monthly into the collateral account and increases the Restricted Cash asset accordingly. The collateral account will remain restricted until the Company either closes the credit account or meets other revenue and/or cash balance criteria, as defined by the financial institution.

In February 2018, the Company closed the corporate credit card account which had been opened in May 2017. As a result, the collateral savings account related to the credit account was closed and the \$100,000 balance plus accrued interest was released to cash.

### **NOTE 10—SUBSEQUENT EVENTS**

#### Convertible Notes

In April 2019, the Company entered into a subscription agreement with existing investors for the sale of 168,068 shares of common stock for \$1,000,000, or \$5.95 per share. This capital raise triggered the conversion features on the convertible debt described in Note 7 above. With regards to the January 2018, June 2018, January 2019, and February 2019 notes, the triggers for conversion met were an equity financing and \$10.0 million of gross proceeds from an investor or group of investors. With regards to the November 2018 and December 2018 notes, the triggers met were an equity financing and \$4.0 million of gross proceeds from an investor or group of investors.

The notes converted with a discount of 30%, which is consistent with the notes issued in January 2018 and June 2018, however, differs from the 0% discount on the November 2018 and December 2018 notes and the 15% on the January 2019 and February 2019 notes. This modification occurred at the time of conversion. The Company issued 2,195,157 shares of common stock on the date of conversion to extinguish the debt. Certain aspects of the accounting for the conversion have not been finalized.

Subsequently, in April 2019 the Company issued a convertible note in the amount of \$900,000, which was converted into equity on May 16, 2019 upon agreement between the Company and the other party. The Company issued 152,521 shares of common stock at the conversion date to extinguish the debt.

#### Proposed Merger

In April 2019, the Company and Histogenics Corporation (“Histogenics”) entered into a Merger Agreement. Upon the terms and subject to the satisfaction of the conditions described in the Merger Agreement, including approval of the transaction by the Company’s stockholders and Histogenics’ stockholders, a wholly-owned subsidiary of Histogenics will be merged with and into Ocugen, with Ocugen surviving the Merger as a wholly-owned subsidiary of Histogenics. The proposed Merger is structured as a stock-for-stock transaction whereby all of Ocugen’s outstanding shares of common stock and securities convertible into or exercisable for Ocugen’s common stock will be converted into the right to receive Histogenics’ common stock and securities convertible into or exercisable for Histogenics’ common stock. Under the exchange ratio formula in the Merger Agreement, as amended on June 13, 2019, the former Ocugen equity holders immediately before the Merger are expected to own approximately 86.24% of the outstanding capital stock of Histogenics, and the stockholders of Histogenics immediately before the Merger are expected to own approximately 13.76% of the outstanding capital stock of Histogenics, including the Initial Shares but excluding the Additional Shares issued in the Financing SPA (as such terms are defined below). If the proposed Merger is not completed and the Merger Agreement is terminated

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under certain circumstances, Histogenics or Ocugen may be required to pay the other party a termination fee of up to \$600,000 or \$700,000, respectively. Even if a termination fee is not payable in connection with a termination of the Merger Agreement, each of Histogenics and Ocugen will have incurred significant fees and expenses, which must be paid whether or not the Merger is completed.

### *Securities Purchase Agreement and Bridge Loan*

In June 2019, the Company and Histogenics entered into a Securities Purchase Agreement with several investors (the “Financing SPA”), pursuant to which, among other things, the Company agreed to issue immediately prior to the Merger 4,574,272 common shares to the investors (the “Initial Shares”), and 4,574,272 common shares into escrow (the “Additional Shares”) on behalf of the investors, and Histogenics agreed to issue after the Merger, warrants to purchase common shares of Histogenics, in exchange for \$25.0 million. In May 2019, the Company entered into a Bridge Loan with certain of the investors to advance \$2.1 million of the \$25.0 million. The Bridge Loan is securitized against the intellectual property of the Company. If the proposed Merger is completed, immediately prior to the Effective Time, the Company will offset \$2.4 million from the remaining amount to be received from the investors under the Financing SPA and the Bridge Loan will be deemed to have been repaid and cancelled. If the proposed Merger is not completed, the Company may be required to pay the note holders \$2.4 million.

Management has evaluated subsequent events through June 14, 2019, the date the financial statements were available to be issued. Adjustments or additional disclosures, if any, have been included in these financial statements.



**AGREEMENT AND PLAN OF MERGER  
AND REORGANIZATION**

among:

**HISTOGENICS CORPORATION,**  
a Delaware corporation;

**RESTORE MERGER SUB, INC.,**  
a Delaware corporation; and

**OCUGEN, INC.,**  
a Delaware corporation

Dated as of April 5, 2019

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## AGREEMENT AND PLAN OF MERGER AND REORGANIZATION

**THIS AGREEMENT AND PLAN OF MERGER AND REORGANIZATION** (this “*Agreement*”) is made and entered into as of April 5, 2019, by and among **Histogenics Corporation**, a Delaware corporation (“*Parent*”), **Restore Merger Sub, Inc.** a Delaware corporation and wholly owned subsidiary of Parent (“*Merger Sub*”), and **Ocugen, Inc.**, a Delaware corporation (the “*Company*”). Certain capitalized terms used in this Agreement are defined in **Exhibit A**.

### RECITALS

A. Parent and the Company intend to effect a merger of Merger Sub with and into the Company (the “*Merger*”) in accordance with this Agreement and the DGCL. Upon consummation of the Merger, Merger Sub will cease to exist and the Company will become a wholly owned subsidiary of Parent.

B. The Parties desire that the Merger qualify as a “reorganization” within the meaning of Section 368(a) of the Code and the Treasury Regulations promulgated thereunder, and by executing this Agreement, the Parties intend to adopt a plan of reorganization within the meaning of Treasury Regulations Sections 1.368-2(g) and 1.368-3.

C. The Parent Board has (i) determined that the Contemplated Transactions are fair to, advisable and in the best interests of Parent and its stockholders, (ii) approved and declared advisable this Agreement and the Contemplated Transactions, including the issuance of shares of Parent Common Stock to the stockholders of the Company pursuant to the terms of this Agreement and (iii) determined to recommend, upon the terms and subject to the conditions set forth in this Agreement, that the stockholders of Parent vote to approve the Parent Stockholder Matters.

D. The Merger Sub Board has (i) determined that the Contemplated Transactions are fair to, advisable, and in the best interests of Merger Sub and its sole stockholder, (ii) approved and declared advisable this Agreement and the Contemplated Transactions and (iii) determined to recommend, upon the terms and subject to the conditions set forth in this Agreement, that the stockholder of Merger Sub votes to adopt this Agreement and thereby approve the Contemplated Transactions.

E. The Company Board has (i) determined that the Contemplated Transactions are fair to, advisable and in the best interests of the Company and its stockholders, (ii) approved and declared advisable this Agreement and the Contemplated Transactions and (iii) determined to recommend, upon the terms and subject to the conditions set forth in this Agreement, that the stockholders of the Company vote to approve the Company Stockholder Matters.

F. Concurrently with the execution and delivery of this Agreement and as a condition and inducement to Parent’s willingness to enter into this Agreement, the officers, directors, stockholders and holders of convertible promissory notes of the Company listed on Section A of the Company Disclosure Schedule (solely in their capacity as such) are executing (a) support agreements in favor of Parent in substantially the form attached hereto as **Exhibit B-1** (the “*Company Stockholder Support Agreement*”), pursuant to which such Persons (the “*Company Signatories*”) have, subject to the terms and conditions set forth therein, agreed to vote all of their shares of Company Capital Stock in favor of the Company Stockholder Matters and against any proposals that compete with the Contemplated Transactions, and (b) lock-up agreements in substantially the form attached hereto as **Exhibit D** executed by the Company Signatories (each, a “*Company Lock-Up Agreement*”).

G. Concurrently with the execution and delivery of this Agreement and as a condition and inducement to the Company’s willingness to enter into this Agreement, the officers and directors of Parent listed on Section A of the Parent Disclosure Schedule (solely in their capacity as stockholders of Parent) are executing (a) support agreements in favor of the Company in substantially the form attached hereto as **Exhibit B-2** (the “*Parent Stockholder Support Agreement*”), pursuant to which such Persons (the “*Parent Signatories*”) have, subject to

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the terms and conditions set forth therein, agreed to vote all of their shares of Parent Common Stock in favor of the Parent Stockholder Matters and against any proposals that compete with the Contemplated Transactions and (b) lock-up agreements in substantially the form attached hereto as **Exhibit D** executed by the Parent Signatories (each, a “**Parent Lock-Up Agreement**”).

H. It is expected that promptly after the Registration Statement is declared effective under the Securities Act (but in no event later than 10 Business Days following the effectiveness of the Registration Statement), the Company shall deliver the Company Stockholder Written Consent evidencing the Required Company Stockholder Vote.

### AGREEMENT

The Parties, intending to be legally bound, agree as follows:

#### Section 1. DESCRIPTION OF TRANSACTION

1.1 **The Merger.** Upon the terms and subject to the conditions set forth in this Agreement, at the Effective Time, Merger Sub shall be merged with and into the Company, and the separate existence of Merger Sub shall cease. The Company will continue as the surviving corporation in the Merger (the “**Surviving Corporation**”).

1.2 **Effects of the Merger.** The Merger shall have the effects set forth in this Agreement, the Certificate of Merger and in the applicable provisions of the DGCL. As a result of the Merger, the Company will become a wholly owned subsidiary of Parent.

1.3 **Closing; Effective Time.** Unless this Agreement is earlier terminated pursuant to the provisions of [Section 9.1](#), and subject to the satisfaction or waiver of the conditions set forth in [Sections 6, 7 and 8](#), the consummation of the Merger (the “**Closing**”) shall take place remotely as promptly as practicable (but in no event later than the second Business Day following the satisfaction or waiver of the last to be satisfied or waived of the conditions set forth in [Sections 6, 7 and 8](#), other than those conditions that by their nature are to be satisfied at the Closing, but subject to the satisfaction or waiver of each of such conditions), or at such other time, date and place as Parent and the Company may mutually agree in writing. The date on which the Closing actually takes place is referred to as the “**Closing Date**.” At the Closing, the Parties shall cause the Merger to be consummated by executing and filing with the Secretary of State of the State of Delaware a certificate of merger with respect to the Merger, satisfying the applicable requirements of the DGCL and in a form reasonably acceptable to Parent and the Company (the “**Certificate of Merger**”). The Merger shall become effective at the time of the filing of such Certificate of Merger with the Secretary of State of the State of Delaware or at such later time as may be specified in such Certificate of Merger with the consent of Parent and the Company (the time as of which the Merger becomes effective being referred to as the “**Effective Time**”).

1.4 **Certificate of Incorporation and Bylaws; Directors and Officers.** At the Effective Time:(a) the certificate of incorporation of the Surviving Corporation shall be amended and restated in its entirety to read identically to the certificate of incorporation of Merger Sub as in effect immediately prior to the Effective Time, until thereafter amended as provided by the DGCL and such certificate of incorporation; *provided, however*, that at the Effective Time, Parent shall file an amendment to the Surviving Company’s certificate of incorporation to (i) change the name of the Surviving Corporation to Ocugen OpCo, Inc. and (ii) make such other changes as are mutually agreed to by Parent and the Company.

(b) the certificate of incorporation of Parent shall be identical to the certificate of incorporation of Parent immediately prior to the Effective Time, until thereafter amended as provided by the DGCL and such certificate of incorporation, *provided, however*, that at the Effective Time, Parent shall file an amendment to its certificate of incorporation to the extent approved by the requisite holders of Parent Common Stock to (i) change the name of Parent to Ocugen, Inc., (ii) as contemplated by [Section 5.3\(a\)\(i\)](#), effect the Nasdaq Reverse Split and (iii) make such other changes as are mutually agreeable to Parent and the Company;

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(c) the bylaws of the Surviving Corporation shall be amended and restated in their entirety to read identically to the bylaws of Merger Sub as in effect immediately prior to the Effective Time (except that the name of the Surviving Corporation in such bylaws shall reflect the name identified in Section 1.4(a)), until thereafter amended as provided by the DGCL and such bylaws;

(d) the directors and officers of Parent, each to hold office in accordance with the certificate of incorporation and bylaws of Parent, shall be as set forth in Section 5.11; and

(e) the directors and officers of the Surviving Corporation, each to hold office in accordance with the certificate of incorporation and bylaws of the Surviving Corporation, shall be the directors and officers of Parent as set forth in Section 5.11, after giving effect to the provisions of Section 5.11, or such other persons as shall be mutually agreed upon by Parent and the Company.

### 1.5 Conversion of Shares.

(a) At the Effective Time, by virtue of the Merger and without any further action on the part of Parent, Merger Sub, the Company or any stockholder of the Company or Parent:

(i) any shares of Company Common Stock held as treasury stock or held or owned by the Company, Merger Sub or any Subsidiary of the Company immediately prior to the Effective Time shall be canceled and retired and shall cease to exist, and no consideration shall be delivered in exchange therefor; and

(ii) subject to Section 1.5(c), each share of Company Common Stock outstanding immediately prior to the Effective Time (including shares to be issued in connection with the exercise or conversion of the Company Converting Notes or Company Warrants but excluding shares to be canceled pursuant to Section 1.5(a)(i) and excluding Dissenting Shares) shall be automatically converted solely into the right to receive a number of shares of Parent Common Stock equal to the Exchange Ratio (the "**Merger Consideration**").

(b) If any shares of Company Common Stock outstanding immediately prior to the Effective Time are unvested or are subject to a repurchase option or a risk of forfeiture under any applicable restricted stock purchase agreement or other similar agreement with the Company, then the shares of Parent Common Stock issued in exchange for such shares of Company Common Stock will to the same extent be unvested and subject to the same repurchase option or risk of forfeiture, and such shares of Parent Common Stock shall accordingly be marked with appropriate legends. The Company shall take all actions that may be reasonably necessary to ensure that, from and after the Effective Time, Parent is entitled to exercise any such repurchase option or other right set forth in any such restricted stock purchase agreement or other agreement in accordance with its terms.

(c) No fractional shares of Parent Common Stock shall be issued in connection with the Merger, and no certificates or scrip for any such fractional shares shall be issued. Any holder of Company Common Stock who would otherwise be entitled to receive a fraction of a share of Parent Common Stock (after aggregating all fractional shares of Parent Common Stock issuable to such holder) shall, in lieu of such fraction of a share and upon surrender by such holder of a letter of transmittal in accordance with Section 1.7 and any accompanying documents as required therein, be paid in cash the dollar amount (rounded to the nearest whole cent), without interest, determined by multiplying such fraction by the Parent Closing Price.

(d) All Company Options outstanding immediately prior to the Effective Time under the Company Plans shall be treated in accordance with Section 5.4(a).

(e) All Company Warrants outstanding immediately prior to the Effective Time (to the extent not exercised immediately prior to the Effective Time) shall be treated in accordance with Section 5.4(c).

(f) Each share of common stock, \$0.0001 par value per share, of Merger Sub issued and outstanding immediately prior to the Effective Time shall be converted into and exchanged for one validly issued, fully paid and nonassessable share of common stock, \$0.0001 par value per share, of the Surviving Corporation. Each stock



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certificate of Merger Sub evidencing ownership of any such shares shall, as of the Effective Time, evidence ownership of such shares of common stock of the Surviving Corporation.

(g) If, between the time of calculating the Exchange Ratio and the Effective Time, any outstanding shares of Company Capital Stock or Parent Common Stock shall have been changed into, or exchanged for, a different number of shares or a different class, by reason of any stock dividend, subdivision, reclassification, recapitalization, split (including the Nasdaq Reverse Split to the extent such split has not been previously taken into account in calculating the Exchange Ratio), combination or exchange of shares or other like change, the Exchange Ratio shall, to the extent necessary, be equitably adjusted to reflect such change to the extent necessary to provide the holders of Company Capital Stock, Parent Common Stock, Company Options and Company Warrants with the same economic effect as contemplated by this Agreement prior to such stock dividend, subdivision, reclassification, recapitalization, split (including the Nasdaq Reverse Split), combination or exchange of shares or other like change; provided, however, that nothing herein will be construed to permit the Company or Parent to take any action with respect to Company Capital Stock or Parent Common Stock, respectively, that is prohibited or not expressly permitted by the terms of this Agreement.

**1.6 Closing of the Company's Transfer Books.** At the Effective Time: (a) all shares of Company Common Stock outstanding immediately prior to the Effective Time shall be treated in accordance with Section 1.5(a), and all holders of certificates representing shares of Company Capital Stock that were outstanding immediately prior to the Effective Time shall cease to have any rights as stockholders of the Company; and (b) the stock transfer books of the Company shall be closed with respect to all shares of Company Capital Stock outstanding immediately prior to the Effective Time. No further transfer of any such shares of Company Capital Stock shall be made on such stock transfer books after the Effective Time. If, after the Effective Time, a valid certificate previously representing any shares of Company Capital Stock outstanding immediately prior to the Effective Time (a "**Company Stock Certificate**") is presented to the Exchange Agent or to the Surviving Corporation, such Company Stock Certificate shall be canceled and shall be exchanged as provided in Sections 1.5 and 1.7.

### **1.7 Surrender of Certificates.**

(a) No later than five Business Days after the date that the Registration Statement is declared effective, Parent and the Company shall agree upon and select a reputable bank, transfer agent or trust company to act as exchange agent in the Merger (the "**Exchange Agent**"). At the Effective Time, Parent shall deposit with the Exchange Agent: (i) certificates or evidence of book-entry shares representing the Parent Common Stock issuable pursuant to Section 1.5(a) and (ii) cash sufficient to make payments in lieu of fractional shares in accordance with Section 1.5(c). The Parent Common Stock and cash amounts so deposited with the Exchange Agent, together with any dividends or distributions received by the Exchange Agent with respect to such shares, are referred to collectively as the "**Exchange Fund**."

(b) Promptly after the Effective Time, the Parties shall cause the Exchange Agent to mail to the Persons who were record holders of shares of Company Capital Stock that were converted into the right to receive the Merger Consideration: (i) a letter of transmittal in customary form and containing such provisions as Parent may reasonably specify (including a provision confirming that delivery of Company Stock Certificates shall be effected, and risk of loss and title to Company Stock Certificates shall pass, only upon proper delivery of such Company Stock Certificates to the Exchange Agent); and (ii) instructions for effecting the surrender of Company Stock Certificates in exchange for shares of Parent Common Stock. Upon surrender of a Company Stock Certificate to the Exchange Agent for exchange, together with a duly executed letter of transmittal and such other documents as may be reasonably required by the Exchange Agent or Parent: (A) the holder of such Company Stock Certificate shall be entitled to receive in exchange therefor a certificate or certificates or book-entry shares representing the Merger Consideration (in a number of whole shares of Parent Common Stock) that such holder has the right to receive pursuant to the provisions of Section 1.5(a) (and cash in lieu of any fractional share of Parent Common Stock pursuant to the provisions of Section 1.5(c)); and (B) the Company Stock Certificate so surrendered shall be canceled. Until surrendered as contemplated by this Section 1.7(b), each

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Company Stock Certificate shall be deemed, from and after the Effective Time, to represent only the right to receive a certificate or certificates or book-entry shares of Parent Common Stock representing the Merger Consideration (and cash in lieu of any fractional share of Parent Common Stock). If any Company Stock Certificate shall have been lost, stolen or destroyed, Parent may, in its discretion and as a condition precedent to the delivery of any shares of Parent Common Stock, require the owner of such lost, stolen or destroyed Company Stock Certificate to provide an applicable affidavit with respect to such Company Stock Certificate that includes an obligation of such owner to indemnify Parent against any claim suffered by Parent related to the lost, stolen or destroyed Company Stock Certificate as Parent may reasonably request. In the event of a transfer of ownership of a Company Stock Certificate that is not registered in the transfer records of the Company, payment of the Merger Consideration in respect of such Company Stock Certificate may be made to a Person other than the Person in whose name such Company Stock Certificate so surrendered is registered if such Company Stock Certificate shall be properly endorsed or otherwise be in proper form for transfer and the Person requesting such payment shall pay any transfer or other Taxes required by reason of the transfer or establish to the reasonable satisfaction of Parent that such Taxes have been paid or are not applicable. The Merger Consideration and any dividends or other distributions as are payable pursuant to Section 1.7(c) shall be deemed to have been in full satisfaction of any and all rights pertaining to Company Capital Stock formerly represented by such Company Stock Certificate.

(c) No dividends or other distributions declared or made with respect to Parent Common Stock with a record date on or after the Effective Time shall be paid to the holder of any unsurrendered Company Stock Certificate with respect to the shares of Parent Common Stock that such holder has the right to receive in the Merger until such holder surrenders such Company Stock Certificate or provides an affidavit of loss or destruction in lieu thereof in accordance with this Section 1.7 (at which time (or, if later, on the applicable payment date) such holder shall be entitled, subject to the effect of applicable abandoned property, escheat or similar Laws, to receive all such dividends and distributions, without interest).

(d) Any portion of the Exchange Fund that remains undistributed to holders of Company Stock Certificates as of the date that is one year after the Closing Date shall be delivered to Parent upon demand, and any holders of Company Stock Certificates who have not theretofore surrendered their Company Stock Certificates in accordance with this Section 1.7 shall thereafter look only to Parent for satisfaction of their claims for Parent Common Stock, cash in lieu of fractional shares of Parent Common Stock and any dividends or distributions with respect to shares of Parent Common Stock.

(e) No Party to this Agreement shall be liable to any holder of any Company Stock Certificate or to any other Person with respect to any shares of Parent Common Stock (or dividends or distributions with respect thereto) or for any cash amounts delivered to any public official pursuant to any applicable abandoned property Law, escheat Law or similar Law.

### **1.8 Appraisal Rights.**

(a) Notwithstanding any provision of this Agreement to the contrary, shares of Company Capital Stock that are outstanding immediately prior to the Effective Time and which are held by stockholders who have exercised and perfected appraisal rights for such shares of Company Capital Stock in accordance with the DGCL, as applicable (collectively, the “*Dissenting Shares*”) shall not be converted into or represent the right to receive the Merger Consideration described in Section 1.5 attributable to such Dissenting Shares. Such stockholders shall be entitled to receive payment of the appraised value of such shares of Company Capital Stock held by them in accordance with the DGCL, as applicable, unless and until such stockholders fail to perfect or effectively withdraw or otherwise lose their appraisal rights under the DGCL, as applicable. All Dissenting Shares held by stockholders who shall have failed to perfect or shall have effectively withdrawn or lost their right to appraisal of such shares of Company Capital Stock under the DGCL, as applicable (whether occurring before, at or after the Effective Time) shall thereupon be deemed to be converted into and to have become exchangeable for, as of the Effective Time, the right to receive the Merger Consideration, without interest, attributable to such Dissenting Shares upon their surrender in the manner provided in Sections 1.5 and 1.7.

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(b) The Company shall give Parent prompt written notice of any demands by dissenting stockholders received by the Company, withdrawals of such demands and any other instruments served on the Company and any material correspondence received by the Company in connection with such demands, and the Company shall have the right to direct all negotiations and proceedings with respect to such demands; provided that Parent shall have the right to participate in such negotiations and proceedings. Neither the Parent nor the Company shall, except with the prior written consent of the other Party, voluntarily make any payment with respect to, or settle or offer to settle, any such demands, or approve any withdrawal of any such demands or agree to do any of the foregoing.

1.9 **Further Action.** If, at any time after the Effective Time, any further action is determined by the Surviving Corporation to be necessary or desirable to carry out the purposes of this Agreement or to vest the Surviving Corporation with full right, title and possession of and to all rights and property of the Company, then the officers and directors of the Surviving Corporation shall be fully authorized, and shall use their and its commercially reasonable efforts (in the name of the Company, in the name of Merger Sub, in the name of the Surviving Corporation and otherwise) to take such action.

1.10 **Withholding.** The Parties and the Exchange Agent shall be entitled to deduct and withhold from the consideration otherwise payable pursuant to this Agreement to any holder of Company Capital Stock or any other Person such amounts as such Party or the Exchange Agent is required to deduct and withhold under the Code or any other Law with respect to the making of such payment. The payor shall provide commercially reasonable notice to the payee upon becoming aware of any such withholding obligation, and the Parties shall cooperate with each other to the extent reasonable to obtain reduction of or relief from such withholding. To the extent that amounts are so deducted and withheld and paid to the appropriate Person, such deducted and withheld amounts shall be treated for all purposes of this Agreement as having been paid to the Person in respect of whom such deduction and withholding was made.

### 1.11 **Calculation of Parent Cash Amount.**

(a) For the purposes of this Agreement, the “**Determination Date**” shall be the date that is 10 Business Days prior to the anticipated date for Closing, as agreed upon by Parent and the Company at least five Business Days prior to the Parent Stockholders’ Meeting (the “**Anticipated Closing Date**”). Within five Business Days following the Determination Date, Parent shall deliver to the Company a schedule (the “**Parent Cash Schedule**”) setting forth, in reasonable detail, Parent’s good faith, estimated calculation of the Parent Cash Amount (using an estimate of the Parent Transaction Expenses, Parent’s accrued investment interest receivable, prepaid refundable deposits, accounts payable and accrued expenses, in each case as of the Anticipated Closing Date and determined in a manner substantially consistent with the manner in which such items were determined for Parent’s most recent SEC filings) (the “**Parent Cash Calculation**”) as of the Anticipated Closing Date prepared and certified by Parent’s principal accounting officer. Parent shall make the work papers and back-up materials used or useful in preparing the Parent Cash Schedule, as reasonably requested by the Company, available to the Company and, if requested by the Company, its accountants and counsel at reasonable times and upon reasonable notice, and the Company shall deliver a schedule evidencing the aggregate principal and accrued interest outstanding under the Company Continuing Notes (such amount the “**Outstanding Convertible Note Amount**”) to Parent no later than three Business Days prior to delivery by Parent of the Parent Cash Schedule.

(b) Within three calendar days following delivery (the “**Response Date**”) of the Parent Cash Schedule to the Company, the Company will have the right to dispute any part of such Parent Cash Schedule by delivering a written notice to that effect (a “**Dispute Notice**”) to Parent. Any Dispute Notice shall identify in reasonable detail the nature of any proposed revisions to the Parent Cash Calculation.

(c) If on or prior to the Response Date, (i) the Company notifies Parent in writing that it has no objections to the Parent Cash Calculation or (ii) the Company fails to deliver a Dispute Notice as provided in Section 1.11(b), then the Parent Cash Calculation as set forth in the Parent Cash Schedule shall be deemed to have been finally determined for purposes of this Agreement and to represent the Parent Cash Amount at the Anticipated Closing Date for purposes of this Agreement.

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(d) If the Company delivers a Dispute Notice on or prior to the Response Date, then Representatives of Parent and the Company shall promptly meet and attempt in good faith to resolve the disputed item(s) and negotiate an agreed-upon determination of the Parent Cash Amount, which agreed upon the Parent Cash Amount shall be deemed to have been finally determined for purposes of this Agreement and to represent the Parent Cash Amount at the Anticipated Closing Date for purposes of this Agreement.

(e) If Representatives of Parent and the Company are unable to negotiate an agreed-upon determination of the Parent Cash Amount at the Anticipated Closing Date pursuant to Section 1.11(d) within three calendar days after delivery of the Dispute Notice (or such other period as Parent and the Company may mutually agree upon), then Parent and the Company shall jointly select an independent auditor of recognized national standing (the “**Accounting Firm**”) to resolve any remaining disagreements as to the Parent Cash Calculation. Parent shall promptly deliver to the Accounting Firm the work papers and back-up materials used in preparing the Parent Cash Schedule, and Parent and the Company shall use commercially reasonable efforts to cause the Accounting Firm to make its determination within 10 calendar days of accepting its selection. The Company and Parent shall be afforded the opportunity to present to the Accounting Firm any material related to the unresolved disputes and to discuss the issues with the Accounting Firm; provided, however, that no such presentation or discussion shall occur without the presence of a Representative of each of the Company and Parent. The determination of the Accounting Firm shall be limited to the disagreements submitted to the Accounting Firm. The determination of the amount of the Parent Cash Amount made by the Accounting Firm shall be deemed to have been finally determined for purposes of this Agreement and to represent the Parent Cash Amount at the Anticipated Closing Date for purposes of this Agreement, and the Parties shall delay the Closing until the resolution of the matters described in this Section 1.11(e). The fees and expenses of the Accounting Firm shall be allocated between Parent and the Company in the same proportion that the disputed amount of the Parent Cash Amount that was unsuccessfully disputed by such Party (as finally determined by the Accounting Firm) bears to the total disputed amount of the Parent Cash Amount (and for the avoidance of doubt the fees and expenses to be paid by Parent shall reduce the Parent Cash Amount). If this Section 1.11(e) applies as to the determination of the Parent Cash Amount at the Anticipated Closing Date described in Section 1.11(a), upon resolution of the matter in accordance with this Section 1.11(e), the Parties shall not be required to determine the Parent Cash Amount again even though the Closing Date may occur later than the Anticipated Closing Date, except that either Party may request a redetermination of the Parent Cash Amount if the Closing Date is more than five Business Days after the Anticipated Closing Date.

## **Section 2. REPRESENTATIONS AND WARRANTIES OF THE COMPANY**

Subject to Section 10.13(h), except as set forth in the written disclosure schedule delivered by the Company to Parent (the “**Company Disclosure Schedule**”), the Company represents and warrants to Parent and Merger Sub as follows:

### **2.1 Due Organization; Subsidiaries.**

(a) The Company is a corporation or other legal entity duly incorporated, validly existing and in good standing under the Laws of Delaware and has all necessary corporate power and authority: (i) to conduct its business in the manner in which its business is currently being conducted; (ii) to own or lease and use its property and assets in the manner in which its property and assets are currently owned or leased and used, except where the failure to have such power or authority would not reasonably be expected to prevent or materially delay the ability of the Company to consummate the Contemplated Transactions; and (iii) to perform its obligations under all Contracts by which it is bound.

(b) The Company is duly licensed and qualified to do business, and is in good standing (to the extent applicable in such jurisdiction), under the Laws of all jurisdictions where the nature of its business requires such licensing or qualification other than in jurisdictions where the failure to be so qualified individually or in the aggregate would not be reasonably expected to have a Company Material Adverse Effect.

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(c) The Company has no Subsidiaries, except for the Entities identified in [Section 2.1\(c\)](#) of the Company Disclosure Schedule; and neither the Company nor any of the Company's Subsidiaries identified in [Section 2.1\(c\)](#) of the Company Disclosure Schedule owns any capital stock of, or any equity, ownership or profit sharing interest of any nature in, or controls, directly or indirectly, any other Entity other than the Entities identified in [Section 2.1\(c\)](#) of the Company Disclosure Schedule. Each of the Company's Subsidiaries is a corporation or other legal entity duly organized, validly existing and, if applicable, in good standing under the Laws of the jurisdiction of its organization and has all necessary corporate or other power and authority to conduct its business in the manner in which its business is currently being conducted and to own or lease and use its property and assets in the manner in which its property and assets are currently owned or leased and used, except where the failure to have such power or authority would not be reasonably expected to have a Company Material Adverse Effect.

(d) Neither the Company nor any of its Subsidiaries is or has otherwise been, directly or indirectly, a party to, member of or participant in any partnership, joint venture or similar business entity. Neither the Company nor any of its Subsidiaries has agreed or is obligated to make, or is bound by any Contract under which it may become obligated to make, any future investment in or capital contribution to any other Entity. Neither the Company nor any of its Subsidiaries has, at any time, been a general partner of, or has otherwise been liable for any of the debts or other obligations of, any general partnership, limited partnership or other Entity.

**2.2 Organizational Documents.** The Company has made available to Parent accurate and complete copies of the Organizational Documents of the Company and each of its Subsidiaries in effect as of the date of this Agreement. Neither the Company nor any of its Subsidiaries is in material breach or violation of its respective Organizational Documents.

### **2.3 Authority; Binding Nature of Agreement.**

(a) The Company has all necessary corporate power and authority to enter into and to perform its obligations under this Agreement and, subject to receipt of the Required Company Stockholder Vote, to perform its obligations hereunder and to consummate the Contemplated Transactions. The Company Board (at meetings duly called and held) has (i) determined that the Contemplated Transactions are fair to, advisable and in the best interests of the Company and its stockholders, (ii) authorized, approved and declared advisable this Agreement and the Contemplated Transactions and (iii) determined to recommend, upon the terms and subject to the conditions set forth in this Agreement, that the stockholders of the Company vote in favor of the Company Stockholder Matters.

(b) This Agreement has been duly executed and delivered by the Company and assuming the due authorization, execution and delivery by Parent and Merger Sub, constitutes the legal, valid and binding obligation of the Company, enforceable against the Company in accordance with its terms, subject to the Enforceability Exceptions. Prior to the execution of the Company Stockholder Support Agreements, the Company Board approved the Company Stockholder Support Agreements and the transactions contemplated thereby.

**2.4 Vote Required.** The affirmative vote (or written consent) of (a) the holders of sixty six and two thirds percent (66 2/3%) of the shares of Company Common Stock entitled to vote thereon, voting as a single class, outstanding on the record date for the written consent in lieu of a meeting pursuant to Section 228 of the DGCL approving the Company Stockholder Matters, (b) the holders of sixty six and two thirds percent (66 2/3%) of the shares of Company Common Stock held by the "Series A Stockholders" (as defined in the Amended and Restated Stockholders Agreement, dated as of May 25, 2017, by and among the Company stockholders and the Company (the "Company Stockholders Agreement") and "Series B Stockholders" (as defined in the Company Stockholders Agreement) entitled to vote thereon, voting as a single class, approving the Contemplated Transactions, as applicable, and (c) the holders of a majority of the Company Common Stock held by the "Series B Stockholders" (as defined in the Company Stockholders Agreement) entitled to vote thereon, voting as a single

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class, approving the Contemplated Transactions, as applicable, in each case, in a form reasonably acceptable to Parent (collectively, the “Company Stockholder Written Consent” and such vote, collectively, the “Required Company Stockholder Vote”), are the only votes (or written consents) of the holders of Company Capital Stock necessary to adopt and approve the Company Stockholder Matters.

**2.5 Non-Contravention; Consents.** Subject to obtaining the Required Company Stockholder Vote, the filing of the Certificate of Merger required by the DGCL, neither (x) the execution, delivery or performance of this Agreement by the Company, nor (y) the consummation of the Contemplated Transactions, will directly or indirectly (with or without notice or lapse of time):

(a) contravene, conflict with or result in a violation of any of the provisions of the Company’s Organizational Documents;

(b) contravene, conflict with or result in a material violation of, or give any Governmental Body or, to the Knowledge of the Company, or other Person the right to challenge the Contemplated Transactions or to exercise any material remedy or obtain any material relief under, any Law or any order, writ, injunction, judgment or decree to which the Company or its Subsidiaries, or any of the assets owned or used by the Company or its Subsidiaries, is subject, except as would not reasonably be expected to be material to the Company or its business;

(c) contravene, conflict with or result in a violation of any of the terms or requirements of, or give any Governmental Body the right to revoke, withdraw, suspend, cancel, terminate or modify, any Governmental Authorization that is held by the Company or its Subsidiaries, except as would not reasonably be expected to be material to the Company or its business;

(d) contravene, conflict with or result in a violation or breach of, or result in a default under, any provision of any Company Material Contract, or give any Person the right to: (i) declare a default or exercise any remedy under any Company Material Contract; (ii) any material payment, rebate, chargeback, penalty or change in delivery schedule under any Company Material Contract; (iii) accelerate the maturity or performance of any Company Material Contract; or (iv) cancel, terminate or modify any term of any Company Material Contract, except in the case of any non-material breach, default, penalty or modification; or

(e) result in the imposition or creation of any Encumbrance upon or with respect to any material asset owned or used by the Company or its Subsidiaries (except for Permitted Encumbrances).

Except for (i) any Consent set forth on Section 2.5 of the Company Disclosure Schedule under any Company Contract, (ii) the Required Company Stockholder Vote, (iii) the filing of the Certificate of Merger with the Secretary of State of the State of Delaware pursuant to the DGCL, and (iv) such consents, waivers, approvals, orders, authorizations, registrations, declarations and filings as may be required under applicable federal and state securities Laws, neither the Company nor any of its Subsidiaries is or will be required to make any filing with or give any notice to, or to obtain any Consent from, any Person in connection with (A) the execution, delivery or performance of this Agreement, the Company Stockholder Support Agreements, and the Company Lock-up Agreements or (B) the consummation of the Contemplated Transactions, which if individually or in the aggregate were not given or obtained, would reasonably be expected to prevent or materially delay the ability of the Company to consummate the Contemplated Transactions. The Company Board has taken and will take all actions necessary to ensure that the restrictions applicable to business combinations contained in Section 203 of the DGCL are, and will be, inapplicable to the execution, delivery and performance of this Agreement, the Company Stockholder Support Agreements, the Company Lock-Up Agreements and to the consummation of the Contemplated Transactions. No other state takeover statute or similar Law applies or purports to apply to the Merger, this Agreement, the Company Stockholder Support Agreements, the Company Lock-Up Agreements or any of the Contemplated Transactions.

## 2.6 Capitalization.

(a) The authorized Company Capital Stock as of the date of this Agreement consists of 20,000,000 shares of Company Common Stock, par value \$0.001 per share, of which 10,347,418 shares have been issued and are outstanding as of the date of this Agreement and 9,652,582 shares are held by the Company as treasury shares as of the date of this Agreement. Company Warrants to purchase 1,814,811 shares of Company Common Stock are issued and outstanding as of the date of this Agreement. [Section 2.6\(a\)](#) of the Company Disclosure Schedule sets forth a listing, as of the Reference Date, of the exercise price of each Company Warrant, the number of Company Shares or other Company Securities that each Company Warrant is exercisable into, whether such Company Warrant has a “net exercise” provision and the term of each Company Warrant, including whether such Company Warrant will survive the Contemplated Transactions.

(b) All of the outstanding shares of Company Common Stock have been duly authorized and validly issued, and are fully paid and nonassessable. Except as set forth in the Company Bylaws or Investor Agreements, none of the outstanding shares of Company Capital Stock is entitled or subject to any preemptive right, right of participation, right of maintenance or any similar right and none of the outstanding shares of Company Capital Stock is subject to any right of first refusal in favor of the Company. Except as contemplated herein and in the Company Bylaws and Investor Agreements, there is no Company Contract relating to the voting or registration of, or restricting any Person from purchasing, selling, pledging or otherwise disposing of (or granting any option or similar right with respect to), any shares of Company Capital Stock. The Company is not under any obligation, nor is it bound by any Contract pursuant to which it may become obligated, to repurchase, redeem or otherwise acquire any outstanding shares of Company Capital Stock or other securities. [Section 2.6\(b\)](#) of the Company Disclosure Schedule accurately and completely lists all repurchase or forfeiture rights held by the Company with respect to shares of Company Capital Stock (including shares issued pursuant to the exercise of stock options).

(c) Except for as described in [Section 2.6\(c\)](#) of the Company Disclosure Schedule, the Company does not have any stock option plan or any other plan, program, agreement or arrangement providing for any equity-based compensation for any Person. As of the date of this Agreement, the Company has reserved 1,632,000 shares of Company Common Stock for issuance under the Company Plans, of which 1,281,367 shares have been issued and are currently outstanding, and 350,633 shares of Company Common Stock remain available for future issuance of awards pursuant to the Company Plans. [Section 2.6\(c\)](#) of the Company Disclosure Schedule sets forth the following information with respect to each Company Option outstanding as of the date of this Agreement: (i) the name of the optionee; (ii) the number of shares of Company Common Stock subject to such Company Option at the time of grant; (iii) the number of shares of Company Common Stock subject to such Company Option as of the date of this Agreement; (iv) the exercise price of such Company Option; (v) the date on which such Company Option was granted; (vi) the applicable vesting schedule, including the number of vested and unvested shares as of the date of this Agreement and any acceleration provisions; (vii) the date on which such Company Option expires; and (viii) whether such Company Option is intended to constitute an “incentive stock option” (as defined in the Code) or a non-qualified stock option. The Company has made available to Parent an accurate and complete copy of the Company Plans and the form of stock option agreement used to evidence outstanding options granted thereunder.

(d) Except for Company Warrants, and the Company Options set forth on [Section 2.6\(c\)](#) of the Company Disclosure Schedule, there is no: (i) outstanding subscription, option, call, warrant or right (whether or not currently exercisable) to acquire any shares of the capital stock or other securities of the Company or any of its Subsidiaries; (ii) outstanding security, instrument or obligation that is or may become convertible into or exchangeable for any shares of the capital stock or other securities of the Company or any of its Subsidiaries; or (iii) condition or circumstance that is reasonably likely to give rise to or provide a basis for the assertion of a claim by any Person to the effect that such Person is entitled to acquire or receive any shares of capital stock or other securities of the Company or any of its Subsidiaries. There are no outstanding or authorized stock appreciation, phantom stock, profit participation or other similar rights with respect to the Company or any of its Subsidiaries.

(e) All outstanding shares of Company Common Stock, Company Options, Company Warrants, and other securities of the Company have been issued and granted in material compliance with (i) all applicable securities Laws and other applicable Law, and (ii) all requirements set forth in applicable Contracts.

## 2.7 Financial Statements.

(a) Concurrently with the execution hereof, the Company has provided to Parent true and complete copies of (i) the Company's audited consolidated balance sheets at December 31, 2017 and 2016 together with related audited consolidated statements of income, stockholders' equity and cash flows, and notes thereto, of the Company for the fiscal years then ended and (ii) the Company Unaudited Interim Balance Sheet, together with the unaudited consolidated statements of income, stockholders' equity and cash flows of the Company for the period reflected in the Company Unaudited Interim Balance Sheet (collectively, the "**Company Financials**"). The Company Financials were prepared in accordance with GAAP (except as may be indicated in the notes to such financial statements and except that the unaudited financial statements may not contain footnotes and are subject to normal and recurring year-end adjustments, none of which are material) and fairly present, in all material respects, the financial position and operating results of the Company and its consolidated Subsidiaries as of the dates and for the periods indicated therein.

(b) Each of the Company and its Subsidiaries maintains accurate books and records reflecting their assets and liabilities and maintains a system of internal accounting controls designed to provide reasonable assurance that: (i) transactions are executed in accordance with management's general or specific authorizations; (ii) transactions are recorded as necessary to permit preparation of the financial statements of the Company and its Subsidiaries and to maintain accountability of the Company's and its Subsidiaries' assets; (iii) access to the Company's and its Subsidiaries' assets is permitted only in accordance with management's general or specific authorization; (iv) the recorded accountability for the Company's assets is compared with the existing assets at regular intervals and appropriate action is taken with respect to any differences; and (v) accounts, notes and other receivables and inventory are recorded accurately, and proper and adequate procedures are implemented to effect the collection thereof on a current and timely basis. The Company and each of its Subsidiaries maintains internal controls over financial reporting that provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes.

(c) Section 2.7(c) of the Company Disclosure Schedule lists, and the Company has delivered to Parent accurate and complete copies of the documentation creating or governing, all securitization transactions and "off-balance sheet arrangements" (as defined in Item 303(c) of Regulation S-K under the Exchange Act) effected by the Company or any of its Subsidiaries since January 1, 2016.

(d) Since January 1, 2016, there have been no formal internal investigations regarding financial reporting or accounting policies and practices discussed with, reviewed by or initiated at the direction of the chief executive officer or interim chief financial officer of the Company, the Company Board or any committee thereof. Since January 1, 2016, neither the Company nor its independent auditors have identified (i) any significant deficiency or material weakness, as compared to the standards and internal accounting controls required of an Emerging Growth Company, in the design or operation of the system of internal accounting controls utilized by the Company and its Subsidiaries as an Emerging Growth Company, (ii) any fraud, whether or not material, that involves the Company, any of and its Subsidiaries, the Company's management or other employees who have a role in the preparation of financial statements or the internal accounting controls utilized by the Company and its Subsidiaries or (iii) any claim or allegation regarding any of the foregoing.

**2.8 Absence of Changes.** Except as set forth on Section 2.8 of the Company Disclosure Schedule, between the date of the Company Unaudited Interim Balance Sheet and the date of this Agreement, the Company has conducted its business only in the Ordinary Course of Business (except for the execution and performance of this Agreement and the discussions, negotiations and transactions related thereto) and there has not been any (a) Company Material Adverse Effect or (b) action, event or occurrence that would have required consent of



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Parent pursuant to [Section 4.2\(b\)](#) had such action, event or occurrence taken place after the execution and delivery of this Agreement.

**2.9 Absence of Undisclosed Liabilities.** As of the date hereof, neither the Company nor any of its Subsidiaries has any liability, indebtedness, obligation or expense of any kind, whether accrued, absolute, contingent, matured or unmatured (each a “**Liability**”), individually or in the aggregate, of a type required to be recorded or reflected on a balance sheet or disclosed in the footnotes thereto under GAAP, except for: (a) Liabilities disclosed, reflected or reserved against in the Company Unaudited Interim Balance Sheet; (b) Liabilities that have been incurred by the Company or its Subsidiaries since the date of the Company Unaudited Interim Balance Sheet in the Ordinary Course of Business; (c) Liabilities for performance of obligations of the Company or any of its Subsidiaries under Company Contracts; (d) Liabilities incurred in connection with the Contemplated Transactions; (e) Liabilities which would not, individually or in the aggregate, reasonably be expected to be material to the Company; and (f) Liabilities described in [Section 2.9](#) of the Company Disclosure Schedule.

**2.10 Title to Assets.** Each of the Company and its Subsidiaries owns, and has good and valid title to, or, in the case of leased properties and assets, valid leasehold interests in, all tangible properties or tangible assets and equipment used or held for use in its business or operations or purported to be owned by it that are material to the Company or its business, including: (a) all tangible assets reflected on the Company Unaudited Interim Balance Sheet; and (b) all other tangible assets reflected in the book and records of the Company or any of its Subsidiaries as being owned by the Company or such Subsidiary. All of such assets are owned or, in the case of leased assets, leased by the Company or any of its Subsidiaries free and clear of any Encumbrances, other than Permitted Encumbrances.

**2.11 Real Property; Leasehold.** Neither the Company nor any of its Subsidiaries owns or has ever owned any real property. The Company has made available to Parent (a) an accurate and complete list of all real properties with respect to which the Company directly or indirectly holds a valid leasehold interest as well as any other real estate that is in the possession of or leased by the Company or any of its Subsidiaries, and (b) copies of all leases under which any such real property is possessed (the “**Company Real Estate Leases**”), each of which is in full force and effect, with no existing material default thereunder. The Company’s use and operation of each such leased property conforms to all applicable Laws in all material respects, and the Company has exclusive possession of each such leased property and has not granted any occupancy rights to tenants or licensees with respect to such leased property. In addition, each such leased property is free and clear of all Encumbrances other than Permitted Encumbrances.

### **2.12 Intellectual Property.**

(a) [Section 2.12\(a\)](#) of the Company Disclosure Schedule identifies each item of material Company IP, including, with respect to each patent and patent application: (i) the name of the applicant/registrant, (ii) the jurisdiction of application/registration, (iii) the application or registration number and (iv) any other co-owners. To the Knowledge of the Company, each of the patents and patent applications included in [Section 2.12\(a\)](#) of the Company Disclosure Schedule properly identifies by name each and every inventor of the inventions claimed therein as determined in accordance with applicable Laws of the United States. To the knowledge of the Company, as of the date of this Agreement, no cancellation, interference, opposition, reissue, reexamination or other proceeding of any nature (other than office actions or similar communications issued by any Governmental Body in the ordinary course of prosecution of any pending applications for registration) is pending or threatened in writing, in which the scope, validity, enforceability or ownership of any Company IP is being or has been contested or challenged.

(b) The Company and its Subsidiaries own, are the assignees of, or have licensed all material Company IP (other than as disclosed on [Section 2.12\(b\)](#) of the Company Disclosure Schedule), free and clear of all Encumbrances other than Permitted Encumbrances. To the Knowledge of the Company, each Company Associate involved in the creation or development of any material Company IP, pursuant to such Company

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Associate's activities on behalf of the Company or its Subsidiaries, has signed a written agreement containing an assignment of such Company Associate's rights in such Company IP to the Company or its Subsidiaries and confidentiality provisions protecting the Company IP.

(c) Except as set forth in Section 2.12(d) of the Company Disclosure Schedule, to the Knowledge of the Company, no funding, facilities or personnel of any Governmental Body or any university, college, research institute or other educational institution has been used to create Company IP, except for any such funding or use of facilities or personnel that does not result in such Governmental Body or institution obtaining ownership rights to such Company IP or the right to receive royalties for the practice of such Company IP.

(d) Section 2.12(d) of the Company Disclosure Schedule sets forth each Contract pursuant to which the Company (i) is granted a license under any material Intellectual Property Right owned by any third party that is used by the Company or its Subsidiaries in its business as currently conducted (each a "**Company In-bound License**") or (ii) grants to any third party a license under any material Company IP or material Intellectual Property Right licensed to the Company or its Subsidiaries under a Company In-bound License (each a "**Company Out-bound License**") (provided, that, Company In-bound Licenses shall not include, when entered into in the ordinary course of business, material transfer agreements, clinical trial agreements, agreements with Company Associates, services agreements, non-disclosure agreements, commercially available Software-as-a-Service offerings, off-the-shelf software licenses or generally available patent license agreements; and Company Out-bound Licenses shall not include, when entered into in the ordinary course of business, material transfer agreements, clinical trial agreements, services agreements, non-disclosure agreements, or nonexclusive outbound licenses).

(e) To the Knowledge of the Company: (i) the operation of the businesses of the Company and its Subsidiaries as currently conducted does not infringe, misappropriate or otherwise violate any valid and enforceable United States patent that is not included on Section 2.12(a) of the Company Disclosure Schedule and (ii) no other Person is infringing, misappropriating or otherwise violating any Company IP. No Legal Proceeding is pending (or, to the Knowledge of the Company, is threatened in writing) (A) against the Company or its Subsidiaries alleging that the operation of the businesses of the Company or its Subsidiaries infringes or constitutes the misappropriation or other violation of any Intellectual Property Rights of another Person or (B) by the Company or its Subsidiaries alleging that another Person has infringed, misappropriated or otherwise violated any of the Company IP or any Intellectual Property Rights exclusively licensed to the Company or its Subsidiaries. Since January 1, 2017, neither the Company nor its Subsidiaries has received any written notice or other written communication alleging that the operation of the business of the Company or its Subsidiaries infringes or constitutes the misappropriation or other violation of any Intellectual Property Right of another Person.

(f) None of the Company IP or, to the Knowledge of the Company, any material Intellectual Property Rights exclusively licensed to the Company or its Subsidiaries is subject to any pending or outstanding injunction, directive, order, judgment or other disposition of dispute that adversely and materially restricts the use, transfer, registration or licensing by the Company or its Subsidiaries of any such Company IP or material Intellectual Property Rights exclusively licensed to the Company or its Subsidiaries.

(g) To the Knowledge of the Company, the Company, its Subsidiaries and the operation of the Company's and its Subsidiaries' business are in substantial compliance with all Laws pertaining to data privacy and data security of any personally identifiable information and sensitive business information (collectively, "**Sensitive Data**") except to the extent that such noncompliance has not and would not reasonably be expected to have a Company Material Adverse Effect. To the Knowledge of the Company, since January 1, 2017, there have been (i) no material losses or thefts of data or security breaches relating to Sensitive Data used in the business of the Company or its Subsidiaries, (ii) no violations of any security policy of the Company regarding any such Sensitive Data used in the business of the Company or its Subsidiaries, and (iii) no unauthorized access, unauthorized use or unintended or improper disclosure of any Sensitive Data used in the business of the Company or its Subsidiaries, in each case of (i) through (iii), except as would not reasonably be expected to, individually or in the aggregate, have a Company Material Adverse Effect.

2.13 **Agreements, Contracts and Commitments.**

(a) Section 2.13(a) of the Company Disclosure Schedule lists the following Company Contracts in effect as of the date of this Agreement other than any Benefit Plans (each, a “**Company Material Contract**” and collectively, the “**Company Material Contracts**”):

- (i) each Company Contract relating to any agreement of indemnification or guaranty not entered into in the Ordinary Course of Business;
- (ii) each Company Contract containing (A) any covenant limiting the freedom of the Company, its Subsidiaries or the Surviving Corporation to engage in any line of business or compete with any Person, (B) any most-favored pricing arrangement, (C) any exclusivity provision, or (D) any non-solicitation provision with respect to employees of other Persons, in each case, except for restrictions that would not materially affect the ability of the Company and its Subsidiaries to conduct its business;
- (iii) each Company Contract relating to capital expenditures and requiring payments after the date of this Agreement in excess of \$250,000 pursuant to its express terms and not cancelable without penalty;
- (iv) each Company Contract relating to the disposition or acquisition of material assets or any ownership interest in any Entity, in each case, involving payments in excess of \$250,000, other than Company Contracts in which the applicable acquisition or disposition has been consummated and there are no material ongoing obligations;
- (v) each Company Contract relating to any mortgages, indentures, loans, notes or credit agreements, security agreements or other agreements or instruments relating to the borrowing of money or extension of credit or creating any material Encumbrances with respect to any assets of the Company or any of its Subsidiaries or any loans or debt obligations with officers or directors of the Company or its Subsidiaries, in each case, having an outstanding principal in an amount in excess of \$250,000;
- (vi) each Company Contract requiring payment by or to the Company or its Subsidiaries after the date of this Agreement in excess of \$250,000 pursuant to its express terms relating to: (A) any distribution agreement (identifying any that contain exclusivity provisions); (B) any agreement involving provision of services or products with respect to any pre-clinical or clinical development activities of the Company or its Subsidiaries; (C) any dealer, distributor, joint marketing, alliance, joint venture, cooperation, development or other agreement currently in force under which the Company or its Subsidiaries has continuing obligations to develop or market any product, technology or service, or any agreement pursuant to which the Company or its Subsidiaries has continuing obligations to develop any Intellectual Property Rights that will not be owned, in whole or in part, by the Company or its Subsidiaries; or (D) any Contract to license any third party to manufacture or produce any product, service or technology of the Company or its Subsidiaries or any Contract to sell, distribute or commercialize any products or service of the Company or its Subsidiaries, in each case, except for Company Contracts entered into in the Ordinary Course of Business;
- (vii) each Company Contract with any financial advisor, broker, finder, investment banker or other similar Person, providing advisory services to the Company in connection with the Contemplated Transactions;
- (viii) each Company Real Estate Lease;
- (ix) each Company Contract with any Governmental Body (other than clinical trial agreements for clinical trial studies);
- (x) each Company Out-bound License and Company In-bound License;

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(xi) each Company Contract containing any royalty, dividend or similar arrangement based on the revenues or profits of the Company or any of its Subsidiaries;

(xii) each Company Contract, offer letter, employment agreement, or independent contractor agreement with any employee, consultant or independent contractor that (A) is not terminable by the Company without less than 60 days' notice, severance, or other cost or liability, or (B) provides for retention payments, change of control payments, severance, accelerated vesting, or any payment or benefit that may or will become due as a result of the Merger (whether alone or in connection with any other event); or

(xiii) any other Company Contract that is not terminable at will (with no penalty or payment) by the Company or its Subsidiaries, as applicable, and (A) which involves payment or receipt by the Company or its Subsidiaries after the date of this Agreement under any such agreement, contract or commitment of more than \$250,000 in the aggregate, or obligations after the date of this Agreement in excess of \$250,000 in the aggregate, or (B) that is material to the business or operations of the Company and its Subsidiaries, taken as a whole.

(b) The Company has delivered or made available to Parent accurate and complete copies of all Company Material Contracts, including all amendments thereto. Except as set forth in Section 2.13(b) of the Company Disclosure Schedule, there are no Company Material Contracts that are not in written form. Neither the Company nor any of its Subsidiaries, has, nor to the Company's Knowledge, as of the date of this Agreement has, any other party to a Company Material Contract, breached, violated or defaulted under, or received notice that it breached, violated or defaulted under, any of the terms or conditions of any Company Material Contract in such manner as would permit any other party to cancel or terminate any such Company Material Contract, or would permit any other party to seek damages which would reasonably be expected to be material to the Company or its business. As to the Company and its Subsidiaries, as of the date of this Agreement, each Company Material Contract is valid, binding, enforceable and in full force and effect, subject to the Enforceability Exceptions. No Person is renegotiating, or has a right pursuant to the terms of any Company Material Contract to change, any material amount paid or payable to the Company under any Company Material Contract or any other material term or provision of any Company Material Contract.

### **2.14 Compliance; Permits; Restrictions.**

(a) The Company and each of its Subsidiaries are, and since January 1, 2016 have been, in compliance in all material respects with all applicable Laws, including the Federal Food, Drug, and Cosmetic Act ("**FDCA**"), the Food and Drug Administration ("**FDA**") regulations adopted thereunder, the Public Health Service Act and any other similar Law administered or promulgated by the FDA or other comparable Governmental Body responsible for regulation of the development, clinical testing, manufacturing, sale, marketing, distribution and importation or exportation of drug and biopharmaceutical products (each, a "**Drug Regulatory Agency**"), except for any noncompliance, either individually or in the aggregate, which would not be material to the Company. No investigation, claim, suit, proceeding, audit or other action by any Governmental Body is pending or, to the Knowledge of the Company, threatened against the Company or any of its Subsidiaries. There is no agreement, judgment, injunction, order or decree binding upon the Company or any of its Subsidiaries which (i) has or would reasonably be expected to have the effect of prohibiting or materially impairing any business practice of the Company or any of its Subsidiaries, any acquisition of material property by the Company or any of its Subsidiaries or the conduct of business by the Company or any of its Subsidiaries as currently conducted, (ii) is reasonably likely to have an adverse effect on the Company's ability to comply with or perform any covenant or obligation under this Agreement, or (iii) is reasonably likely to have the effect of preventing, delaying, making illegal or otherwise interfering with the Contemplated Transactions.

(b) The Company and its Subsidiaries hold all required Governmental Authorizations which are material to the operation of the business of the Company and its Subsidiaries as currently conducted (the "**Company Permits**"). Section 2.14(b) of the Company Disclosure Schedule identifies each Company Permit.

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Each of the Company and its Subsidiaries is in material compliance with the terms of the Company Permits. No Legal Proceeding is pending or, to the Knowledge of the Company, threatened, which seeks to revoke, limit, suspend, or materially modify any Company Permit. The rights and benefits of each Company Permit will be available to the Surviving Corporation or its Subsidiaries, as applicable, immediately after the Effective Time on terms substantially identical to those enjoyed by the Company and its Subsidiaries as of the date of this Agreement and immediately prior to the Effective Time.

(c) There are no proceedings pending or, to the Knowledge of the Company, threatened against the Company with respect to an alleged material violation by the Company or any of its Subsidiaries of the FDCA, FDA regulations adopted thereunder, the Public Health Service Act or any other similar Law administered or promulgated by any Drug Regulatory Agency.

(d) All clinical, pre-clinical and other studies and tests conducted by or on behalf of, or sponsored by, the Company or its Subsidiaries, or in which the Company or its Subsidiaries or their respective current products or product candidates have participated, were and, if still pending, are being conducted in all material respects in accordance with standard medical and scientific research procedures and in compliance in all material respects with the applicable regulations of any applicable Drug Regulatory Agency and other applicable Law, as applicable, including 21 C.F.R. Parts 50, 54, 56, 58 and 312. No preclinical or clinical trial conducted by or on behalf of the Company or any of its Subsidiaries has been terminated or suspended prior to completion for safety or non-compliance reasons. Since January 1, 2016, neither the Company nor any of its Subsidiaries has received any notices, correspondence, or other communications from any Drug Regulatory Agency requiring, or to the Knowledge of the Company threatening to initiate, the termination or suspension of any clinical studies conducted by or on behalf of, or sponsored by, the Company or any of its Subsidiaries or in which the Company or any of its Subsidiaries or their respective current products or product candidates have participated.

(e) Neither the Company nor any of its Subsidiaries is the subject of any pending or, to the Knowledge of the Company, threatened investigation in respect of its business or products by the FDA pursuant to its “Fraud, Untrue Statements of Material Facts, Bribery, and Illegal Gratuities” Final Policy set forth in 56 Fed. Reg. 46191 (September 10, 1991) and any amendments thereto. To the Knowledge of the Company, neither the Company nor any of its Subsidiaries has committed any acts, made any statement, or failed to make any statement, in each case in respect of its business or products that would violate the FDA’s “Fraud, Untrue Statements of Material Facts, Bribery, and Illegal Gratuities” Final Policy, and any amendments thereto. None of the Company, any of its Subsidiaries or any of their respective officers, employees or, to the Knowledge of the Company, agents has been convicted of any crime or engaged in any conduct that could result in a debarment or exclusion (i) under 21 U.S.C. Section 335a or (ii) any similar applicable Law. No debarment or exclusionary claims, actions, proceedings or investigations in respect of their business or products are pending or, to the Knowledge of the Company, threatened against the Company, any of its Subsidiaries or any of their respective officers, employees or, to the Knowledge of the Company, agents.

(f) The Company and its Subsidiaries have complied with all Laws relating to patient, medical or individual health information, including the Health Insurance Portability and Accountability Act of 1996 and its implementing regulations promulgated thereunder, all as amended from time to time (collectively “**HIPAA**”), including the standards for the privacy of Individually Identifiable Health Information at 45 C.F.R. Parts 160 and 164, Subparts A and E, the standards for the protection of Electronic Protected Health Information set forth at 45 C.F.R. Part 160 and 45 C.F.R. Part 164, Subpart A and Subpart C, the standards for transactions and code sets used in electronic transactions at 45 C.F.R. Part 160, Subpart A and Part 162, and the standards for Breach Notification for Unsecured Protected Health Information at 45 C.F.R. Part 164, Subpart D, all as amended from time to time. The Company and its Subsidiaries have entered into, where required, and are in compliance in all material respects with the terms of all Business Associate (as defined in HIPAA) agreements (“**Business Associate Agreements**”) to which the Company or a Subsidiary is a party or otherwise bound. The Company and its Subsidiaries have created and maintained written policies and procedures to protect the privacy of all protected health information, provide training to all employees and agents as required under HIPAA, and have

implemented security procedures, including physical, technical and administrative safeguards, to protect all personal information and Protected Health Information stored or transmitted in electronic form. Neither the Company nor any of its Subsidiaries has received written notice from the Office for Civil Rights for the U.S. Department of Health and Human Services or any other Governmental Body of any allegation regarding its failure to comply with HIPAA or any other state law or regulation applicable to the protection of individually identifiable health information or personally identifiable information. No successful Security Incident, Breach of Unsecured Protected Health Information or breach of personally identifiable information under applicable state or federal laws have occurred with respect to information maintained or transmitted to the Company, any of its Subsidiaries or an agent or third party subject to a Business Associate Agreement with the Company or a Subsidiary of the Company. The Company is currently submitting, receiving and handling or is capable of submitting receiving and handling transactions in accordance with the Standard Transaction Rule. All capitalized terms in this [Section 2.14\(f\)](#) not otherwise defined in this Agreement shall have the meanings set forth under HIPAA.

**2.15 Legal Proceedings; Orders.**

(a) As of the date of this Agreement, there is no material pending Legal Proceeding and, to the Knowledge of the Company, no Person has threatened in writing to commence any Legal Proceeding: (i) that involves (A) the Company, (B) any of its Subsidiaries, (C) any Company Associate (in his or her capacity as such) or (D) any of the material assets owned or used by the Company or any of its Subsidiaries; or (ii) that challenges, or that would have the effect of preventing, delaying, making illegal or otherwise interfering with, the Contemplated Transactions.

(b) Except as set forth in [Section 2.15\(b\)](#) of the Company Disclosure Schedule, since January 1, 2016 through the date of this Agreement, no Legal Proceeding has been pending against the Company that resulted in material liability to the Company.

(c) There is no order, writ, injunction, judgment or decree to which the Company or any of its Subsidiaries, or any of the material assets owned or used by the Company or any of its Subsidiaries, is subject. To the Knowledge of the Company, no officer of the Company or any of its Subsidiaries is subject to any order, writ, injunction, judgment or decree that prohibits such officer or employee from engaging in or continuing any conduct, activity or practice relating to the business of the Company or any of its Subsidiaries or to any material assets owned or used by the Company or any of its Subsidiaries.

**2.16 Tax Matters.**

(a) The Company and each of its Subsidiaries have timely filed all income Tax Returns and other material Tax Returns that they were required to file under applicable Law. All such Tax Returns are correct and complete in all material respects and have been prepared in compliance with all applicable Law. No claim has ever been made by any Governmental Body in any jurisdiction where the Company or any of its Subsidiaries does not file a particular Tax Return or pay a particular Tax that the Company or such Subsidiary is subject to taxation by that jurisdiction.

(b) All income and other material Taxes due and owing by the Company or any its Subsidiaries on or before the date hereof (whether or not shown on any Tax Return) have been fully paid. The unpaid Taxes of the Company and its Subsidiaries did not, as of the date of the Company Unaudited Interim Balance Sheet, materially exceed the reserve for Tax liability (excluding any reserve for deferred Taxes established to reflect timing differences between book and Tax items) set forth on the face of the Company Unaudited Interim Balance Sheet. Since the date of the Company Unaudited Interim Balance Sheet, neither the Company nor any of its Subsidiaries has incurred any material Liability for Taxes outside the Ordinary Course of Business.

(c) All Taxes that the Company or any of its Subsidiaries are or were required by Law to withhold or collect have been duly and timely withheld or collected in all material respects on behalf of its respective

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employees, independent contractors, stockholders, lenders, customers or other third parties and, have been timely paid to the proper Governmental Body or other Person or properly set aside in accounts for this purpose.

(d) There are no Encumbrances for material Taxes (other than Permitted Encumbrances) upon any of the assets of the Company or any of its Subsidiaries.

(e) No deficiencies for income or other material Taxes with respect to the Company or any of its Subsidiaries have been claimed, proposed or assessed by any Governmental Body in writing. There are no pending or ongoing, and to the Knowledge of the Company, threatened audits, assessments or other actions for or relating to any liability in respect of a material amount of Taxes of the Company or any of its Subsidiaries. Neither the Company nor any of its Subsidiaries (or any of their predecessors) has not waived any statute of limitations in respect of any income or other material Taxes or agreed to any extension of time with respect to any income or other material Tax assessment or deficiency.

(f) The Company has not been a United States real property holding corporation within the meaning of Section 897(c)(2) of the Code during the applicable period specified in Section 897(c)(1)(A)(ii) of the Code.

(g) Neither the Company nor any of its Subsidiaries is a party to any Tax allocation agreement, Tax sharing agreement, Tax indemnity agreement, or similar agreement or arrangement, other than customary commercial contracts entered into in the Ordinary Course of Business the principal subject matter of which is not Taxes.

(h) Neither the Company nor any of its Subsidiaries will be required to include any material item of income in, or exclude any material item of deduction from, taxable income for any Tax period (or portion thereof) ending after the Closing Date as a result of any: (i) change in method of accounting for Tax purposes filed on or prior to the Closing Date; (ii) use of an improper method of accounting for a Tax period ending on or prior to the Closing Date; (iii) "closing agreement" as described in Section 7121 of the Code (or any similar provision of state, local or foreign Law) executed on or prior to the Closing Date; (iv) intercompany transaction or excess loss account described in Treasury Regulations under Section 1502 of the Code (or any similar provision of state, local or foreign Law) entered into on or prior to the Closing Date; (v) installment sale or open transaction disposition made on or prior to the Closing Date; (vi) prepaid amount received on or prior to the Closing Date; or (vii) election under Section 108(i) of the Code (or any similar provision of state, local or foreign Law) made on or prior to the Closing Date. The Company has not made any election under Section 965(h) of the Code.

(i) Neither the Company nor any of its Subsidiaries have ever been (i) a member of a consolidated, combined or unitary Tax group (other than such a group the common parent of which is the Company) or (ii) a party to any joint venture, partnership, or other arrangement that is treated as a partnership for U.S. federal income Tax purposes. Neither the Company nor any of its Subsidiaries has any Liability for any material Taxes of any Person (other than the Company and any of its Subsidiaries) under Treasury Regulations Section 1.1502-6 (or any similar provision of state, local, or foreign Law), or as a transferee or successor.

(j) Neither the Company nor any of its Subsidiaries have, since January 1, 2017, distributed stock of another Person, or had its stock distributed by another Person, in a transaction that was purported or intended to be governed in whole or in part by Section 355 of the Code or Section 361 of the Code (or any similar provisions of state, local or foreign Law).

(k) Neither the Company nor any of its Subsidiaries (i) is a "controlled foreign corporation" as defined in Section 957 of the Code; (ii) is a "passive foreign investment company" within the meaning of Section 1297 of the Code; (iii) has ever had a permanent establishment (within the meaning of an applicable Tax treaty) or otherwise had an office or fixed place of business in a country other than the country in which it is organized; (iv) is or was a "surrogate foreign corporation" within the meaning of Section 7874(a)(2)(B) or is

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treated as a U.S. corporation under Section 7874(b) of the Code; or (v) was created or organized in the U.S. such that such entity would be taxable in the U.S. as a domestic entity pursuant to the dual charter provision of Treasury Regulations Section 301.7701-5(a).

(l) Neither the Company nor any of its Subsidiaries has participated in or been a party to a transaction that, as of the date of this Agreement, constitutes a “listed transaction” that is required to be reported to the IRS pursuant to Section 6011 of the Code and applicable Treasury Regulations thereunder.

(m) Neither the Company nor any of its Subsidiaries has taken or agreed to take any action or knows of any fact that would reasonably be expected to prevent the Merger from qualifying for the Intended Tax Treatment.

For purposes of this [Section 2.16](#), each reference to the Company or any of its Subsidiaries shall be deemed to include any Person that was liquidated into, merged with, or is otherwise a predecessor to, the Company or such Subsidiary, respectively.

### **2.17 Employee and Labor Matters; Benefit Plans.**

(a) [Section 2.17\(a\)](#) of the Company Disclosure Schedule is a list of all Company Benefit Plans, including, without limitation, each Company Benefit Plan that provides for retirement, change in control, stay or retention, deferred compensation, incentive compensation, severance or retiree medical or life insurance benefits. “**Company Benefit Plan**” means each (i) “employee benefit plan” as defined in Section 3(3) of ERISA and (ii) other pension, retirement, deferred compensation, excess benefit, profit sharing, bonus, incentive, equity or equity-based (other than individual Company Options made pursuant to the Company’s standard forms, in which case only representative standard forms of such stock option agreements shall be scheduled), phantom equity, employment agreement or offer letter (other than at-will employment agreements or offer letters on the Company’s standard forms, in which case only representative standard form of such employment agreements or offer letters shall be scheduled), consulting, severance, change-of-control, retention, health, life, disability, group insurance, paid-time off, holiday, welfare and fringe benefit plan, program, agreement, contract, or arrangement (whether written or unwritten, qualified or nonqualified, funded or unfunded and including any that have been frozen), in any case, maintained, contributed to, or required to be contributed to, by the Company or any of its Subsidiaries or Company ERISA Affiliates for the benefit of any current or former employee, director, officer or independent contractor of the Company or any of its Subsidiaries or under which the Company or any of its Subsidiaries has any actual or contingent liability (including, without limitation, as to the result of it being treated as a single employer under Code Section 414 with any other person).

(b) As applicable with respect to each Company Benefit Plan, the Company has made available to Parent, true and complete copies of (i) each Company Benefit Plan, including all amendments thereto, and in the case of an unwritten Company Benefit Plan, a written description thereof, (ii) all current trust documents, investment management contracts, custodial agreements, administrative services agreements and insurance and annuity contracts relating thereto, (iii) the current summary plan description and each summary of material modifications thereto, (iv) the most recently filed annual reports with any Governmental Body (*e.g.*, Form 5500 and all schedules thereto), (v) the most recent IRS determination, opinion or advisory letter, (vi) the most recent summary annual reports, nondiscrimination testing reports, actuarial reports, financial statements and trustee reports, (vii) all records, notices and filings concerning IRS or Department of Labor or other Governmental Body audits or investigations, “prohibited transactions” within the meaning of Section 406 of ERISA or Section 4975 of the Code, (viii) all policies and procedures established to comply with the privacy and security rules of HIPAA and (ix) any written reports constituting a valuation of the Company’s capital stock for purposes of Sections 409A or 422 of the Code, whether prepared internally by the Company or by an outside, third-party valuation firm.



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(c) Each Company Benefit Plan has been maintained, operated and administered in compliance in all material respects with its terms and any related documents or agreements and the applicable provisions of ERISA, the Code and all other Laws.

(d) The Company Benefit Plans which are “employee pension benefit plans” within the meaning of Section 3(2) of ERISA and which are intended to meet the qualification requirements of Section 401(a) of the Code have received determination or opinion letters from the IRS on which they may currently rely to the effect that such plans are qualified under Section 401(a) of the Code and the related trusts are exempt from federal income Taxes under Section 501(a) of the Code, respectively, and to the Knowledge of the Company, nothing has occurred that would reasonably be expected to materially adversely affect the qualification of such Company Benefit Plan or the tax exempt status of the related trust.

(e) Neither the Company, any of its Subsidiaries nor any Company ERISA Affiliate maintains, contributes to, is required to contribute to, or has any actual or contingent liability with respect to, (i) any “employee pension benefit plan” (within the meaning of Section 3(2) of ERISA) that is subject to Title IV or Section 302 of ERISA or Section 412 of the Code, (ii) any “multiemployer plan” (within the meaning of Section 3(37) of ERISA), (iii) any “multiple employer plan” (within the meaning of Section 413 of the Code) or (iv) any “multiple employer welfare arrangement” (within the meaning of Section 3(40) of ERISA).

(f) There are no pending audits or investigations by any Governmental Body involving any Company Benefit Plan, and no pending or, to the Knowledge of the Company, threatened claims (except for individual claims for benefits payable in the normal operation of the Company Benefit Plans), suits or proceedings involving any Company Benefit Plan, any fiduciary thereof or service provider thereto, in any case except as would not be reasonably expected to result in material liability to the Company or any of its Subsidiaries. All contributions and premium payments required to have been made under any of the Company Benefit Plans or by applicable Law (without regard to any waivers granted under Section 412 of the Code), have been timely made in all material respects and neither the Company nor any Company ERISA Affiliate has any material liability for any unpaid contributions with respect to any Company Benefit Plan.

(g) Neither the Company, any of its Subsidiaries nor Company ERISA Affiliates, nor to the Knowledge of the Company, any fiduciary, trustee or administrator of any Company Benefit Plan, has engaged in, or in connection with the Contemplated Transactions will engage in, any transaction with respect to any Company Benefit Plan which would subject any such Company Benefit Plan, the Company or Company ERISA Affiliates or Parent to a material Tax, material penalty or material liability for a “prohibited transaction” under Section 406 of ERISA or Section 4975 of the Code.

(h) Except as provided in [Section 2.17\(h\)](#) of the Company Disclosure Schedule, no Company Benefit Plan provides death, medical, dental, vision, life insurance or other welfare benefits beyond termination of service or retirement other than coverage mandated by Law and neither the Company nor any of its Subsidiaries or Company ERISA Affiliates has made a written or oral representation promising the same.

(i) Neither the execution of, nor the performance of the Contemplated Transactions will either alone or in connection with any other event(s) (i) result in any payment becoming due to any current or former employee, director, officer, or independent contractor of the Company or any of its Subsidiaries, (ii) increase any amount of compensation or benefits otherwise payable under any Company Benefit Plan, (iii) result in the acceleration of the time of payment, funding or vesting of any benefits under any Company Benefit Plan, (iv) require any contribution or payment to fund any obligation under any Company Benefit Plan or (v) limit the right to merge, amend or terminate any Company Benefit Plan.

(j) Neither the execution of, nor the consummation of the Contemplated Transactions (either alone or when combined with the occurrence of any other event, including without limitation, a termination of employment) will result in the receipt or retention by any person who is a “disqualified individual” (within the

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meaning of Code Section 280G) with respect to the Company and its Subsidiaries of any payment or benefit that is or could be characterized as a “parachute payment” (within the meaning of Code Section 280G), determined without regard to the application of Code Section 280G(b)(5).

(k) The exercise price of each Company Option is not and never has been less than the fair market value of one share of Company Common Stock as of the grant date of such Company Option.

(l) Each Company Benefit Plan providing for deferred compensation that constitutes a “nonqualified deferred compensation plan” (as defined in Section 409A(d)(1) of the Code and the regulations promulgated thereunder) is, and has been, established, administered and maintained in compliance with the requirements of Section 409A of the Code and the regulations promulgated thereunder in all material respects.

(m) No current or former employee, officer, director or independent contractor of the Company or any of its Subsidiaries has any “gross up” agreements with the Company or any of its Subsidiaries other assurance of reimbursement by the Company or any of its Subsidiaries for any Taxes imposed under Code Section 409A or Code Section 4999.

(n) No Company Benefit Plan is maintained outside of the United States.

(o) The Company has provided to Parent a true and correct list, as of the date of this Agreement, containing the names of all full-time, part-time or temporary employees and independent contractors (and indication as such), and, as applicable: (i) the annual dollar amount of all compensation (including wages, salary or fees, commissions, director’s fees, fringe benefits, bonuses, profit sharing payments, and other payments or benefits of any type) payable to each person; (ii) dates of employment or service; (iii) title; (iv) any eligibility to receive severance, retention payment, change of control payment, or other similar compensation; (v) visa status, if applicable; and (vi) with respect to employees, a designation of whether they are classified as exempt or non-exempt for purposes of the Fair Labor Standards Act, as amended (“*FLSA*”) and any similar state law.

(p) Neither the Company nor any of its Subsidiaries has ever been a party to, bound by, or has a duty to bargain under, any collective bargaining agreement or other Contract with a labor union, labor organization, or similar Person representing any of its employees, and there is no labor union, labor organization, or similar Person representing or, to the Knowledge of the Company, purporting to represent or seeking to represent any employees of the Company or its Subsidiaries, including through the filing of a petition for representation election. There is not and has not been in the past three years, nor is there or has there been in the past three years any threat of, any strike, slowdown, work stoppage, lockout, union election petition, demand for recognition, or any similar activity or dispute, or, to the Knowledge of the Company, any union organizing activity, against the Company or any of its Subsidiaries. No event has occurred, and no condition or circumstance exists, that might directly or indirectly be likely to give rise to or provide a basis for the commencement of any such strike, slowdown, work stoppage, lockout, union election petition, demand for recognition, any similar activity or dispute, or, to the Knowledge of the Company, any union organizing activity.

(q) The Company and each of its Subsidiaries is, and since January 1, 2016 has been, in material compliance with all applicable Laws respecting labor, employment, employment practices, and terms and conditions of employment, including worker classification, discrimination, harassment and retaliation, equal employment opportunities, fair employment practices, meal and rest periods, immigration, employee safety and health, payment of wages (including overtime wages), unemployment and workers’ compensation, leaves of absence, and hours of work. Except as would not be reasonably likely to result in a material liability to the Company or any of its Subsidiaries, with respect to employees of the Company and its Subsidiaries, each of the Company and its Subsidiaries, since January 1, 2016: (i) has withheld and reported all amounts required by Law or by agreement to be withheld and reported with respect to wages, salaries and other payments, benefits, or compensation to employees, (ii) is not liable for any arrears of wages (including overtime wages), severance pay or any Taxes or any penalty for failure to comply with any of the foregoing, and (iii) is not liable for any

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payment to any trust or other fund governed by or maintained by or on behalf of any Governmental Body, with respect to unemployment compensation benefits, disability, social security or other benefits or obligations for employees (other than routine payments to be made in the Ordinary Course of Business). There are no actions, suits, claims, charges, lawsuits, investigations, audits or administrative matters pending or, to the Knowledge of the Company or any of its Subsidiaries, threatened or reasonably anticipated against the Company relating to any employee, applicant for employment, consultant, employment agreement or Company Benefit Plan (other than routine claims for benefits).

(r) Except as would not be reasonably likely to result in a material liability to the Company or any of its Subsidiaries, with respect to each individual who currently renders services to the Company or any of its Subsidiaries, the Company and each of its Subsidiaries has accurately classified each such individual as an employee, independent contractor, or otherwise under all applicable Laws and, for each individual classified as an employee, the Company and each of its Subsidiaries has accurately classified him or her as exempt or non-exempt under all applicable Laws. Neither the Company nor any of its Subsidiaries has any material liability with respect to any misclassification of: (a) any Person as an independent contractor rather than as an employee, (b) any employee leased from another employer, or (c) any employee currently or formerly classified as exempt under all applicable Laws.

(s) Within the preceding five (5) years, the Company has not implemented any “plant closing” or “mass layoff” of employees that would reasonably be expected to require notification under the WARN Act or any similar state or local Law, no such “plant closing” or “mass layoff” will be implemented before the Closing Date without advance notification to and approval of Parent, and there has been no “employment loss” as defined by the WARN Act within the ninety (90) days prior to the Closing Date.

(t) There is no Legal Proceeding, claim, unfair labor practice charge or compliant, labor dispute or grievance pending or, to the Knowledge of the Company, threatened against the Company relating to labor, employment, employment practices, or terms and conditions of employment.

**2.18 Environmental Matters.** The Company and each of its Subsidiaries are in compliance with and since January 1, 2016 have complied with all applicable Environmental Laws, which compliance includes the possession by the Company of all permits and other Governmental Authorizations required under applicable Environmental Laws and compliance with the terms and conditions thereof, except for any failure to be in such compliance that, either individually or in the aggregate, would not reasonably be expected to be material to the Company or its business. Neither the Company nor any of its Subsidiaries has received since January 1, 2016 (or prior to that time, which is pending and unresolved), any written notice or other communication (in writing or otherwise), whether from a Governmental Body or other Person, that alleges that the Company or any of its Subsidiaries is not in compliance with or has liability pursuant to any Environmental Law and, to the Knowledge of the Company, there are no circumstances that would reasonably be expected to prevent or interfere with the Company’s or any of its Subsidiaries’ compliance in any material respects with any Environmental Law, except where such failure to comply would not reasonably be expected to be material to the Company or its business. No current or (during the time a or any of its Subsidiaries prior property was leased or controlled by the Company) prior property leased or controlled by the Company or any of its Subsidiaries has had a release of or exposure to Hazardous Materials in material violation of or as would reasonably be expected to result in any material liability of the Company or any of its Subsidiaries pursuant to Environmental Law. No consent, approval or Governmental Authorization of or registration or filing with any Governmental Body is required by Environmental Laws in connection with the execution and delivery of this Agreement or the Contemplated Transactions. Prior to the date hereof, the Company has provided or otherwise made available to Parent true and correct copies of all material environmental reports, assessments, studies and audits in the possession or control of the Company or any of its Subsidiaries with respect to any property leased or controlled by the Company or any of its Subsidiaries or any business operated by them.

**2.19 Insurance.** The Company has delivered or made available to Parent accurate and complete copies of all material insurance policies and all material self-insurance programs and arrangements relating to the business,

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assets, liabilities and operations of the Company and each of its Subsidiaries. Each of such insurance policies is in full force and effect and the Company and each of its Subsidiaries are in compliance in all material respects with the terms thereof. Other than customary end of policy notifications from insurance carriers, since January 1, 2016, neither the Company nor any of its Subsidiaries has received any notice or other communication regarding any actual or possible: (i) cancellation or invalidation of any insurance policy; or (ii) refusal or denial of any coverage, reservation of rights or rejection of any material claim under any insurance policy. The Company and each of its Subsidiaries have provided timely written notice to the appropriate insurance carrier(s) of each Legal Proceeding that is currently pending against the Company or any of its Subsidiaries for which the Company or such Subsidiary has insurance coverage, and no such carrier has issued a denial of coverage or a reservation of rights with respect to any such Legal Proceeding, or informed the Company or any of its Subsidiaries of its intent to do so.

**2.20 No Financial Advisors.** Except as set forth on [Section 2.20](#) of the Company Disclosure Schedule, no broker, finder or investment banker is entitled to any brokerage fee, finder's fee, opinion fee, success fee, transaction fee or other fee or commission in connection with the Contemplated Transactions based upon arrangements made by or on behalf of the Company or any of its Subsidiaries.

**2.21 Disclosure.** The information supplied by the Company and each of its Subsidiaries for inclusion in the Proxy Statement (including any of the Company Financials) will not, as of the date of the Proxy Statement or as of the date such information is first mailed to Parent stockholders, (i) contain any statement that is inaccurate or misleading with respect to any material facts, or (ii) omit to state any material fact necessary in order to make such information, in light of the circumstances under which such information will be provided, not false or misleading.

### **2.22 Transactions with Affiliates.**

(a) [Section 2.22\(a\)](#) of the Company Disclosure Schedule (i) describes any material transactions or relationships, since January 1, 2016, between, on one hand, the Company or any of its Subsidiaries and, on the other hand, any (A) executive officer or director of the Company or, to the Knowledge of the Company, any of its Subsidiaries or any of such executive officer's or director's immediate family members, (B) owner of more than 5% of the voting power of the outstanding Company Capital Stock or (C) to the Knowledge of the Company, any "related person" (within the meaning of Item 404 of Regulation S-K under the Securities Act) of any such officer, director or owner (other than the Company or its Subsidiaries) in the case of each of (A), (B) or (C) that is of the type that would be required to be disclosed under Item 404 of Regulation S-K under the Securities Act; and (ii) identifies each Person who is (or who may be deemed to be) an Affiliate of the Company as of the date of this Agreement.

(b) [Section 2.22\(b\)](#) of the Company Disclosure Schedule lists each stockholders agreement, voting agreement, registration rights agreement, co-sale agreement or other similar Contract between the Company and any holders of Company Capital Stock, including any such Contract granting any Person investor rights, rights of first refusal, rights of first offer, registration rights, director designation rights or similar rights (collectively, the "**Investor Agreements**").

**2.23 Anti-Bribery.** None of the Company or any of its Subsidiaries or any of their respective directors, officers, employees or, to the Company's Knowledge, agents or any other Person acting on their behalf has directly or indirectly made any bribes, rebates, payoffs, influence payments, kickbacks, illegal payments, illegal political contributions, or other payments, in the form of cash, gifts, or otherwise, or taken any other action, in violation of the Foreign Corrupt Practices Act of 1977, or any other anti-bribery or anti-corruption Law (collectively, the "**Anti-Bribery Laws**"). Neither the Company nor any of its Subsidiaries has been the subject of any investigation or inquiry by any Governmental Body with respect to potential violations of Anti-Bribery Laws.

## 2.24 Disclaimer of Other Representations or Warranties.

(a) Except as previously set forth in this [Section 2](#) or in any certificate delivered by the Company to Parent and/or Merger Sub pursuant to this Agreement, the Company makes no representation or warranty, express or implied, at law or in equity, with respect to it or any of its assets, liabilities or operations, and any such other representations or warranties are hereby expressly disclaimed.

(b) The Company acknowledges and agrees that, except for the representations and warranties of Parent and Merger Sub set forth in [Section 3](#), none of Parent, Merger Sub or any of their respective Representatives is relying on any other representation or warranty of Parent or any other Person made outside of [Section 3](#), including regarding the accuracy or completeness of any such other representations or warranties or the omission of any material information, whether express or implied, in each case, with respect to the Contemplated Transactions.

## Section 3. REPRESENTATIONS AND WARRANTIES OF PARENT AND MERGER SUB

Subject to [Section 10.13\(h\)](#), except (a) as set forth in the written disclosure schedule delivered by Parent to the Company (the “**Parent Disclosure Schedule**”) or (b) as disclosed in the Parent SEC Documents filed with the SEC prior to the date hereof and publicly available on the SEC’s Electronic Data Gathering Analysis and Retrieval system (but (i) without giving effect to any amendment thereof filed with, or furnished to the SEC on or after the date hereof and (ii) excluding any disclosures contained under the heading “Risk Factors” and any disclosure of risks included in any “forward-looking statements” disclaimer or in any other section to the extent they are forward-looking statements or cautionary, predictive or forward-looking in nature), it being understood that any matter disclosed in the Parent SEC Documents (x) shall not be deemed disclosed for the purposes of [Section 3.1](#), [Section 3.2](#), [Section 3.3](#), [Section 3.4](#), [Section 3.5](#) or [Section 3.6](#) and (y) shall be deemed to be disclosed in a section of the Parent Disclosure Schedule only to the extent that it is readily apparent from a reading of such Parent SEC Document that it is applicable to such section of the Parent Disclosure Schedule, Parent and Merger Sub represent and warrant to the Company as follows:

### 3.1 Due Organization; Subsidiaries.

(a) Each of Parent and Merger Sub is a corporation duly incorporated, validly existing and in good standing under the Laws of Delaware, and has all necessary corporate power and authority: (i) to conduct its business in the manner in which its business is currently being conducted; (ii) to own or lease and use its property and assets in the manner in which its property and assets are currently owned or leased and used, except where the failure to have such power or authority would not reasonably be expected to prevent or materially delay the ability of Parent and Merger Sub to consummate the Contemplated Transactions; and (iii) to perform its obligations under all Contracts by which each is bound. Since the date of its incorporation, Merger Sub has not engaged in any activities other than activities incident to its formation or in connection with or as contemplated by this Agreement. Parent is duly licensed and qualified to do business, and is in good standing (to the extent applicable in such jurisdiction), under the Laws of all jurisdictions where the nature of its business requires such licensing or qualification other than in jurisdictions where the failure to be so qualified individually or in the aggregate would not be reasonably expected to have a Parent Material Adverse Effect.

(b) Parent has no Subsidiaries, except for the Entities identified in [Section 3.1\(b\)](#) of the Parent Disclosure Schedule; and neither Parent nor any of the Entities identified in [Section 3.1\(b\)](#) of the Parent Disclosure Schedule owns any capital stock of, or any equity, ownership or profit sharing interest of any nature in, or controls directly or indirectly, any other Entity other than the Entities identified in [Section 3.1\(b\)](#) of the Parent Disclosure Schedule. Each of the Company’s Subsidiaries is a corporation or other legal entity duly organized, validly existing and, if applicable, in good standing under the Laws of the jurisdiction of its organization and has all necessary corporate or other power and authority to conduct its business in the manner in which its business is currently being conducted and to own or lease and use its property and assets in the manner

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in which its property and assets are currently owned or leased and used, except where the failure to have such power or authority would not be reasonably expected to have a Parent Material Adverse Effect.

(c) Neither Parent nor any of its Subsidiaries is or has otherwise been, directly or indirectly, a party to, member of or participant in any partnership, joint venture or similar business entity. Neither Parent nor any of its Subsidiaries has agreed or is obligated to make, or is bound by any Contract under which it may become obligated to make, any future investment in or capital contribution to any other Entity. Neither Parent nor any of its Subsidiaries has, at any time, been a general partner of, or has otherwise been liable for any of the debts or other obligations of, any general partnership, limited partnership or other Entity.

**3.2 Organizational Documents.** Parent has made available to the Company accurate and complete copies of the Organizational Documents of Parent and each of its Subsidiaries in effect as of the date of this Agreement. Neither Parent nor any of its Subsidiaries is in material breach or violation of its respective Organizational Documents.

### **3.3 Authority; Binding Nature of Agreement.**

(a) Each of Parent and Merger Sub has all necessary corporate power and authority to enter into and to perform its obligations under this Agreement and, subject, with respect to Parent, to receipt of the Required Parent Stockholder Vote and, with respect to Merger Sub, the adoption of this Agreement by Parent in its capacity as sole stockholder of Merger Sub, to perform its obligations hereunder and to consummate the Contemplated Transactions. The Parent Board (at meetings duly called and held or unanimous written consent in lieu of a meeting) has: (i) determined that the Contemplated Transactions are fair to, advisable and in the best interests of Parent and its stockholders; (ii) authorized, approved and declared advisable this Agreement and the Contemplated Transactions, including the issuance of shares of Parent Common Stock to the stockholders of the Company pursuant to the terms of this Agreement and the treatment of the Company Options pursuant to this Agreement; and (iii) determined to recommend, upon the terms and subject to the conditions set forth in this Agreement, that the stockholders of Parent vote to approve the Parent Stockholder Matters. The Merger Sub Board (by unanimous written consent) has: (A) determined that the Contemplated Transactions are fair to, advisable, and in the best interests of Merger Sub and its sole stockholder; (B) authorized, approved and declared advisable this Agreement and the Contemplated Transactions; and (C) determined to recommend, upon the terms and subject to the conditions set forth in this Agreement, that the stockholder of Merger Sub vote to adopt this Agreement and thereby approve the Contemplated Transactions.

(b) This Agreement has been duly executed and delivered by each of Parent and Merger Sub and, assuming the due authorization, execution and delivery by the Company, constitutes the legal, valid and binding obligation of Parent and Merger Sub, enforceable against each of Parent and Merger Sub in accordance with its terms, subject to the Enforceability Exceptions. Prior to the execution of the Parent Stockholder Support Agreements, the Parent Board approved the Parent Stockholder Support Agreements and the transactions contemplated thereby.

**3.4 Vote Required.** (a) The affirmative vote of the holders of a majority of the outstanding shares of Parent Common Stock is the only vote of the holders of any class or series of Parent's capital stock necessary to approve the proposals in [Section 5.3\(a\)\(i\)](#) and [\(ii\)](#) and (b) the affirmative vote of a majority of the votes cast at the Parent Stockholders' Meeting is the only vote of the holders of any class or series of Parent's capital stock necessary to approve the proposals in [Section 5.3\(a\)\(iii\)](#) (the "**Required Parent Stockholder Vote**").

**3.5 Non Contravention; Consents.** Subject to obtaining the Required Parent Stockholder Vote and the filing of the Certificate of Merger required by the DGCL, neither (x) the execution, delivery or performance of this Agreement by Parent or Merger Sub, nor (y) the consummation of the Contemplated Transactions, will directly or indirectly (with or without notice or lapse of time):

- (a) contravene, conflict with or result in a violation of any of the provisions of the Organizational Documents of Parent or Merger Sub;

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(b) contravene, conflict with or result in a material violation of, or to the Knowledge of Parent give any Governmental Body or other Person the right to challenge the Contemplated Transactions or to exercise any material remedy or obtain any material relief under, any Law or any order, writ, injunction, judgment or decree to which Parent or its Subsidiaries, or any of the assets owned or used by Parent or its Subsidiaries, is subject, except as would not reasonably be expected to be material to Parent or its business;

(c) contravene, conflict with or result in a violation of any of the terms or requirements of, or give any Governmental Body the right to revoke, withdraw, suspend, cancel, terminate or modify, any Governmental Authorization that is held by Parent, or its Subsidiaries except as would not reasonably be expected to be material to Parent or its business;

(d) contravene, conflict with or result in a violation or breach of, or result in a default under, any provision of any Parent Material Contract, or give any Person the right to: (i) declare a default or exercise any remedy under any Parent Material Contract; (ii) any material payment, rebate, chargeback, penalty or change in delivery schedule under any Parent Material Contract; (iii) accelerate the maturity or performance of any Parent Material Contract; or (iv) cancel, terminate or modify any term of any Parent Material Contract, except in the case of any non-material breach, default, penalty or modification; or

(e) result in the imposition or creation of any Encumbrance upon or with respect to any material asset owned or used by Parent or its Subsidiaries (except for Permitted Encumbrances).

Except for (i) any Consent set forth on Section 3.5 of the Parent Disclosure Schedule under any Parent Contract, (ii) the Required Parent Stockholder Vote, (iii) the filing of the Certificate of Merger with the Secretary of State of the State of Delaware pursuant to the DGCL, and (iv) such consents, waivers, approvals, orders, authorizations, registrations, declarations and filings as may be required under applicable federal and state securities Laws, neither Parent nor any of its Subsidiaries is or will be required to make any filing with or give any notice to, or to obtain any Consent from, any Person in connection with (A) the execution, delivery or performance of this Agreement, the Parent Stockholder Support Agreements, and the Parent Lock-up Agreements or (B) the consummation of the Contemplated Transactions, which if individually or in the aggregate were not given or obtained, would reasonably be expected to prevent or materially delay the ability of Parent and Merger Sub to consummate the Contemplated Transactions. The Parent Board and the Merger Sub Board have taken and will take all actions necessary to ensure that the restrictions applicable to business combinations contained in Section 203 of the DGCL are, and will be, inapplicable to the execution, delivery and performance of this Agreement, the Parent Stockholder Support Agreements, the Parent Lock-Up Agreements and to the consummation of the Contemplated Transactions. No other state takeover statute or similar Law applies or purports to apply to the Merger, this Agreement, the Parent Stockholder Support Agreements, the Parent Lock-Up Agreements or any of the other Contemplated Transactions.

### **3.6 Capitalization.**

(a) The authorized capital stock of Parent as of the date of this Agreement consists of (i) 100,000,000 shares of Parent Common Stock, par value \$0.01 per share, of which 94,599,601 shares have been issued and are outstanding as of the close of business on the Reference Date, and (ii) 10,000,000 shares of preferred stock of Parent, par value \$0.01 per share, of which 400.4910 shares have been designated Series A Convertible Preferred Stock and have been issued and are outstanding as of the close of business on the Reference Date and 177,996 shares of Parent Common Stock were reserved for future issuance upon the conversion of such outstanding shares of Company Series A Convertible Preferred Stock. Parent does not hold any shares of its capital stock in its treasury. Section 3.6(a) of the Parent Disclosure Schedule sets forth a listing, as of the Reference Date, of the exercise price of each Parent Warrant, the number of shares of capital stock that each Company Warrant is exercisable into and the term of each Parent Warrant.

(b) All of the outstanding shares of Parent Common Stock have been duly authorized and validly issued, and are fully paid and nonassessable. None of the outstanding shares of Parent Common Stock is entitled

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or subject to any preemptive right, right of participation, right of maintenance or any similar right and none of the outstanding shares of Parent Common Stock is subject to any right of first refusal in favor of Parent. Except as contemplated herein, there is no Parent Contract relating to the voting or registration of, or restricting any Person from purchasing, selling, pledging or otherwise disposing of (or granting any option or similar right with respect to), any shares of Parent Common Stock. Parent is not under any obligation, nor is it bound by any Contract pursuant to which it may become obligated, to repurchase, redeem or otherwise acquire any outstanding shares of Parent Common Stock or other securities. There are no repurchase or forfeiture rights with respect to shares of Parent Common Stock (including shares issued pursuant to the exercise of stock options).

(c) Except for the Parent Stock Plans, Parent does not have any stock option plan or any other plan, program, agreement or arrangement providing for any equity-based compensation for any Person. As of the close of business on the Reference Date, 3,156,694 shares have been reserved for issuance upon exercise of Parent Options granted under the Parent Stock Plans that are outstanding as of the date of this Agreement, and 1,039,788 shares remain available for future issuance pursuant to the Parent Stock Plans. Section 3.6(c) of the Parent Disclosure Schedule sets forth the following information with respect to each Parent Option outstanding as of the date of this Agreement: (i) the name of the holder; (ii) the number of shares of Parent Common Stock subject to such Parent Option at the time of grant; (iii) the number of shares of Parent Common Stock subject to such Parent Option as of the date of this Agreement; (iv) the exercise price of such Parent Option; (v) the date on which such Parent Option was granted; (vi) the applicable vesting schedule, including the number of vested and unvested shares as of the date of this Agreement and any acceleration provisions; (vii) the date on which such Parent Option expires (and whether there has been any extension of such expiration date or any other provisions or agreements that may result in an extension of the expiration date of such Parent Option beyond the date(s) provided in the form of stock option agreement provided to the Company); and (viii) whether such Parent Option is intended to constitute an “incentive stock option” (as defined in the Code) or a non-qualified stock option. Parent has made available to the Company accurate and complete copies of the Parent Stock Plans and all forms of the stock option and other award agreements evidencing outstanding awards granted thereunder.

(d) Except for the Parent Warrants, the Parent Stock Plans, and the Parent Options, there is no: (i) outstanding subscription, option, call, warrant or right (whether or not currently exercisable) to acquire any shares of the capital stock or other securities of Parent or any of its Subsidiaries; (ii) outstanding security, instrument or obligation that is or may become convertible into or exchangeable for any shares of the capital stock or other securities of Parent or any of its Subsidiaries; or (iii) condition or circumstance that is reasonably likely to give rise to or provide a basis for the assertion of a claim by any Person to the effect that such Person is entitled to acquire or receive any shares of capital stock or other securities of Parent or any of its Subsidiaries. There are no outstanding or authorized stock appreciation, phantom stock, profit participation or other similar rights with respect to Parent or any of its Subsidiaries.

(e) All outstanding shares of Parent Common Stock, Parent Options, Parent Warrants and other securities of Parent have been issued and granted in material compliance with (i) all applicable securities Laws and other applicable Law, and (ii) all requirements set forth in applicable Contracts.

### **3.7 SEC Filings; Financial Statements.**

(a) Parent has delivered or made available to the Company accurate and complete copies of all registration statements, proxy statements, Certifications (as defined below) and other statements, reports, schedules, forms and other documents filed by Parent with the SEC since January 1, 2018 (the “**Parent SEC Documents**”), other than such documents that can be obtained on the SEC’s website at [www.sec.gov](http://www.sec.gov). Since January 1, 2017, all material statements, reports, schedules, forms and other documents required to have been filed by Parent or its officers with the SEC have been so filed on a timely basis. As of the time it was filed with the SEC (or, if amended or superseded by a filing prior to the date of this Agreement, then on the date of such filing), each of the Parent SEC Documents complied in all material respects with the applicable requirements of the Securities Act or the Exchange Act (as the case may be) and, as of the time they were filed, none of the



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Parent SEC Documents contained any untrue statement of a material fact or omitted to state a material fact required to be stated therein or necessary in order to make the statements therein, in light of the circumstances under which they were made, not misleading. The certifications and statements required by (i) Rule 13a-14 under the Exchange Act and (ii) 18 U.S.C. §1350 (Section 906 of the Sarbanes-Oxley Act) relating to the Parent SEC Documents (collectively, the “*Certifications*”) are accurate and complete and comply as to form and content with all applicable Laws. As used in this [Section 3.7](#), the term “file” and variations thereof shall be broadly construed to include any manner in which a document or information is furnished, supplied or otherwise made available to the SEC. From the time of the initial filing of Parent’s registration statement on Form S-1 with the SEC, Parent has been and is an “emerging growth company,” as defined in Section 2(a) of the Securities Act, as modified by the Jumpstart our Business Startups Act of 2012. As of the date hereof, there are no outstanding or unresolved comments in any comment letters of the staff of the SEC relating to the Parent SEC Documents and none of the Parent SEC Documents is, to the knowledge of Parent, the subject of ongoing SEC review.

(b) The financial statements (including any related notes) contained or incorporated by reference in the Parent SEC Documents: (i) complied as to form in all material respects with the published rules and regulations of the SEC applicable thereto; (ii) were prepared in accordance with GAAP (except as may be indicated in the notes to such financial statements or, in the case of unaudited financial statements, except as permitted by Form 10-K of the SEC, and except that the unaudited financial statements may not contain footnotes and are subject to normal and recurring year-end adjustments) applied on a consistent basis unless otherwise noted therein throughout the periods indicated; and (iii) fairly present, in all material respects, the financial position of Parent and its consolidated Subsidiaries as of the respective dates thereof and the results of operations and cash flows of Parent and its consolidated Subsidiaries for the periods covered thereby. Other than as expressly disclosed in the Parent SEC Documents filed prior to the date hereof, there has been no material change in Parent’s accounting methods or principles that would be required to be disclosed in Parent’s financial statements in accordance with GAAP. The books of account and other financial records of Parent and its consolidated Subsidiaries are true and complete in all material respects.

(c) Parent’s independent registered accounting firm has at all times since the date Parent became subject to the applicable provisions of the Sarbanes-Oxley Act been; (i) a registered public accounting firm (as defined in Section 2(a)(12) of the Sarbanes-Oxley Act); (ii) to the Knowledge of Parent “Independent” with respect to Parent within the meaning of Regulation S-X under the Exchange Act; and (iii) to the Knowledge of Parent, in compliance with subsections (g) through (l) of Section 10A of the Exchange Act and the rules and regulations promulgated by the SEC and the Public Company Accounting Oversight Board thereunder.

(d) Except as set forth on [Section 3.7\(d\)](#) of the Parent Disclosure Schedule, since January 1, 2017 through the date of this Agreement, Parent has not received any comment letter from the SEC or the staff thereof or any correspondence from officials of Nasdaq or the staff thereof relating to the delisting or maintenance of listing of the Parent Common Stock on Nasdaq. Parent has not disclosed any unresolved comments in the Parent SEC Documents.

(e) Since January 1, 2017, there have been no formal investigations regarding financial reporting or accounting policies and practices discussed with, reviewed by or initiated at the direction of the chief executive officer, chief financial officer, principal accounting officer or general counsel of Parent, the Parent Board or any committee thereof, other than ordinary course audits or reviews of accounting policies and practices or internal controls required by the Sarbanes-Oxley Act.

(f) Parent is and since January 1, 2017 has been, in compliance in all material respects with the applicable current listing and governance rules and regulations of Nasdaq.

(g) Parent maintains, and at all times since January 1, 2017 has maintained, a system of internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act) that is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of

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financial statements for external purposes in accordance with GAAP and to provide reasonable assurance (i) that Parent maintains records in reasonable detail accurately and fairly reflect the transactions and dispositions of the assets of Parent and its Subsidiaries; (ii) that transactions are recorded as necessary to permit preparation of financial statements in accordance with GAAP, (iii) that receipts and expenditures are made only in accordance with authorizations of management and the Parent Board and (iv) regarding prevention or timely detection of the unauthorized acquisition, use or disposition of Parent's assets that could have a material effect on Parent's financial statements. Parent has evaluated the effectiveness of Parent's internal control over financial reporting as of December 31, 2018 and, to the extent required by applicable Law, presented in any applicable Parent SEC Document that is a report on Form 10-K or Form 10-Q (or any amendment thereto) its conclusions about the effectiveness of the internal control over financial reporting as of the end of the period covered by such report or amendment based on such evaluation. Parent has disclosed, based on its most recent evaluation of internal control over financial reporting, to Parent's auditors and audit committee (and made available to the Company a summary of the significant aspects of such disclosure) (A) all material weaknesses and significant deficiencies, if any, in the design or operation of internal control over financial reporting that are reasonably likely to adversely affect Parent's ability to record, process, summarize and report financial information and (B) any known fraud that involves management or other employees who have a significant role in Parent's internal control over financial reporting. Other than as disclosed in the Parent SEC Documents or as set forth on Section 3.7(g) of the Parent Disclosure Schedule, Parent has not identified, based on its most recent evaluation of internal control over financial reporting, any material weaknesses in the design or operation of Parent's internal control over financial reporting.

(h) Parent maintains "disclosure controls and procedures" (as defined in Rules 13a-15(e) and 15d-15(e) of the Exchange Act) that are reasonably designed to ensure that all information required to be disclosed by Parent in the periodic reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods required by the SEC, and that all such information is accumulated and communicated to Parent's management as appropriate to allow timely decisions regarding required disclosure and to make the Certifications.

**3.8 Absence of Changes.** Except as set forth on Section 3.8 of the Parent Disclosure Schedule, between the date of the Parent Balance Sheet and the date of this Agreement, Parent and its Subsidiaries have conducted its business only in the Ordinary Course of Business (except for the execution and performance of this Agreement and the discussions, negotiations and transactions related thereto) and there has not been any (a) Parent Material Adverse Effect or (b) action, event or occurrence that would have required consent of the Company pursuant to Section 4.1(b) had such action, event or occurrence taken place after the execution and delivery of this Agreement.

**3.9 Absence of Undisclosed Liabilities.** As of the date hereof, Parent and its Subsidiaries do not have any Liability, individually or in the aggregate, of a type required to be recorded or reflected on a balance sheet or disclosed in the footnotes thereto under GAAP except for: (a) Liabilities disclosed, reflected or reserved against in the Parent Balance Sheet; (b) Liabilities that have been incurred by Parent or its Subsidiaries since the date of the Parent Balance Sheet in the Ordinary Course of Business (which Liabilities shall be satisfied prior to the Closing Date); (c) Liabilities for performance of obligations of Parent or its Subsidiaries under Parent Contracts; (d) Liabilities incurred in connection with the Contemplated Transactions; and (e) Liabilities described in Section 3.9 of the Parent Disclosure Schedule.

**3.10 Title to Assets.** Parent or its Subsidiaries owns, and has good and valid title to, or, in the case of leased properties and assets, valid leasehold interests in, all tangible properties or tangible assets and equipment used or held for use in its business or operations or purported to be owned by it that are material to Parent or its Subsidiaries or their respective businesses, including: (a) all tangible assets reflected on the Parent Balance Sheet; and (b) all other tangible assets reflected in the books and records of Parent as being owned by Parent or its Subsidiaries, in each case, other than assets disposed of since the date of the Parent Balance Sheet. All of such assets are owned or, in the case of leased assets, leased by Parent or its Subsidiaries free and clear of any Encumbrances, other than Permitted Encumbrances.

3.11 **Real Property; Leasehold.** Parent and its Subsidiaries do not own any real property. Parent has made available to the Company (a) an accurate and complete list of all real properties with respect to which Parent or its Subsidiaries directly or indirectly holds a valid leasehold interest as well as any other real estate that is in the possession of or leased by Parent or its Subsidiaries, and (b) copies of all leases under which any such real property is possessed (the “**Parent Real Estate Leases**”), each of which is in full force and effect, with no existing material default thereunder. Parent’s use and operation of each such leased property conforms to all applicable Laws in all material respects, and Parent or its Subsidiaries have exclusive possession of each such leased property and has not granted any occupancy rights to tenants or licensees with respect to such leased property. In addition, each such leased property is free and clear of all Encumbrances other than Permitted Encumbrances.

3.12 **Intellectual Property.**

(a) Section 3.12(a) of the Parent Disclosure Schedule identifies each item of material Parent IP, including, with respect to each patent and patent application: (i) the name of the applicant/registrant, (ii) the jurisdiction of application/registration, (iii) the application or registration number and (iv) any other co-owners. To the Knowledge of Parent, each of the patents and patent applications included in Section 3.12(a) of the Company Disclosure Schedule properly identifies by name each and every inventor of the inventions claimed therein as determined in accordance with applicable Laws of the United States. To the Knowledge of Parent, each of the patents and patent applications included in the Section 3.12(a) of the Parent Disclosure Schedule properly identifies by name each and every inventor of the inventions claimed therein as determined in accordance with applicable Laws of the United States. To the knowledge of Parent, as of the date of this Agreement, no cancellation, interference, opposition, reissue, reexamination or other proceeding of any nature (other than office actions or similar communications issued by any Governmental Body in the ordinary course of prosecution of any pending applications for registration) is pending or threatened in writing, in which the scope, validity, enforceability or ownership of any Parent IP is being or has been contested or challenged.

(b) Except as has not had and would not reasonably be expected to have, individually or in the aggregate, a Parent Material Adverse Effect, Parent owns, is the assignee of, or has licensed all material Parent IP (other than as disclosed on Section 3.12(b) of the Parent Disclosure Schedule), free and clear of all Encumbrances other than Permitted Encumbrances. To the Knowledge of Parent, each Parent Associate involved in the creation or development of any material Parent IP, pursuant to such Parent Associate’s activities on behalf of Parent, has signed a written agreement containing an assignment of such Parent Associate’s rights in such Parent IP to Parent and confidentiality provisions protecting the Parent IP.

(c) To the Knowledge of Parent, no funding, facilities or personnel of any Governmental Body or any university, college, research institute or other educational institution has been used to create Parent IP, except for any such funding or use of facilities or personnel that does not result in such Governmental Body or institution obtaining ownership rights to such Parent IP or the right to receive royalties for the practice of such Parent IP.

(d) Section 3.12(d) of Parent Disclosure Schedule sets forth each license agreement pursuant to which the Parent or its Subsidiaries (i) is granted a license under any material Intellectual Property Right owned by any third party that is used by Parent in its business as currently conducted (each a “**Parent In-bound License**”) or (ii) grants to any third party a license under any material Parent IP or material Intellectual Property Right licensed to the Parent or its Subsidiaries under a Parent In-bound License (each a “**Parent Out-bound License**”) (provided, that, Parent In-bound Licenses shall not include, when entered into in the ordinary course of business, material transfer agreements, services agreements, clinical trial agreements, agreements with Parent Associates, non-disclosure agreements, commercially available Software-as-a-Service offerings, off-the-shelf software licenses or generally available patent license agreements; and Parent Out-bound Licenses shall not include, when entered into in the ordinary course of business, material transfer agreements, clinical trial agreements, services agreements, non-disclosure agreements, or non-exclusive outbound licenses).

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(e) To the Knowledge of Parent: (i) the operation of the business of Parent and its Subsidiaries as currently conducted does not infringe, misappropriate or otherwise violate any valid and enforceable United States patent that is not included on [Section 2.12\(a\)](#) of the Company Disclosure Schedule and (ii) no other Person is infringing, misappropriating or otherwise violating any Parent IP. No Legal Proceeding is pending (or, to the Knowledge of Parent, is threatened in writing) (A) against Parent alleging that the operation of the business of Parent infringes or constitutes the misappropriation or other violation of any Intellectual Property Rights of another Person or (B) by Parent alleging that another Person has infringed, misappropriated or otherwise violated any of Parent IP or any Intellectual Property Rights exclusively licensed to Parent. Since January 1, 2017, Parent has not received any written notice or other written communication alleging that the operation of the business of Parent infringes or constitutes the misappropriation or other violation of any Intellectual Property Right of another Person.

(f) None of Parent IP or, to the Knowledge of Parent, any material Intellectual Property Rights exclusively licensed to Parent is subject to any pending or outstanding injunction, directive, order, judgment or other disposition of dispute that adversely and materially restricts the use, transfer, registration or licensing by Parent of any such Parent IP or material Intellectual Property Rights exclusively licensed to Parent or its Subsidiaries.

(g) To the Knowledge of Parent, the operation of Parent's and its Subsidiaries' business are in substantial compliance with all Laws pertaining to data privacy and data security of Sensitive Data, except to the extent that such noncompliance has not and would not reasonably be expected to have a Parent Material Adverse Effect. To the Knowledge of Parent, since January 1, 2017, there have been (i) no material losses or thefts of data or security breaches relating to Sensitive Data used in the business of Parent or its Subsidiaries, (ii) no violations of any security policy of Parent regarding any such Sensitive Data used in the business of Parent or its Subsidiaries, (iii) no unauthorized access, unauthorized use or unintended or improper disclosure of any Sensitive Data used in the business of Parent or its Subsidiaries, in each case of (i) through (iii), except as would not reasonably be expected to, individually or in the aggregate, have a Parent Material Adverse Effect.

**3.13 Agreements, Contracts and Commitments.** [Section 3.13](#) of the Parent Disclosure Schedule lists the following Parent Contracts in effect as of the date of this Agreement (and, except with respect to clauses (m) and (n) below, other than any Benefit Plans) (each, a "**Parent Material Contract**" and collectively, the "**Parent Material Contracts**"):

(a) a material contract as defined in Item 601 (b)(10) of Regulation S-K as promulgated under the Securities Act;

(b) each Contract relating to any agreement of indemnification or guaranty not entered into in the Ordinary Course of Business;

(c) each Contract containing (A) any covenant limiting the freedom of Parent or its Subsidiaries to engage in any line of business or compete with any Person, (B) any most-favored pricing arrangement, (C) any exclusivity provision, or (D) any non-solicitation provision with respect to employees of other Persons, in each case, except for restrictions that would not materially affect the ability of Parent or its Subsidiaries to conduct their respective businesses;

(d) each Contract relating to capital expenditures and requiring payments after the date of this Agreement in excess of \$150,000 pursuant to its express terms and not cancelable without penalty;

(e) each Contract relating to the disposition or acquisition of material assets or any ownership interest in any Entity, in each case, involving payments in excess of \$150,000, other than Parent Contracts in which the applicable acquisition or disposition has been consummated and there are no material ongoing obligations;

(f) each Contract relating to any mortgages, indentures, loans, notes or credit agreements, security agreements or other agreements or instruments relating to the borrowing of money or extension of credit or

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creating any material Encumbrances with respect to any assets of Parent or its Subsidiaries or any loans or debt obligations with officers or directors of Parent or its Subsidiaries, in each case, having an outstanding principal in an amount in excess of \$150,000;

(g) each Contract requiring payment by or to Parent after the date of this Agreement in excess of \$150,000 pursuant to its express terms relating to: (A) any distribution agreement (identifying any that contain exclusivity provisions); (B) any agreement involving provision of services or products with respect to any pre-clinical or clinical development activities of Parent; (C) any dealer, distributor, joint marketing, alliance, joint venture, cooperation, development or other agreement currently in force under which Parent has continuing obligations to develop or market any product, technology or service, or any agreement pursuant to which Parent has continuing obligations to develop any Intellectual Property Rights that will not be owned, in whole or in part, by Parent; or (D) any Contract to license any third party to manufacture or produce any product, service or technology of Parent or any Contract to sell, distribute or commercialize any products or service of Parent, in each case, except for Contracts entered into in the Ordinary Course of Business;

(h) each Contract with any financial advisor, broker, finder, investment banker or other similar Person, providing advisory services to Parent or its Subsidiaries in connection with the Contemplated Transactions;

(i) each Parent Real Estate Lease;

(j) each Contract with any Governmental Body (other than clinical trial agreements for clinical trial studies);

(k) each Parent Out-bound License and Parent In-bound License;

(l) each Contract containing any royalty, dividend or similar arrangement based on the revenues or profits of Parent or its Subsidiaries in excess of \$150,000;

(m) each offer letter, employment agreement, or independent contractor agreement with any employee, consultant or independent contractor currently providing services to the Company; or

(n) any other Contract that is not terminable at will (with no penalty or payment) by Parent and (A) which involves payment or receipt by Parent after the date of this Agreement under any such agreement, contract or commitment of more than \$150,000 in the aggregate, or obligations after the date of this Agreement in excess of \$150,000 in the aggregate, or (B) that is material to the business or operations of Parent.

Parent has delivered or made available to the Company accurate and complete copies of all Parent Material Contracts, including all amendments thereto. There are no Parent Material Contracts that are not in written form. Neither Parent nor any of its Subsidiaries has nor, to Parent's Knowledge, as of the date of this Agreement, has any other party to a Parent Material Contract, breached, violated or defaulted under, or received notice that it breached, violated or defaulted under, any of the terms or conditions of any Parent Material Contract in such manner as would permit any other party to cancel or terminate any such Parent Material Contract, or would permit any other party to seek damages which would reasonably be expected to be material to Parent or its Subsidiaries or their respective businesses. As to Parent or its Subsidiaries, as of the date of this Agreement, each Parent Material Contract is valid, binding, enforceable and in full force and effect, subject to the Enforceability Exceptions. No Person is renegotiating, or has a right pursuant to the terms of any Parent Material Contract to change, any material amount paid or payable to Parent or its Subsidiaries under any Parent Material Contract or any other material term or provision of any Parent Material Contract.

### **3.14 Compliance; Permits.**

(a) Parent and each of its Subsidiaries is, and since January 1, 2016 has been, in compliance in all material respects with all applicable Laws, including the FDCA, the FDA regulations adopted thereunder, the

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Public Health Service Act and any other similar Law administered or promulgated by the FDA or other Drug Regulatory Agency, except for any noncompliance, either individually or in the aggregate, which would not be material to Parent. No investigation, claim, suit, proceeding, audit or other action by any Governmental Body is pending or, to the Knowledge of Parent, threatened against Parent or its Subsidiaries. There is no agreement, judgment, injunction, order or decree binding upon Parent or its Subsidiaries which (i) has or would reasonably be expected to have the effect of prohibiting or materially impairing any business practice of Parent or its Subsidiaries, any acquisition of material property by Parent or its Subsidiaries or the conduct of business by Parent or its Subsidiaries as currently conducted, (ii) is reasonably likely to have an adverse effect on Parent's ability to comply with or perform any covenant or obligation under this Agreement, or (iii) is reasonably likely to have the effect of preventing, delaying, making illegal or otherwise interfering with the Contemplated Transactions.

(b) Parent or its Subsidiaries holds all required Governmental Authorizations which are material to the operation of the business of Parent and its Subsidiaries as currently conducted (the "**Parent Permits**"). [Section 3.14\(b\)](#) of the Parent Disclosure Schedule identifies each Parent Permit. Parent and its Subsidiaries are in material compliance with the terms of the Parent Permits, as applicable. No Legal Proceeding is pending or, to the Knowledge of Parent, threatened, which seeks to revoke, limit, suspend, or materially modify any Parent Permit.

(c) There are no proceedings pending or, to the Knowledge of Parent, threatened against Parent or its Subsidiaries with respect to an alleged material violation by Parent of the FDCA, FDA regulations adopted thereunder, the Public Health Service Act or any other similar Law administered or promulgated by any Drug Regulatory Agency.

(d) All clinical, pre-clinical and other studies and tests conducted by or on behalf of, or sponsored by, Parent or its Subsidiaries, or in which Parent or its Subsidiaries or their respective current products or product candidates have participated, were and, if still pending, are being conducted in all material respects in accordance with standard medical and scientific research procedures and in compliance in all material respects with the applicable regulations of any applicable Drug Regulatory Agency and other applicable Law, as applicable, including 21 C.F.R. Parts 50, 54, 56, 58 and 312. No preclinical or clinical trial conducted by or on behalf of Parent has been terminated or suspended prior to completion for safety or non-compliance reasons. Since January 1, 2016, neither Parent nor its Subsidiaries has received any notices, correspondence, or other communications from any Drug Regulatory Agency requiring, or to the Knowledge of Parent threatening to initiate, the termination or suspension of any clinical studies conducted by or on behalf of, or sponsored by, Parent or its Subsidiaries or in which Parent or its current products or product candidates have participated.

(e) Parent and each of its Subsidiaries is not the subject of any pending or, to the Knowledge of Parent, threatened investigation in respect of its business or products by the FDA pursuant to its "Fraud, Untrue Statements of Material Facts, Bribery, and Illegal Gratuities" Final Policy set forth in 56 Fed. Reg. 46191 (September 10, 1991) and any amendments thereto. To the Knowledge of Parent, Parent and each of its Subsidiaries has not committed any acts, made any statement, or has not failed to make any statement, in each case in respect of its business or products that would violate the FDA's "Fraud, Untrue Statements of Material Facts, Bribery, and Illegal Gratuities" Final Policy, and any amendments thereto. Parent, each of its Subsidiaries, and any of their respective officers, employees or, to the Knowledge of Parent, agents has not been convicted of any crime or engaged in any conduct that could result in a debarment or exclusion (i) under 21 U.S.C. Section 335a or (ii) any similar applicable Law. No debarment or exclusionary claims, actions, proceedings or investigations in respect of their business or products are pending or, to the Knowledge of Parent, threatened against Parent, its Subsidiaries, or any of their officers, employees or, to the Knowledge of Parent, agents.

(f) Neither Parent or any of its Subsidiaries is a Covered Entity governed by HIPAA, but each of Parent's and its Subsidiaries' health plans, if required, has complied with all Laws relating to HIPAA, including the standards for the privacy of Individually Identifiable Health Information at 45 C.F.R. Parts 160 and 164,

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Subparts A and E, the standards for the protection of Electronic Protected Health Information set forth at 45 C.F.R. Part 160 and 45 C.F.R. Part 164, Subpart A and Subpart C, the standards for transactions and code sets used in electronic transactions at 45 C.F.R. Part 160, Subpart A and Part 162, and the standards for Breach Notification for Unsecured Protected Health Information at 45 C.F.R. Part 164, Subpart D, all as amended from time to time. Each of Parent's health plans has entered into, where required, and are in compliance in all material respects with the terms of all Business Associate Agreements to which Parent has signed as plan sponsor where the plan is a party or otherwise bound. Each of Parent's and its Subsidiaries' health plans, where required, has created and maintained written policies and procedures to protect the privacy of all protected health information, provide training to all employees and agents as required under HIPAA, and have implemented security procedures, including physical, technical and administrative safeguards, to protect all personal information and Protected Health Information stored or transmitted in electronic form. Parent has not received written notice from the Office for Civil Rights for the U.S. Department of Health and Human Services or any other Governmental Body of any allegation regarding its failure to comply with HIPAA or any other state law or regulation applicable to the protection of individually identifiable health information or personally identifiable information. No successful Security Incident, Breach of Unsecured Protected Health Information or breach of personally identifiable information under applicable state or federal laws have occurred with respect to information maintained or transmitted to any health plan of Parent or its Subsidiaries or an agent or third party subject to a Business Associate Agreement with any health plan of Parent or its Subsidiaries. If required, each health plan of Parent or its Subsidiaries is currently submitting, receiving and handling or is capable of submitting receiving and handling transactions in accordance with the Standard Transaction Rule. Parent and each of its Subsidiaries has materially complied with its requirements related to protection of Protected Health Information under its clinical trial agreements with health care provider Covered Entities that have participated in Parent's or its Subsidiaries' clinical studies under such agreements. All capitalized terms in this Section 3.14(f) not otherwise defined in this Agreement shall have the meanings set forth under HIPAA.

### **3.15 Legal Proceedings; Orders.**

(a) As of the date of this Agreement, there is no material pending Legal Proceeding and, to the Knowledge of Parent, no Person has threatened in writing to commence any Legal Proceeding: (i) that involves (A) Parent, (C) any of Parent's Subsidiaries, (C) any Parent Associate (in his or her capacity as such) or (D) any of the material assets owned or used by Parent or its Subsidiaries; or (ii) that challenges, or that would have the effect of preventing, delaying, making illegal or otherwise interfering with, the Contemplated Transactions.

(b) Since January 1, 2016 through the date of this Agreement, no Legal Proceeding has been pending against Parent or its Subsidiaries that resulted in material liability to Parent or its Subsidiaries.

(c) There is no order, writ, injunction, judgment or decree to which Parent, any of its Subsidiaries, or any of the material assets owned or used by Parent or any of its Subsidiaries, is subject. To the Knowledge of Parent, no officer of Parent or its Subsidiaries is subject to any order, writ, injunction, judgment or decree that prohibits such officer or employee from engaging in or continuing any conduct, activity or practice relating to the business of Parent or its Subsidiaries or to any material assets owned or used by Parent or its Subsidiaries.

### **3.16 Tax Matters.**

(a) Parent and its Subsidiaries have timely filed all income Tax Returns and other material Tax Returns that they were required to file under applicable Law. All such Tax Returns are correct and complete in all material respects and have been prepared in compliance with all applicable Law. No claim has ever been made by any Governmental Body in any jurisdiction where Parent or its Subsidiaries does not file a particular Tax Return or pay a particular Tax that Parent or its Subsidiaries is subject to taxation by that jurisdiction.

(b) All income and other material Taxes due and owing by Parent or its Subsidiaries on or before the date hereof (whether or not shown on any Tax Return) have been fully paid. The unpaid Taxes of Parent and its

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Subsidiaries did not, as of the date of the Parent Balance Sheet, materially exceed the reserve for Tax liability (excluding any reserve for deferred Taxes established to reflect timing differences between book and Tax items) set forth on the face of the Parent Balance Sheet. Since the Parent Balance Sheet Date, neither Parent nor its Subsidiaries has incurred any material Liability for Taxes outside the Ordinary Course of Business.

(c) All Taxes that Parent or its Subsidiaries are or were required by Law to withhold or collect have been duly and timely withheld or collected in all material respects on behalf of its respective employees, independent contractors, stockholders, lenders, customers or other third parties and, have been timely paid to the proper Governmental Body or other Person or properly set aside in accounts for this purpose.

(d) There are no Encumbrances for material Taxes (other than Permitted Encumbrances) upon any of the assets of Parent or its Subsidiaries.

(e) No deficiencies for income or other material Taxes with respect to Parent or its Subsidiaries have been claimed, proposed or assessed by any Governmental Body in writing. There are no pending or ongoing, and to the Knowledge of Parent, threatened audits, assessments or other actions for or relating to any liability in respect of a material amount of Taxes of Parent or Merger Sub. Neither Parent nor its Subsidiaries (or any of their predecessors) has waived any statute of limitations in respect of any income or other material Taxes or agreed to any extension of time with respect to any income or other material Tax assessment or deficiency.

(f) Parent and each of its Subsidiaries has not been a United States real property holding corporation within the meaning of Section 897(c)(2) of the Code during the applicable period specified in Section 897(c)(1)(A)(ii) of the Code.

(g) Neither Parent nor its Subsidiaries is a party to any Tax allocation agreement, Tax sharing agreement, Tax indemnity agreement, or similar agreement or arrangement, other than customary commercial contracts entered into in the Ordinary Course of Business the principal subject matter of which is not Taxes.

(h) Neither Parent nor its Subsidiaries will be required to include any material item of income in, or exclude any material item of deduction from, taxable income for any Tax period (or portion thereof) ending after the Closing Date as a result of any: (i) change in method of accounting for Tax purposes filed on or prior to the Closing Date; (ii) use of an improper method of accounting for a Tax period ending on or prior to the Closing Date; (iii) "closing agreement" as described in Section 7121 of the Code (or any similar provision of state, local or foreign Law) executed on or prior to the Closing Date; (iv) intercompany transaction or excess loss account described in Treasury Regulations under Section 1502 of the Code (or any similar provision of state, local or foreign Law) entered into on or prior to the Closing Date; (v) installment sale or open transaction disposition made on or prior to the Closing Date; (vi) prepaid amount received on or prior to the Closing Date; or (vii) election under Section 108(i) of the Code (or any similar provision of state, local or foreign Law) made on or prior to the Closing Date. Parent has not made any election under Section 965(h) of the Code.

(i) Neither Parent nor its Subsidiaries has ever been (i) a member of a consolidated, combined or unitary Tax group (other than such a group the common parent of which is Parent) or (ii) a party to any joint venture, partnership, or other arrangement that is treated as a partnership for U.S. federal income Tax purposes. Neither Parent nor Merger Sub has any Liability for any material Taxes of any Person (other than Parent and Merger Sub) under Treasury Regulations Section 1.1502-6 (or any similar provision of state, local, or foreign Law), or as a transferee or successor.

(j) Neither Parent nor its Subsidiaries has, since January 1, 2017, distributed stock of another Person, or had its stock distributed by another Person, in a transaction that was purported or intended to be governed in whole or in part by Section 355 of the Code or Section 361 of the Code (or any similar provisions of state, local or foreign Law).



(k) Neither Parent nor its Subsidiaries (i) is a “controlled foreign corporation” as defined in Section 957 of the Code; (ii) is a “passive foreign investment company” within the meaning of Section 1297 of the Code; (iii) has ever had a permanent establishment (within the meaning of an applicable Tax treaty) or otherwise had an office or fixed place of business in a country other than the country in which it is organized; (iv) is or was a “surrogate foreign corporation” within the meaning of Section 7874(a)(2)(B) or is treated as a U.S. corporation under Section 7874(b) of the Code; or (v) was created or organized in the U.S. such that such entity would be taxable in the U.S. as a domestic entity pursuant to the dual charter provision of Treasury Regulations Section 301.7701-5(a).

(l) Neither Parent nor its Subsidiaries has participated in or been a party to a transaction that, as of the date of this Agreement, constitutes a “listed transaction” that is required to be reported to the IRS pursuant to Section 6011 of the Code and applicable Treasury Regulations thereunder.

(m) Neither Parent nor its Subsidiaries has taken or agreed to take any action or knows of any fact that would reasonably be expected to prevent the Merger from qualifying for the Intended Tax Treatment.

For purposes of this [Section 3.16](#), each reference to Parent or its Subsidiaries shall be deemed to include any Person that was liquidated into, merged with, or is otherwise a predecessor to, Parent or its Subsidiaries, respectively.

### 3.17 **Employee and Labor Matters; Benefit Plans.**

(a) [Section 3.17\(a\)](#) of the Parent Disclosure Schedule is a list of all Parent Benefit Plans, including, without limitation, each Parent Benefit Plan that provides for retirement, change in control, stay or retention deferred compensation, incentive compensation, severance or retiree medical or life insurance benefits. “**Parent Benefit Plan**” means each (i) “employee benefit plan” as defined in Section 3(3) of ERISA and (ii) other pension, retirement, deferred compensation, excess benefit, profit sharing, bonus, incentive, equity or equity-based (other than individual Parent Options made pursuant to the Parent’s or its Subsidiaries’ standard forms, in which case only representative standard forms of such stock option agreements shall be scheduled), phantom equity, employment agreement or offer letter (other than at-will employment agreements or offer letters on the Company’s standard forms, in which case only representative standard form of such employment agreements or offer letters shall be scheduled), consulting, severance, change-of-control, retention, health, life, disability, group insurance, paid-time off, holiday, welfare and fringe benefit plan, program, contract, or arrangement (whether written or unwritten, qualified or nonqualified, funded or unfunded and including any that have been frozen), in any case, maintained, contributed to, or required to be contributed to, by Parent or Parent ERISA Affiliates for the benefit of any current or former employee, director, officer or independent contractor of Parent its Subsidiaries or under which Parent its Subsidiaries has any actual or contingent liability (including, without limitation, as to the result of it being treated as a single employer under Code Section 414 with any other person).

(b) As applicable with respect to each material Parent Benefit Plan, Parent has made available to the Company, true and complete copies of (i) each material Parent Benefit Plan, including all amendments thereto, and in the case of an unwritten material Parent Benefit Plan, a written description thereof, (ii) all current trust documents, investment management contracts, custodial agreements, administrative services agreements and insurance and annuity contracts relating thereto, (iii) the current summary plan description and each summary of material modifications thereto, (iv) the most recently filed annual reports with any Governmental Body (e.g., Form 5500 and all schedules thereto), (v) the most recent IRS determination, opinion or advisory letter, (vi) the most recent summary annual reports, nondiscrimination testing reports, actuarial reports, financial statements and trustee reports, (vii) all records, notices and filings concerning IRS or Department of Labor or other Governmental Body audits or investigations, “prohibited transactions” within the meaning of Section 406 of ERISA or Section 4975 of the Code and (viii) all policies and procedures established to comply with the privacy and security rules of HIPAA.

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(c) Each Parent Benefit Plan has been maintained, operated and administered in compliance in all material respects with its terms and any related documents or agreements and the applicable provisions of ERISA, the Code and all other Laws.

(d) The Parent Benefit Plans which are “employee pension benefit plans” within the meaning of Section 3(2) of ERISA and which are intended to meet the qualification requirements of Section 401(a) of the Code have received determination or opinion letters from the IRS on which they may currently rely to the effect that such plans are qualified under Section 401(a) of the Code and the related trusts are exempt from federal income Taxes under Section 501(a) of the Code, respectively, and to the Knowledge of Parent nothing has occurred that would reasonably be expected to materially adversely affect the qualification of such Parent Benefit Plan or the tax exempt status of the related trust.

(e) Neither Parent nor any of its Subsidiaries nor any Parent ERISA Affiliate maintains, contributes to, is required to contribute to, or has any actual or contingent liability with respect to, (i) any “employee pension benefit plan” (within the meaning of Section 3(2) of ERISA) that is subject to Title IV or Section 302 of ERISA or Section 412 of the Code, (ii) any “multiemployer plan” (within the meaning of Section 3(37) of ERISA), (iii) any “multiple employer plan” (within the meaning of Section 413 of the Code) or (iv) any “multiple employer welfare arrangement” (within the meaning of Section 3(40) of ERISA).

(f) There are no pending audits or investigations by any Governmental Body involving any Parent Benefit Plan, and no pending or, to the Knowledge of Parent, threatened claims (except for individual claims for benefits payable in the normal operation of the Parent Benefit Plans), suits or proceedings involving any Parent Benefit Plan, any fiduciary thereof or service provider thereto, in any case, except as would not be reasonably expected to result in material liability to Parent or its Subsidiaries. All contributions and premium payments required to have been made under any of the Parent Benefit Plans or by applicable Law (without regard to any waivers granted under Section 412 of the Code), have been timely made in all material respects and neither Parent nor its Subsidiaries nor any Parent ERISA Affiliate has any material liability for any unpaid contributions with respect to any Parent Benefit Plan.

(g) Neither Parent nor its Subsidiaries nor any Parent ERISA Affiliates, nor to the Knowledge of Parent, any fiduciary, trustee or administrator of any Parent Benefit Plan, has engaged in, or in connection with the transactions contemplated by this Agreement will engage in, any transaction with respect to any Parent Benefit Plan which would subject any such Parent Benefit Plan, Parent or its Subsidiaries, or Parent ERISA Affiliates to a material Tax, material penalty or material liability for a “prohibited transaction” under Section 406 of ERISA or Section 4975 of the Code.

(h) No Parent Benefit Plan provides death, medical, dental, vision, life insurance or other welfare benefits beyond termination of service or retirement other than coverage mandated by Law and neither Parent nor any of its Subsidiaries nor any Parent ERISA Affiliates has made a written or oral representation promising the same.

(i) Neither the execution of, nor the performance of the transactions contemplated by, this Agreement will either alone or in connection with any other event(s) (i) result in any payment becoming due to any current or former employee, director, officer, or independent contractor of Parent or its Subsidiaries, (ii) increase any amount of compensation or benefits otherwise payable under any Parent Benefit Plan, (iii) result in the acceleration of the time of payment, funding or vesting of any benefits under any Parent Benefit Plan, (iv) require any contribution or payment to fund any obligation under any Parent Benefit Plan or (v) limit the right to merge, amend or terminate any Parent Benefit Plan.

(j) Neither the execution of, nor the consummation of the transactions contemplated by this Agreement (either alone or when combined with the occurrence of any other event, including without limitation, a termination of employment) will result in the receipt or retention by any person who is a “disqualified

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individual” (within the meaning of Code Section 280G) with respect to Parent of any payment or benefit that is or could be characterized as a “parachute payment” (within the meaning of Code Section 280G), determined without regard to the application of Code Section 280G(b) (5).

(k) The exercise price of each Parent Option is not, never has been, less than the fair market value of one share of Parent Common Stock as of the grant date of such Parent Option.

(l) Each Parent Benefit Plan providing for deferred compensation that constitutes a “nonqualified deferred compensation plan” (as defined in Section 409A(d)(1) of the Code and the regulations promulgated thereunder) is, and has been, established, administered and maintained in compliance with the requirements of Section 409A of the Code and the regulations promulgated thereunder in all material respects.

(m) No current or former employee, officer, director or independent contractor of Parent or its Subsidiaries has any “gross up” agreements with the Parent or other assurance of reimbursement by the Parent or its Subsidiaries for any Taxes imposed under Code Section 409A or Code Section 4999.

(n) Parent has provided or made available to the Company an accurate list, as of the date of this Agreement, containing the names of independent contractors of Parent and its Subsidiaries and, as applicable: (i) the annual dollar amount of all compensation (including wages, salary or fees, commissions, director’s fees, fringe benefits, bonuses, profit sharing payments, and other payments or benefits of any type) payable to each person; (ii), dates of employment or service; (iii) title; (iv) any eligibility to receive severance, notice of termination, retention payment, change of control payment, or other similar compensation; (v) visa status, if applicable; and (vi) with respect to employees, a designation of whether they are classified as exempt or non-exempt for purposes of FLSA and any similar state law. Parent has one full-time employee and no part-time or temporary employees. Parent’s Subsidiaries have no full-time, part-time or temporary employees. As of the Closing Date, Parent and its Subsidiaries shall have no employees of any type.

(o) Parent and each of its Subsidiaries is not and never has been a party to, bound by, or has a duty to bargain under, any collective bargaining agreement or other Contract with a labor union, labor organization, or similar Person representing any of its employees, and there is no labor union, labor organization, or similar Person representing or, to the Knowledge of Parent, purporting to represent or seeking to represent any employees of Parent or its Subsidiaries, including through the filing of a petition for representation election. There is not and has not been in the past three years, nor is there or has there been in the past three years any threat of, any strike, slowdown, work stoppage, lockout, union election petition, demand for recognition, or any similar activity or dispute, or, to the Knowledge of Parent, any union organizing activity, against Parent or any of its Subsidiaries. No event has occurred, and no condition or circumstance exists, that might directly or indirectly be likely to give rise to or provide a basis for the commencement of any such strike, slowdown, work stoppage, lockout, union election petition, demand for recognition, any similar activity or dispute, or, to the Knowledge of Parent, any union organizing activity.

(p) Parent and each of its Subsidiaries is, and since January 1, 2016 has been, in material compliance with all applicable Laws respecting labor, employment, employment practices, and terms and conditions of employment, including worker classification, discrimination, harassment and retaliation, equal employment opportunities, fair employment practices, meal and rest periods, immigration, employee safety and health, payment of wages (including overtime wages), unemployment and workers’ compensation, leaves of absence, and hours of work. Except as would not be reasonably likely to result in a material liability to Parent and its Subsidiaries, with respect to employees of Parent and its Subsidiaries, Parent and each Subsidiary, since January 1, 2016: (i) has withheld and reported all amounts required by Law or by agreement to be withheld and reported with respect to wages, salaries and other payments, benefits, or compensation to employees, (ii) is not liable for any arrears of wages (including overtime wages), severance pay or any Taxes or any penalty for failure to comply with any of the foregoing, and (iii) is not liable for any payment to any trust or other fund governed by or maintained by or on behalf of any Governmental Body, with respect to unemployment compensation benefits,

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disability, social security or other benefits or obligations for employees (other than routine payments to be made in the Ordinary Course of Business). There are no actions, suits, claims, charges, lawsuits, investigations, audits or administrative matters pending or, to the Knowledge of Parent, threatened or reasonably anticipated against Parent or its Subsidiaries relating to any employee, applicant for employment, consultant, employment agreement or Parent Benefit Plan (other than routine claims for benefits).

(q) Except as would not be reasonably likely to result in a material liability to Parent or its Subsidiaries, with respect to each individual who currently renders services to Parent or its Subsidiaries, Parent has accurately classified each such individual as an employee, independent contractor, or otherwise under all applicable Laws and, for each individual classified as an employee, Parent has accurately classified him or her as exempt or non-exempt under all applicable Laws. Parent has no material liability with respect to any misclassification of: (i) any Person as an independent contractor rather than as an employee, (ii) any employee leased from another employer, or (iii) any employee currently or formerly classified as exempt under all applicable Laws.

(r) Within the preceding five (5) years, neither Parent nor any of its Subsidiaries has implemented any "plant closing" or "mass layoff" of employees that would reasonably be expected to require notification under the WARN Act or any similar state or local Law, no such "plant closing" or "mass layoff" will be implemented before the Closing Date without advance notification to and approval of Parent, and there has been no "employment loss" as defined by the WARN Act within the 90 days prior to the Closing Date.

(s) There is no Legal Proceeding, claim, unfair labor practice charge or complaint, labor dispute or grievance pending or, to the Knowledge of Parent, threatened against Parent or its Subsidiaries relating to labor, employment, employment practices, or terms and conditions of employment.

(t) No Parent Benefit Plan is maintained outside the United States.

(u) As of the Closing Date, Parent and its Subsidiaries shall have no material Liability pursuant to any Parent Benefit Plan.

**3.18 Environmental Matters.** Parent and each of its Subsidiaries is and since January 1, 2016 has complied with all applicable Environmental Laws, which compliance includes the possession by Parent of all permits and other Governmental Authorizations required under applicable Environmental Laws and compliance with the terms and conditions thereof, except for any failure to be in such compliance that, either individually or in the aggregate, would not reasonably be expected to be material to Parent or its Subsidiaries or their respective businesses. Parent has not received since January 1, 2016 (or prior to that time, which is pending and unresolved), any written notice or other communication (in writing or otherwise), whether from a Governmental Body or other Person, that alleges that Parent or its Subsidiaries is not in compliance with or has liability pursuant to any Environmental Law and, to the Knowledge of Parent, there are no circumstances that would reasonably be expected to prevent or interfere with Parent's or its Subsidiaries' compliance in any material respects with any Environmental Law, except where such failure to comply would not reasonably be expected to be material to Parent or its Subsidiaries or their respective businesses. No current or (during the time a prior property was leased or controlled by Parent) prior property leased or controlled by Parent or its Subsidiaries has had a release of or exposure to Hazardous Materials in material violation of or as would reasonably be expected to result in any material liability of Parent or its Subsidiaries pursuant to Environmental Law. No consent, approval or Governmental Authorization of or registration or filing with any Governmental Body is required by Environmental Laws in connection with the execution and delivery of this Agreement or the consummation of Contemplated Transactions by Parent and its Subsidiaries. Prior to the date hereof, Parent has provided or otherwise made available to the Company true and correct copies of all material environmental reports, assessments, studies and audits in the possession or control of Parent with respect to any property leased or controlled by each of Parent or its Subsidiaries or any business operated by it.

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3.19 **Transactions with Affiliates.** Except as set forth in the Parent SEC Documents filed prior to the date of this Agreement, since the date of Parent's Annual Report on Form 10-K for the year ended December 31, 2018 as filed with the SEC, no event has occurred that would be required to be reported by Parent pursuant to Item 404 of Regulation S-K.

3.20 **Insurance.** Parent has delivered or made available to the Company accurate and complete copies of all material insurance policies and all material self-insurance programs and arrangements relating to the business, assets, liabilities and operations of Parent and its Subsidiaries, which include accurate and complete copies of the existing policies (primary and excess) of directors' and officers' liability insurance maintained by Parent. Each of such insurance policies is in full force and effect and Parent and its Subsidiaries is in compliance in all material respects with the terms thereof. Other than customary end of policy notifications from insurance carriers, since January 1, 2016, Parent has not received any notice or other communication regarding any actual or possible: (a) cancellation or invalidation of any insurance policy; or (b) refusal or denial of any coverage, reservation of rights or rejection of any material claim under any insurance policy. Parent has provided timely written notice to the appropriate insurance carrier(s) of each Legal Proceeding that is currently pending against Parent or its Subsidiaries for which Parent has insurance coverage, and no such carrier has issued a denial of coverage or a reservation of rights with respect to any such Legal Proceeding, or informed Parent of its intent to do so.

3.21 **No Financial Advisors.** Other than Canaccord Genuity LLC, no broker, finder or investment banker is entitled to any brokerage fee, finder's fee, opinion fee, success fee, transaction fee or other fee or commission in connection with the Contemplated Transactions based upon arrangements made by or on behalf of Parent or its Subsidiaries.

3.22 **Anti-Bribery.** Neither Parent nor any of its Subsidiaries nor any of their respective directors, officers, employees or, to Parent's Knowledge, agents or any other Person acting on its behalf has directly or indirectly made any bribes, rebates, payoffs, influence payments, kickbacks, illegal payments, illegal political contributions, or other payments, in the form of cash, gifts, or otherwise, or taken any other action, in violation of Anti-Bribery Laws. Parent and each of its Subsidiaries is not nor has not been the subject of any investigation or inquiry by any Governmental Body with respect to potential violations of Anti-Bribery Laws.

3.23 **Valid Issuance.** The Parent Common Stock to be issued in the Merger will, when issued in accordance with the provisions of this Agreement, be validly issued, fully paid and nonassessable.

3.24 **Opinion of Financial Advisor.** The Parent Board has received an opinion of Canaccord Genuity LLC to the effect that, as of the date of this Agreement and subject to the assumptions, qualifications, limitations and other matters set forth therein, the Exchange Ratio is fair, from a financial point of view, to Parent. It is agreed and understood that such opinion is for the benefit of the Parent Board and may not be relied upon by the Company.

### 3.25 **Disclaimer of Other Representations or Warranties.**

(a) Except as previously set forth in this [Section 3](#) or in any certificate delivered by Parent or Merger Sub to the Company pursuant to this Agreement, neither Parent nor Merger Sub makes any representation or warranty, express or implied, at law or in equity, with respect to it or any of its assets, liabilities or operations, and any such other representations or warranties are hereby expressly disclaimed.

(b) Each of Parent and Merger Sub acknowledges and agrees that, except for the representations and warranties of the Company set forth in [Section 2](#), none of the Company or any of their respective Representatives is relying on any other representation or warranty of the Company or any other Person made outside of [Section 2](#), including regarding the accuracy or completeness of any such other representations or warranties or the omission of any material information, whether express or implied, in each case, with respect to the Contemplated Transactions.

## Section 4. CERTAIN COVENANTS OF THE PARTIES

### 4.1 Operation of Parent's Business.

(a) Except as set forth on [Section 4.1\(a\)](#) of the Parent Disclosure Schedule, as expressly permitted by this Agreement (including in connection with the Divestiture Transactions), as required by applicable Law or unless the Company shall otherwise consent in writing (which consent shall not be unreasonably withheld, delayed or conditioned), during the period commencing on the date of this Agreement and continuing until the earlier to occur of the termination of this Agreement pursuant to [Section 9](#) and the Effective Time (the "**Pre-Closing Period**"): each of Parent and its Subsidiaries shall conduct its business and operations in the Ordinary Course of Business and in compliance in all material respects with all applicable Laws and the requirements of all Contracts that constitute Parent Material Contracts.

(b) Except (i) as expressly permitted by this Agreement (including in connection with the Divestiture Transactions), (ii) as set forth in [Section 4.1\(b\)](#) of the Parent Disclosure Schedule, (iii) as required by applicable Law or (iv) with the prior written consent of the Company (which consent shall not be unreasonably withheld, delayed or conditioned), at all times during the Pre-Closing Period, Parent shall not, nor shall it cause or permit its Subsidiaries to, do any of the following:

(i) declare, accrue, set aside or pay any dividend or make any other distribution in respect of any shares of its capital stock or repurchase, redeem or otherwise reacquire any shares of its capital stock or other securities (except in connection with the payment of withholding Taxes incurred upon the exercise, settlement or vesting of any award granted under the Parent Stock Plans in accordance with the terms of such award in effect on the date of this Agreement);

(ii) sell, issue, grant, pledge or otherwise dispose of or encumber or authorize any of the foregoing with respect to: (A) any capital stock or other security of Parent (except for Parent Common Stock issued upon the valid exercise of outstanding Parent Options, Parent Warrants or Parent's Series A Convertible Preferred Stock); (B) any option, warrant or right to acquire any capital stock or any other security; or (C) any instrument convertible into or exchangeable for any capital stock or other security of Parent;

(iii) except as required to give effect to anything in contemplation of the Closing, amend any of its Organizational Documents, or effect or be a party to any merger, consolidation, share exchange, business combination, recapitalization, reclassification of shares, stock split, reverse stock split or similar transaction except, for the avoidance of doubt, the Contemplated Transactions;

(iv) form any Subsidiary or acquire any equity interest or other interest in any other Entity or enter into a joint venture with any other Entity;

(v) (A) lend money to any Person, (B) incur or guarantee any indebtedness for borrowed money, (C) guarantee any debt securities of others, or (D) make any capital expenditure or commitment;

(vi) other than as required by applicable Law or the terms of any Parent Benefit Plan as in effect on the date of this Agreement: (A) adopt, terminate, establish or enter into any Parent Benefit Plan; (B) cause or permit any Parent Benefit Plan to be amended in any material respect (other than in connection with the termination thereof); (C) pay any bonus or make any profit-sharing or similar payment to, or increase the amount of the wages, salary, commissions, benefits or other compensation or remuneration payable to, any of its directors, officers or employees; (D) increase the severance, retention or change of control benefits offered to any current or former or new employees, directors or consultants; (E) hire or retain any officer, employee or consultant; or (F) terminate or give notice of termination to any officer or employee, other than any termination for cause;

(vii) recognize any labor union, labor organization, or similar Person except as otherwise required by law and after advance notice to the Company;

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- (viii) acquire any asset or sell, lease or otherwise irrevocably dispose of any of its material assets or properties, other than the Divestiture Transactions, or grant any Encumbrance with respect to any assets or properties;
- (ix) sell, assign, transfer, license, sublicense or otherwise dispose of any material Parent IP (other than the Divestiture Transactions or pursuant to non-exclusive licenses in the Ordinary Course of Business);
- (x) make, change or revoke any material Tax election, fail to pay any income or other material Tax as such Tax becomes due and payable, file any amendment making any material change to any Tax Return, settle or compromise any income or other material Tax liability, enter into any Tax allocation, sharing, indemnification or other similar agreement or arrangement (other than customary commercial contracts entered into in the Ordinary Course of Business the principal subject matter of which is not Taxes), request or consent to any extension or waiver of any limitation period with respect to any claim or assessment for any income or other material Taxes (other than pursuant to an extension of time to file any Tax Return granted in the Ordinary Course of Business of not more than six months), or adopt or change any material accounting method in respect of Taxes;
- (xi) enter into, materially amend or terminate any Parent Material Contract other than in connection with the Divestiture Transactions;
- (xii) other than incurrence or payment of Parent Transaction Expenses up to an aggregate of \$1,000,000, make any expenditures or incur any liabilities other than in the Ordinary Course of Business up to, individually or in the aggregate, \$25,000 (other than in connection with the Divestiture Transactions);
- (xiii) enter into any transaction other than in the Ordinary Course of Business or in connection with the Divestiture Transactions;
- (xiv) other than as required by Law or GAAP, take any action to change accounting policies or procedures;
- (xv) initiate or settle any Legal Proceeding; or
- (xvi) agree, resolve or commit to do any of the foregoing.

(c) Notwithstanding anything to the contrary contained herein, Parent shall be permitted to take all actions necessary to negotiate and executed definitive documentation relating to the Divestiture Transactions.

Nothing contained in this Agreement shall give the Company, directly or indirectly, the right to control or direct the operations of Parent prior to the Effective Time. Prior to the Effective Time, Parent shall exercise, consistent with the terms and conditions of this Agreement, complete unilateral control and supervision over its business operations.

#### **4.2 Operation of the Company's Business.**

(a) Except as set forth on Section 4.2(a) of the Company Disclosure Schedule, as expressly permitted by this Agreement (including in connection with the Concurrent Financing), as required by applicable Law or unless Parent shall otherwise consent in writing (which consent shall not be unreasonably withheld, delayed or conditioned), during the Pre-Closing Period: each of the Company and its Subsidiaries shall conduct its business and operations in the Ordinary Course of Business and in compliance in all material respects with all applicable Laws and the requirements of all Contracts that constitute Company Material Contracts.

(b) Except (i) as expressly permitted by this Agreement (including in connection with the Concurrent Financing), (ii) as set forth in Section 4.2(b) of the Company Disclosure Schedule, (iii) as required by applicable Law or (iv) with the prior written consent of Parent (which consent shall not be unreasonably withheld, delayed

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or conditioned), at all times during the Pre-Closing Period, the Company shall not, nor shall it cause or permit any of its Subsidiaries to, do any of the following:

(i) declare, accrue, set aside or pay any dividend or make any other distribution in respect of any shares of its capital stock or repurchase, redeem or otherwise reacquire any shares of its capital stock or other securities (except for shares of Company Common Stock from terminated employees, directors or consultants of the Company);

(ii) sell, issue, grant, pledge or otherwise dispose of or encumber or authorize any of the foregoing with respect to: (A) any capital stock or other security of the Company or any of its Subsidiaries (except for shares of outstanding Company Common Stock issued upon the valid exercise of Company Options or Company Warrants); (B) any option, warrant, right to acquire any capital stock or any other security; or (C) any other instrument convertible into or exchangeable for any capital stock or other security of the Company or any of its Subsidiaries;

(iii) except as required to give effect to anything in contemplation of the Closing, amend any of its or its Subsidiaries' Organizational Documents, or effect or be a party to any merger, consolidation, share exchange, business combination, recapitalization, reclassification of shares, stock split, reverse stock split or similar transaction except, for the avoidance of doubt, the Contemplated Transactions;

(iv) form any Subsidiary or acquire any equity interest or other interest in any other Entity or enter into a joint venture with any other Entity;

(v) (A) lend money to any Person, (B) incur or guarantee any indebtedness for borrowed money, (C) guarantee any debt securities of others, or (D) make any capital expenditure or commitment in excess of \$500,000;

(vi) other than as required by applicable Law or the terms of any Company Benefit Plan as in effect on the date of this Agreement: (A) adopt, terminate, establish or enter into any Company Benefit Plan; (B) cause or permit any Company Benefit Plan to be amended in any material respect; (C) pay any bonus or make any profit-sharing or similar payment to, or increase the amount of the wages, salary, commissions, benefits or other compensation or remuneration payable to, any of its directors, officers or employees; (D) increase the severance or change of control benefits offered to any current or new employees, directors or consultants or (E) terminate or give notice of termination to any (x) officer or (y) employee whose annual base salary is or is expected to be more than \$125,000 per year, other than any termination for cause;

(vii) recognize any labor union, labor organization, or similar Person, except as otherwise required by law and after advance notice to the Parent;

(viii) enter into any transaction other than in the Ordinary Course of Business;

(ix) acquire any material asset or sell, lease or otherwise irrevocably dispose of any of its material assets or properties, or grant any Encumbrance with respect to such assets or properties;

(x) sell, assign, transfer, license, sublicense or otherwise dispose of any material Company IP (other than pursuant to non-exclusive licenses in the Ordinary Course of Business);

(xi) make, change or revoke any material Tax election, fail to pay any income or other material Tax as such Tax becomes due and payable, file any amendment making any material change to any Tax Return, settle or compromise any income or other material Tax liability, enter into any Tax allocation, sharing, indemnification or other similar agreement or arrangement (other than customary commercial contracts entered into in the Ordinary Course of Business the principal subject matter of which is not Taxes), request or consent to any extension or waiver of any limitation period with respect to any claim or assessment for any income or other material Taxes (other than pursuant to an extension of time to file any Tax Return granted in the Ordinary Course of Business of not more than six months), or adopt or change any material accounting method in respect of Taxes;



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- (xii) enter into, materially amend or terminate any Company Material Contract;
- (xiii) other than incurrence or payment of any Company Transaction Expenses, make any expenditures, incur any Liabilities or discharge or satisfy any Liabilities, in each case, in amounts that exceed \$500,000 in the aggregate;
- (xiv) other than as required by Law or GAAP, take any action to change accounting policies or procedures;
- (xv) initiate or settle any Legal Proceeding; or
- (xvi) agree, resolve or commit to do any of the foregoing.

(c) Nothing contained in this Agreement shall give Parent, directly or indirectly, the right to control or direct the operations of the Company prior to the Effective Time. Prior to the Effective Time, the Company shall exercise, consistent with the terms and conditions of this Agreement, complete unilateral control and supervision over its business operations.

### **4.3 Access and Investigation.**

(a) Subject to the terms of the Confidentiality Agreement, which the Parties agree will continue in full force following the date of this Agreement, during the Pre-Closing Period, upon reasonable notice, Parent, on the one hand, and the Company, on the other hand, shall and shall use commercially reasonable efforts to cause such Party's Representatives to: (i) provide the other Party and such other Party's Representatives with reasonable access, upon reasonable notice and during normal business hours to such Party's Representatives, personnel, property and assets and to all existing books, records, Tax Returns, work papers and other documents and information relating to such Party and its Subsidiaries; (ii) provide the other Party and such other Party's Representatives with such copies of the existing books, records, Tax Returns, work papers, product data, and other documents and information relating to such Party and its Subsidiaries, and with such additional financial, operating and other data and information regarding such Party and its Subsidiaries as the other Party may reasonably request; (iii) permit the other Party's officers and other employees to meet, upon reasonable notice and during normal business hours, with the chief financial officer (or interim chief financial officer, as applicable), chief executive officer, and other officers and managers of such Party responsible for such Party's financial statements and the internal controls of such Party to discuss such matters as the other Party may deem necessary or appropriate and; (iv) make available to the other Party copies of unaudited financial statements, material operating and financial reports prepared for senior management or the board of directors of such Party, and any material notice, report or other document filed with or sent to or received from any Governmental Body in connection with the Contemplated Transactions. Any investigation conducted by either Parent or the Company pursuant to this Section 4.3 shall be conducted in such manner as not to interfere unreasonably with the conduct of the business of the other Party.

(b) Notwithstanding the foregoing, any Party may restrict the foregoing access to the extent that any Law applicable to such Party requires such Party to restrict or prohibit access to any such properties or information or as may be necessary to preserve the attorney-client privilege under any circumstances in which such privilege may be jeopardized by such disclosure or access.

### **4.4 Parent Non-Solicitation.**

(a) Parent agrees that, during the Pre-Closing Period, it shall not, and shall not authorize any of its Representatives to, directly or indirectly: (i) solicit, initiate or knowingly encourage, induce or facilitate the communication, making, submission or announcement of any Acquisition Proposal or Acquisition Inquiry or take any action that could reasonably be expected to lead to an Acquisition Proposal or Acquisition Inquiry; (ii) furnish any non-public information regarding Parent to any Person in connection with or in response to an Acquisition Proposal or Acquisition Inquiry; (iii) engage in discussions (other than to inform any Person of the

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existence of the provisions contained in this [Section 4.4](#)) or negotiations with any Person with respect to any Acquisition Proposal or Acquisition Inquiry; (iv) approve, endorse or recommend any Acquisition Proposal (subject to [Section 5.3](#)); (v) execute or enter into any letter of intent or any Contract contemplating or otherwise relating to any Acquisition Transaction (other than a confidentiality agreement permitted under this [Section 4.4\(a\)](#)); or (vi) publicly propose to do any of the foregoing; provided, however, that, notwithstanding anything contained in this [Section 4.4](#) and subject to compliance with this [Section 4.4](#), prior to obtaining the Required Parent Stockholder Vote, Parent may furnish non-public information regarding Parent to, and enter into discussions or negotiations with, any Person in response to a *bona fide* written Acquisition Proposal by such Person, which the Parent Board determines in good faith, after consultation with Parent's outside financial advisors and outside legal counsel, constitutes, or is reasonably likely to result in, a Superior Offer (and is not withdrawn) if: (A) neither Parent nor any of its Representatives shall have breached this [Section 4.4](#) in any material respect, (B) the Parent Board concludes in good faith based on the advice of outside legal counsel, that the failure to take such action is reasonably likely to be inconsistent with the fiduciary duties of the Parent Board under applicable Law; (C) at least two (2) Business Days prior to furnishing such nonpublic confidential information to, or entering into discussions with, such Person, Parent gives the Company written notice of the identity of such Person and of Parent's intention to furnish nonpublic information to, or enter into discussions with, such Person; (D) Parent receives from such Person an executed confidentiality agreement containing provisions, in the aggregate, at least as favorable to Parent as those contained in the Confidentiality Agreement; and (E) at least two (2) Business Days prior to furnishing any such nonpublic information to such Person, Parent furnishes such nonpublic information to the Company (to the extent such information has not been previously furnished by Parent to the Company). Without limiting the generality of the foregoing, Parent acknowledges and agrees that, in the event any Representative of Parent (whether or not such Representative is purporting to act on behalf of Parent) takes any action that, if taken by Parent, would constitute a breach of this [Section 4.4](#), the taking of such action by such Representative shall be deemed to constitute a breach of this [Section 4.4](#) by Parent for purposes of this Agreement.

(b) If Parent or any Representative of Parent receives an Acquisition Proposal or Acquisition Inquiry at any time during the Pre-Closing Period, then Parent shall promptly (and in no event later than twenty-four (24) hours after Parent becomes aware of such Acquisition Proposal or Acquisition Inquiry) advise the Company orally and in writing of such Acquisition Proposal or Acquisition Inquiry (including the identity of the Person making or submitting such Acquisition Proposal or Acquisition Inquiry, and the material terms thereof). Parent shall keep the Company reasonably informed with respect to the status and material terms of any such Acquisition Proposal or Acquisition Inquiry and any material modification or proposed material modification thereto.

(c) Parent shall immediately cease and cause to be terminated any existing discussions, negotiations and communications with any Person that relate to any Acquisition Proposal or Acquisition Inquiry as of the date of this Agreement and request the destruction or return of any nonpublic information of Parent provided to such Person.

### **4.5 Company Non-Solicitation.**

(a) The Company agrees that, during the Pre-Closing Period, neither it nor any of its Subsidiaries shall, nor shall it or any of its Subsidiaries authorize any of its Representatives to, directly or indirectly: (i) solicit, initiate or knowingly encourage, induce or facilitate the communication, making, submission or announcement of any Acquisition Proposal or Acquisition Inquiry or take any action that could reasonably be expected to lead to an Acquisition Proposal or Acquisition Inquiry; (ii) furnish any non-public information regarding the Company or any of its Subsidiaries to any Person in connection with or in response to an Acquisition Proposal or Acquisition Inquiry; (iii) engage in discussions (other than to inform any Person of the existence of the provisions contained in this [Section 4.5](#)) or negotiations with any Person with respect to any Acquisition Proposal or Acquisition Inquiry; (iv) approve, endorse or recommend any Acquisition Proposal; (v) execute or enter into any letter of intent or any Contract contemplating or otherwise relating to any

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Acquisition Transaction; or (vi) publicly propose to do any of the foregoing provided, however, that, notwithstanding anything contained in this Section 4.5 and subject to compliance with this Section 4.5, prior to obtaining the Required Company Stockholder Vote, the Company may furnish non-public information regarding the Company to, and enter into discussions or negotiations with, any Person in response to a *bona fide* Acquisition Proposal by such Person, which the Company Board determines in good faith, after consultation with the Company's outside financial advisors and outside legal counsel, constitutes, or is reasonably likely to result in, a Superior Offer (and is not withdrawn) if: (A) neither the Company nor any of its Representatives shall have breached this Section 4.5 in any material respect, (B) the Company Board concludes in good faith based on the advice of outside legal counsel, that the failure to take such action is reasonably likely to be inconsistent with the fiduciary duties of the Company Board under applicable Law; (C) at least two (2) Business Days prior to furnishing such nonpublic confidential information to, or entering into discussions with, such Person, the Company gives Parent written notice of the identity of such Person and of the Company's intention to furnish nonpublic information to, or enter into discussions with, such Person; (D) the Company receives from such Person an executed confidentiality agreement containing provisions, in the aggregate, at least as favorable to the Company as those contained in the Confidentiality Agreement; and (E) at least two (2) Business Days prior to furnishing any such nonpublic information to such Person, the Company furnishes such nonpublic information to Parent (to the extent such information has not been previously furnished by the Company to Parent). Without limiting the generality of the foregoing, the Company acknowledges and agrees that, in the event any Representative of the Company (whether or not such Representative is purporting to act on behalf of the Company) takes any action that, if taken by the Company, would constitute a breach of this Section 4.5, the taking of such action by such Representative shall be deemed to constitute a breach of this Section 4.5 by the Company for purposes of this Agreement.

(b) If the Company or any Representative of the Company receives an Acquisition Proposal or Acquisition Inquiry at any time during the Pre-Closing Period, then the Company shall promptly (and in no event later than twenty-four (24) hours after the Company becomes aware of such Acquisition Proposal or Acquisition Inquiry) advise Parent orally and in writing of such Acquisition Proposal or Acquisition Inquiry (including the identity of the Person making or submitting such Acquisition Proposal or Acquisition Inquiry, and the material terms thereof). The Company shall keep Parent reasonably informed with respect to the status and material terms of any such Acquisition Proposal or Acquisition Inquiry and any material modification or proposed material modification thereto.

(c) The Company shall immediately cease and cause to be terminated any existing discussions, negotiations and communications with any Person that relate to any Acquisition Proposal or Acquisition Inquiry as of the date of this Agreement and request the destruction or return of any nonpublic information of the Company or any of its Subsidiaries provided to such Person.

#### **4.6 Notification of Certain Matters.**

(a) During the Pre-Closing Period, the Company shall promptly notify Parent (and, if in writing, furnish copies of) if any of the following occurs: (i) any notice or other communication is received from any Person alleging that the Consent of such Person is or may be required in connection with any of the Contemplated Transactions; (ii) any Legal Proceeding against or involving or otherwise affecting the Company or its Subsidiaries is commenced, or, to the Knowledge of the Company, threatened against the Company or its Subsidiaries or, to the Knowledge of the Company, any director or officer of the Company or its Subsidiaries; (iii) the Company becomes aware of any inaccuracy in any representation or warranty made by it in this Agreement; or (iv) the failure of the Company to comply with any covenant or obligation of the Company; in the case of (iii) and (iv) that could reasonably be expected to make the timely satisfaction of any of the conditions set forth in Sections 6 or 7, as applicable, impossible or materially less likely. No notification given to Parent pursuant to this Section 4.6(a) shall change, limit or otherwise affect any of the representations, warranties, covenants or obligations of the Company or any of its Subsidiaries contained in this Agreement or the Company Disclosure Schedule for purposes of Sections 6 and 7, as applicable.

(b) During the Pre-Closing Period, Parent shall promptly notify the Company (and, if in writing, furnish copies of) if any of the following occurs: (i) any notice or other communication is received from any Person alleging that the Consent of such Person is or may be required in connection with any of the Contemplated Transactions; (ii) any Legal Proceeding against or involving or otherwise affecting Parent is commenced, or, to the Knowledge of Parent, threatened against Parent or, to the Knowledge of Parent, any director or officer of Parent; (iii) Parent becomes aware of any inaccuracy in any representation or warranty made by it in this Agreement; or (iv) the failure of Parent to comply with any covenant or obligation of Parent or Merger Sub; in the case of (iii) and (iv) that could reasonably be expected to make the timely satisfaction of any of the conditions set forth in [Sections 6](#) or [8](#), as applicable, impossible or materially less likely. No notification given to the Company pursuant to this [Section 4.6\(b\)](#) shall change, limit or otherwise affect any of the representations, warranties, covenants or obligations of Parent contained in this Agreement or the Parent Disclosure Schedule for purposes of [Sections 6](#) and [8](#), as applicable.

## **Section 5. ADDITIONAL AGREEMENTS OF THE PARTIES**

### **5.1 Registration Statement; Proxy Statement.**

(a) As promptly as practicable after the date of this Agreement (but in no event later than May 15, 2019), the Company shall prepare, and Parent shall cause to be filed with the SEC, the Registration Statement, in which the Proxy Statement will be included as a prospectus. Parent covenants and agrees that the information provided by Parent or its Subsidiaries to the Company for inclusion in the Proxy Statement, including any pro forma financial statements included therein (and the letter to stockholders, notice of meeting and form of proxy included therewith), will not, at the time that the Proxy Statement or any amendment or supplement thereto is filed with the SEC or is first mailed to the Parent stockholders contain any untrue statement of a material fact or omit to state any material fact required to be stated therein or necessary in order to make the statements made therein, in light of the circumstances under which they were made, not misleading. The Company covenants and agrees that the information provided by the Company or its Subsidiaries to Parent for inclusion in the Proxy Statement (including the Company Financials) will not contain any untrue statement of a material fact or omit to state any material fact required to be stated therein or necessary in order to make such information not misleading. Notwithstanding the foregoing, (i) Parent makes no covenant, representation or warranty with respect to statements made in the Proxy Statement (and the letter to stockholders, notice of meeting and form of proxy included therewith), if any, based on information provided by the Company or its Subsidiaries or any of their Representatives specifically for inclusion therein and (ii) the Company makes no covenant, representation or warranty with respect to statements made in the Proxy Statement (and the letter to stockholders, notice of meeting and form of proxy included therewith), if any, other than with respect to the written information provided by the Company or its Subsidiaries or any of their Representatives for inclusion therein. Parent and its legal counsel shall be given reasonable opportunity to review and comment on the Proxy Statement, including all amendments and supplements thereto, prior to the filing thereof with the SEC, and on the response to any comments of the SEC on the Proxy Statement, prior to the filing thereof with the SEC. Each of the Parties shall use commercially reasonable efforts to cause the Registration Statement and the Proxy Statement to comply with the applicable rules and regulations promulgated by the SEC, to respond promptly to any comments of the SEC or its staff and to have the Registration Statement declared effective under the Securities Act as promptly as practicable after it is filed with the SEC. Parent shall use commercially reasonable efforts to cause the Proxy Statement to be mailed to Parent's stockholders as promptly as practicable after the Registration Statement is declared effective under the Securities Act. Each Party shall promptly furnish to the other Party all information concerning such Party and such Party's Affiliates and such Party's stockholders that may be required or reasonably requested in connection with any action contemplated by this [Section 5.1](#). If Parent, Merger Sub or the Company become aware of any event or information that, pursuant to the Securities Act or the Exchange Act, should be disclosed in an amendment or supplement to the Registration Statement or Proxy Statement, as the case may be, then such Party, as the case may be, shall promptly inform the other Parties thereof and shall cooperate with such other Parties in filing such amendment or supplement with the SEC and, if appropriate, in mailing such amendment or supplement to the Parent stockholders.

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(b) Prior to the Effective Time, Parent shall use commercially reasonable efforts to obtain all regulatory approvals needed to ensure that the Parent Common Stock to be issued in the Merger (to the extent required) shall be registered or qualified or exempt from registration or qualification under the securities law of every jurisdiction of the United States in which any registered holder of Company Capital Stock has an address of record on the applicable record date for determining the holders of Company Capital Stock entitled to notice and to vote pursuant to the Company Stockholder Written Consent.

(c) Parent shall reasonably cooperate with the Company and provide, and require its Representatives to provide, the Company and its Representatives, with all true, correct and complete information regarding Parent or its Subsidiaries that is required by Law to be included in the Registration Statement or reasonably requested by the Company to be included in the Registration Statement. The Company will use commercially reasonable efforts to cause to be delivered to Parent a consent letter of the Company's independent accounting firm, dated no more than two Business Days before the date on which the Registration Statement becomes effective (and reasonably satisfactory in form and substance to Parent), that is customary in scope and substance for consent letters delivered by independent public accountants in connection with registration statements similar to the Registration Statement.

### 5.2 Company Information Statement; Stockholder Written Consent.

(a) Promptly after the Registration Statement shall have been declared effective under the Securities Act, and in any event no later than three Business Days thereafter, the Company shall prepare, with the cooperation of Parent, and commence mailing to its stockholders an information statement (the "**Information Statement**") to solicit the Company Stockholder Consent evidencing the Required Company Stockholder Vote for purposes of (within five Business Days after the Registration Statement shall have been declared effective) (i) adopting and approving this Agreement and the Contemplated Transactions, (ii) acknowledging that the approval given thereby is irrevocable and that such stockholder is aware of its rights to demand appraisal for its shares pursuant to Section 262 of the DGCL, a true and correct copy of which will be attached thereto, and that such stockholder has received and read a copy of Section 262 of the DGCL and (iii) acknowledging that by its approval of the Merger it is not entitled to appraisal rights with respect to its shares in connection with the Merger and thereby waives any rights to receive payment of the fair value of its capital stock under the DGCL (collectively, the "**Company Stockholder Matters**"). Under no circumstances shall the Company assert that any other approval or consent is necessary by its stockholders to approve the Company Stockholder Matters. All materials (including any amendments thereto) submitted to the stockholders of the Company in accordance with this Section 5.2(a) shall be subject to Parent's advance review and reasonable approval.

(b) The Company covenants and agrees that the Information Statement, including any pro forma financial statements included therein (and the letter to stockholders and form of Company Stockholder Written Consent included therewith), will not, at the time that the Information Statement or any amendment or supplement thereto is first mailed to the stockholders of the Company, at the time of receipt of the Required Company Stockholder Vote and at the Effective Time, contain any untrue statement of a material fact or omit to state any material fact required to be stated therein or necessary in order to make the statements made therein, in light of the circumstances under which they were made, not misleading. Notwithstanding the foregoing, the Company makes no covenant, representation or warranty with respect to statements made in the Information Statement (and the letter to the stockholders and form of Company Stockholder Written Consent included therewith), if any, based on information furnished in writing by Parent specifically for inclusion therein. Each of the Parties shall use commercially reasonable efforts to cause the Information Statement to comply with the applicable rules and regulations promulgated by the SEC in all material respects.

(c) Promptly following receipt of the Required Company Stockholder Vote, the Company shall prepare and mail a notice (the "**Stockholder Notice**") to every stockholder of the Company that did not execute the Company Stockholder Written Consent. The Stockholder Notice shall (i) be a statement to the effect that the Company Board determined that the Merger is advisable in accordance with Section 251(b) of the DGCL and in

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the best interests of the stockholders of the Company and approved and adopted this Agreement, the Merger and the other Contemplated Transactions, (ii) provide the stockholders of the Company to whom it is sent with notice of the actions taken in the Company Stockholder Written Consent, including the adoption and approval of this Agreement, the Merger and the other Contemplated Transactions in accordance with Section 228(e) of the DGCL and the certificate of incorporation and bylaws of the Company and (iii) include a description of the appraisal rights of the Company's stockholders available under the DGCL, along with such other information as is required thereunder and pursuant to applicable Law. All materials (including any amendments thereto) submitted to the stockholders of the Company in accordance with this Section 5.2(c) shall be subject to Parent's advance review and reasonable approval.

(d) The Company agrees that: (i) the Company Board shall recommend that the Company's stockholders vote to approve the Company Stockholder Matters and shall use reasonable best efforts to solicit such approval from each of the Company stockholders necessary to deliver the Company Stockholder Written Consent evidencing the Required Company Stockholder Vote within the time set forth in Section 5.2(a) (the recommendation of the Company Board that the Company's stockholders vote to adopt and approve this Agreement being referred to as the "**Company Board Recommendation**"); and (ii) the Company Board Recommendation shall not be withdrawn or modified (and the Company Board shall not publicly propose to withdraw or modify the Company Board Recommendation) in a manner adverse to Parent, and no resolution by the Company Board or any committee thereof to withdraw or modify the Company Board Recommendation in a manner adverse to Parent or to adopt, approve or recommend (or publicly propose to adopt, approve or recommend) any Acquisition Proposal shall be adopted or proposed (the actions set forth in the foregoing clause (ii), collectively, a "**Company Board Adverse Recommendation Change**").

(e) Notwithstanding anything to the contrary contained in this Agreement, if at any time prior to the approval of Company Stockholder Matters by the Required Company Stockholder Vote:

(i) if Company has received a written Acquisition Proposal (which Acquisition Proposal did not arise out of a material breach of Section 4.5) from any Person that has not been withdrawn and after consultation with outside legal counsel, the Company Board shall have determined, in good faith, that such Acquisition Proposal is a Superior Offer, the Company Board may make a Company Board Adverse Recommendation Change, if and only if: (A) the Company Board determines in good faith, after consultation with Company's outside legal counsel, that the failure to do so could be inconsistent with the fiduciary duties of the Company Board to the Company's stockholders under applicable Law; (B) Company shall have given the Parent prior written notice of its intention to consider making a Company Board Adverse Recommendation Change or terminate this Agreement pursuant to Section 9.1(g) at least four Business Days prior to making any such Company Board Adverse Recommendation Change or termination (a "**Company Determination Notice**") (which notice shall not constitute a Company Board Adverse Recommendation Change); and (C) (1) the Company shall have provided to Parent a summary of the material terms and conditions of the Acquisition Proposal in accordance with Section 4.5(b), (2) the Company shall have given Parent the four Business Days after the Company Determination Notice to propose revisions to the terms of this Agreement or make another proposal and shall have made its Representatives reasonably available to negotiate in good faith with Parent (to the extent Parent desires to negotiate) with respect to such proposed revisions or other proposal, if any, and (3) after considering the results of any such negotiations and giving effect to the proposals made by Parent, if any, after consultation with outside legal counsel, the Company Board shall have determined, in good faith, that such Acquisition Proposal is a Superior Offer and that the failure to make the Company Board Adverse Recommendation Change or terminate this Agreement pursuant to Section 9.1(g) could be inconsistent with the fiduciary duties of the Company Board to the Company's stockholders under applicable Law. For the avoidance of doubt, the provisions of this Section 5.2(e)(i) shall also apply to any material change to the facts and circumstances relating to such Acquisition Proposal and require a new Company Determination Notice, except that the references to four Business Days shall be deemed to be three Business Days.

(ii) other than in connection with an Acquisition Proposal, the Company Board may make a Company Board Adverse Recommendation Change in response to a Company Change in Circumstance, if and only if: (A) the Company Board determines in good faith, after consultation with the Company's outside legal counsel, that the failure to do so could be inconsistent with the fiduciary duties of the Company Board to Parent's stockholders under applicable Law; (B) the Company shall have given Parent a Company Determination Notice at least four Business Days prior to making any such Company Board Adverse Recommendation Change; and (C) (1) Company shall have specified the Company Change in Circumstance in reasonable detail, (2) the Company shall have given Parent the four Business Days after the Company Determination Notice to propose revisions to the terms of this Agreement or make another proposal, and shall have made its Representatives reasonably available to negotiate in good faith with Parent (to the extent Parent desires to do so) with respect to such proposed revisions or other proposal, if any, and (3) after considering the results of any such negotiations and giving effect to the proposals made by Parent, if any, after consultation with outside legal counsel, the Company Board shall have determined, in good faith, that the failure to make the Company Board Adverse Recommendation Change in response to such Company Change in Circumstance could be inconsistent with the fiduciary duties of the Company Board to the Company's stockholders under applicable Law. For the avoidance of doubt, the provisions of this [Section 5.2\(e\)\(ii\)](#) shall also apply to any material change to the facts and circumstances relating to such Company Change in Circumstance and require a new Company Determination Notice, except that the references to four Business Days shall be deemed to be three Business Days.

(f) The Company's obligation to solicit the consent of its stockholders to sign the Company Stockholder Written Consent in accordance with [Section 5.2\(a\)](#) and [Section 5.2\(d\)](#) shall not be limited or otherwise affected by the commencement, disclosure, announcement or submission of any Superior Offer or other Acquisition Proposal.

### 5.3 Parent Stockholders' Meeting.

(a) Promptly after the Registration Statement has been declared effective by the SEC under the Securities Act, Parent shall take all action necessary under applicable Law to call, give notice of and hold a meeting of the holders of Parent Common Stock for the purpose of seeking approval of:

- (i) the amendment of Parent's certificate of incorporation to effect the Nasdaq Reverse Split;
- (ii) this Agreement, including the issuance of shares of Parent Common Stock to the Company's stockholders in connection with the Contemplated Transactions; and
- (iii) the change of control of Parent resulting from the Merger pursuant to the Nasdaq rules (the matters contemplated by the clauses 5.3(a)(i) – (iii) are referred to as the "**Parent Stockholder Matters**," and such meeting, the "**Parent Stockholders' Meeting**").

(b) The Parent Stockholders' Meeting shall be held as promptly as practicable after the Registration Statement is declared effective under the Securities Act. Parent shall take reasonable measures to ensure that all proxies solicited in connection with the Parent Stockholders' Meeting are solicited in compliance with all applicable Law. Notwithstanding anything to the contrary contained herein, if on the date of the Parent Stockholders' Meeting, or a date preceding the date on which the Parent Stockholders' Meeting is scheduled, Parent reasonably believes that (i) it will not receive proxies sufficient to obtain the Required Parent Stockholder Vote, whether or not a quorum would be present or (ii) it will not have sufficient shares of Parent Common Stock represented (whether in person or by proxy) to constitute a quorum necessary to conduct the business of the Parent Stockholders' Meeting, Parent may postpone or adjourn, or make up to two (but no more than two) successive postponements or adjournments of, the Parent Stockholders' Meeting as long as the date of the Parent Stockholders' Meeting is not postponed or adjourned more than an aggregate of 20 calendar days in connection with each such postponement or adjournment.

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(c) Parent agrees that, subject to Section 5.3(d): (i) the Parent Board shall recommend that the holders of Parent Common Stock vote to approve the Parent Stockholder Matters and shall use commercially reasonable efforts to solicit such approval, (ii) the Proxy Statement shall include a statement to the effect that the Parent Board recommends that Parent's stockholders vote to approve the Parent Stockholder Matters (the recommendation of the Parent Board with respect to the Parent Stockholder Matters being referred to as the "**Parent Board Recommendation**"); and (iii) the Parent Board Recommendation shall not be withheld, amended, withdrawn or modified (and the Parent Board shall not publicly propose to withhold, amend, withdraw or modify the Parent Board Recommendation) in a manner adverse to the Company (the actions set forth in the foregoing clause (iii), collectively, a "**Parent Board Adverse Recommendation Change**").

(d) Notwithstanding anything to the contrary contained in this Agreement, if at any time prior to the approval of Parent Stockholder Matters by the Required Parent Stockholder Vote:

(i) if Parent has received a written Acquisition Proposal (which Acquisition Proposal did not arise out of a material breach of Section 4.4) from any Person that has not been withdrawn and after consultation with outside legal counsel, the Parent Board shall have determined, in good faith, that such Acquisition Proposal is a Superior Offer, the Parent Board may make a Parent Board Adverse Recommendation Change, if and only if: (A) the Parent Board determines in good faith, after consultation with Parent's outside legal counsel, that the failure to do so could be inconsistent with the fiduciary duties of the Parent Board to Parent's stockholders under applicable Law; (B) Parent shall have given the Company prior written notice of its intention to consider making a Parent Board Adverse Recommendation Change or terminate this Agreement pursuant to Section 9.1(f) at least four Business Days prior to making any such Parent Board Adverse Recommendation Change or termination (a "**Determination Notice**") (which notice shall not constitute a Parent Board Adverse Recommendation Change); and (C) (1) Parent shall have provided to the Company a summary of the material terms and conditions of the Acquisition Proposal in accordance with Section 4.4(b), (2) Parent shall have given the Company the four Business Days after the Determination Notice to propose revisions to the terms of this Agreement or make another proposal and shall have made its Representatives reasonably available to negotiate in good faith with the Company (to the extent the Company desires to negotiate) with respect to such proposed revisions or other proposal, if any, and (3) after considering the results of any such negotiations and giving effect to the proposals made by the Company, if any, after consultation with outside legal counsel, the Parent Board shall have determined, in good faith, that such Acquisition Proposal is a Superior Offer and that the failure to make the Parent Board Adverse Recommendation Change or terminate this Agreement pursuant to Section 9.1(f) could be inconsistent with the fiduciary duties of the Parent Board to Parent's stockholders under applicable Law. For the avoidance of doubt, the provisions of this Section 5.3(d)(i) shall also apply to any material change to the facts and circumstances relating to such Acquisition Proposal and require a new Determination Notice, except that the references to four Business Days shall be deemed to be three Business Days.

(ii) other than in connection with an Acquisition Proposal, the Parent Board may make a Parent Board Adverse Recommendation Change in response to a Parent Change in Circumstance, if and only if: (A) the Parent Board determines in good faith, after consultation with Parent's outside legal counsel, that the failure to do so could be inconsistent with the fiduciary duties of the Parent Board to Parent's stockholders under applicable Law; (B) Parent shall have given the Company a Determination Notice at least four Business Days prior to making any such Parent Board Adverse Recommendation Change; and (C) (1) Parent shall have specified the Parent Change in Circumstance in reasonable detail, (2) Parent shall have given the Company the four Business Days after the Determination Notice to propose revisions to the terms of this Agreement or make another proposal, and shall have made its Representatives reasonably available to negotiate in good faith with the Company (to the extent the Company desires to do so) with respect to such proposed revisions or other proposal, if any, and (3) after considering the results of any such negotiations and giving effect to the proposals made by the Company, if any, after consultation with outside legal counsel, the Parent Board shall have determined,



in good faith, that the failure to make the Parent Board Adverse Recommendation Change in response to such Parent Change in Circumstance could be inconsistent with the fiduciary duties of the Parent Board to Parent's stockholders under applicable Law. For the avoidance of doubt, the provisions of this [Section 5.3\(d\)\(ii\)](#) shall also apply to any material change to the facts and circumstances relating to such Parent Change in Circumstance and require a new Determination Notice, except that the references to four Business Days shall be deemed to be three Business Days.

(e) Parent's obligation to solicit the consent of its stockholders to approve the Parent Stockholder Matters shall not be limited or otherwise affected by the commencement, disclosure, announcement or submission of any Superior Offer or other Acquisition Proposal.

(f) Nothing contained in this Agreement shall prohibit Parent or the Parent Board from (i) complying with Rules 14d-9 and 14e-2(a) promulgated under the Exchange Act, (ii) issuing a "stop, look and listen" communication or similar communication of the type contemplated by Section 14d-9(f) under the Exchange Act or (iii) otherwise making any disclosure to the Parent stockholders; *provided however*, that in the case of the foregoing clause (iii) the Parent Board determines in good faith, after consultation with its outside legal counsel, that failure to make such disclosure is reasonably likely to be inconsistent with applicable Law, including its fiduciary duties under applicable Law.

#### 5.4 Company Options and Company Warrants.

(a) At the Effective Time, each Company Option that is outstanding and unexercised immediately prior to the Effective Time under the Company Plan, whether or not vested, shall be converted into and become an option to purchase Parent Common Stock, and Parent shall assume the Company Plan and each such Company Option in accordance with the terms (as in effect as of the date of this Agreement) of the Company Plan and the terms of the stock option agreement by which such Company Option is evidenced (but with changes to such documents as Parent and the Company mutually agree are appropriate to reflect the substitution of the Company Options by Parent to purchase shares of Parent Common Stock). All rights with respect to Company Common Stock under Company Options assumed by Parent shall thereupon be converted into rights with respect to Parent Common Stock. Accordingly, from and after the Effective Time: (i) each Company Option assumed by Parent may be exercised solely for shares of Parent Common Stock; (ii) the number of shares of Parent Common Stock subject to each Company Option assumed by Parent shall be determined by multiplying (A) the number of shares of Company Common Stock that were subject to such Company Option, as in effect immediately prior to the Effective Time, by (B) the Exchange Ratio, and rounding the resulting number down to the nearest whole number of shares of Parent Common Stock; (iii) the per share exercise price for the Parent Common Stock issuable upon exercise of each Company Option assumed by Parent shall be determined by dividing (A) the per share exercise price of Company Common Stock subject to such Company Option, as in effect immediately prior to the Effective Time, by (B) the Exchange Ratio and rounding the resulting exercise price up to the nearest whole cent; and (iv) any restriction on the exercise of any Company Option assumed by Parent shall continue in full force and effect and the term, exercisability, vesting schedule and other provisions of such Company Option shall otherwise remain unchanged; *provided, however*, that: (A) to the extent provided under the terms of a Company Option and the Company Plans, such Company Option may be further adjusted as necessary to reflect Parent's substitution of the Company Options with options to purchase Parent Common Stock (such as by making any change in control or similar definition relate to Parent and having any provision that provides for the adjustment of Company Options upon the occurrence of certain corporate events relate to corporate events that relate to Parent and/or Parent Common Stock); and (B) the Parent Board or a committee thereof shall succeed to the authority and responsibility of the Company Board or any committee thereof with respect to each Company Option assumed by Parent. Notwithstanding anything to the contrary in this [Section 5.4\(a\)](#), the conversion of each Company Option (regardless of whether such option qualifies as an "incentive stock option" within the meaning of Section 422 of the Code) into an option to purchase shares of Parent Common Stock shall be made in a manner consistent with Treasury Regulation Section 1.424-1, such that the conversion of a Company Option shall not constitute a "modification" of such Company Option for purposes of Section 409A or Section 424 of the Code.

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(b) Parent shall file with the SEC, promptly after the Effective Time, a registration statement on Form S-8 (or any successor or alternative form), relating to the shares of Parent Common Stock issuable with respect to Company Options assumed by Parent in accordance with Section 5.4(a).

(c) At the Effective Time, each Company Warrant that is outstanding and unexercised as of immediately prior to the Effective Time (for the avoidance of doubt, excluding Company Warrants that are deemed to have been automatically exercised or terminated pursuant to their terms as a result of the consummation of the Merger), if any, shall be converted into and become a warrant to purchase Parent Common Stock and Parent shall assume each such Company Warrant in accordance with its terms. All rights with respect to Company Capital Stock under Company Warrants assumed by Parent shall thereupon be converted into rights with respect to Parent Common Stock. Accordingly, from and after the Effective Time: (i) each Company Warrant assumed by Parent may be exercised solely for shares of Parent Common Stock; (ii) the number of shares of Parent Common Stock subject to each Company Warrant assumed by Parent shall be determined by multiplying (A) the number of shares of Company Common Stock, or the number of shares of Company Common Stock issuable upon exercise of the Company Warrant, as applicable, that were subject to such Company Warrant immediately prior to the Effective Time by (B) the Exchange Ratio and rounding the resulting number down to the nearest whole number of shares of Parent Common Stock; (iii) the per share exercise price for the Parent Common Stock issuable upon exercise of each Company Warrant assumed by Parent shall be determined by dividing the per share exercise price of Company Capital Stock subject to such Company Warrant, as in effect immediately prior to the Effective Time, by the Exchange Ratio and rounding the resulting exercise price up to the nearest whole cent; and (iv) any restriction on any Company Warrant assumed by Parent shall continue in full force and effect and the term and other provisions of such Company Warrant shall otherwise remain unchanged.

(d) Prior to the Effective Time, the Company shall take all actions that may be necessary (under the Company Plan, the Company Warrants, and otherwise) to effectuate the provisions of this Section 5.4 and to ensure that, from and after the Effective Time, holders of Company Options, and Company Warrants have no rights with respect thereto other than those specifically provided in this Section 5.4.

### **5.5 Indemnification of Officers and Directors.**

(a) From the Effective Time through the sixth anniversary of the date on which the Effective Time occurs, each of Parent and the Surviving Corporation shall, jointly and severally, indemnify and hold harmless each person who is now, or has been at any time prior to the date hereof, or who becomes prior to the Effective Time, a director, officer, fiduciary or agent of Parent or the Company and their respective Subsidiaries, respectively (the “**D&O Indemnified Parties**”), against all claims, losses, liabilities, damages, judgments, fines and reasonable fees, costs and expenses, including attorneys’ fees and disbursements (collectively, “**Costs**”), incurred in connection with any claim, action, suit, proceeding or investigation, whether civil, criminal, administrative or investigative, arising out of or pertaining to the fact that the D&O Indemnified Party is or was a director, officer, fiduciary or agent of Parent or of the Company, whether asserted or claimed prior to, at or after the Effective Time, in each case, to the fullest extent permitted under applicable Law. Each D&O Indemnified Party will be entitled to advancement of expenses incurred in the defense of any such claim, action, suit, proceeding or investigation from each of Parent and the Surviving Corporation, jointly and severally, upon receipt by Parent or the Surviving Corporation from the D&O Indemnified Party of a request therefor; *provided* that any such person to whom expenses are advanced provides an undertaking to Parent, to the extent then required by the DGCL, to repay such advances if it is ultimately determined that such person is not entitled to indemnification.

(b) The provisions of the certificate of incorporation and bylaws of Parent with respect to indemnification, advancement of expenses and exculpation of present and former directors and officers of Parent that are presently set forth in the certificate of incorporation and bylaws of Parent shall not be amended, modified or repealed for a period of six years from the Effective Time in a manner that would adversely affect the rights

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thereunder of individuals who, at or prior to the Effective Time, were officers or directors of Parent. The certificate of incorporation and bylaws of the Surviving Corporation shall contain, and Parent shall cause the certificate of incorporation and bylaws of the Surviving Corporation to so contain, provisions no less favorable with respect to indemnification, advancement of expenses and exculpation of present and former directors and officers as those presently set forth in the certificate of incorporation and bylaws of Parent.

(c) From and after the Effective Time, (i) the Surviving Corporation shall fulfill and honor in all respects the obligations of the Company to its D&O Indemnified Parties as of immediately prior to the Closing pursuant to any indemnification provisions under the Company's Organizational Documents and pursuant to any indemnification agreements between the Company and such D&O Indemnified Parties, with respect to claims arising out of matters occurring at or prior to the Effective Time and (ii) Parent shall fulfill and honor in all respects the obligations of Parent to its D&O Indemnified Parties as of immediately prior to the Closing pursuant to any indemnification provisions under Parent's Organizational Documents and pursuant to any indemnification agreements between Parent and such D&O Indemnified Parties, with respect to claims arising out of matters occurring at or prior to the Effective Time.

(d) From and after the Effective Time, Parent shall maintain directors' and officers' liability insurance policies, with an effective date as of the Closing Date, on commercially available terms and conditions and with coverage limits customary for U.S. public companies similarly situated to Parent. In addition, Parent shall purchase, prior to the Effective Time, a six-year prepaid "tail policy" for the non-cancellable extension of the directors' and officers' liability coverage of Parent's existing directors' and officers' insurance policies for a claims reporting or discovery period of at least six years from and after the Effective Time with respect to any claim related to any period of time at or prior to the Effective Time (the "**D&O Tail Policy**").

(e) From and after the Effective Time, Parent shall pay all expenses, including reasonable attorneys' fees, that are incurred by the persons referred to in this Section 5.5 in connection with their successful enforcement of the rights provided to such persons in this Section 5.5.

(f) The provisions of this Section 5.5 are intended to be in addition to the rights otherwise available to the current and former officers and directors of Parent and the Company by Law, charter, statute, bylaw or agreement, and shall operate for the benefit of, and shall be enforceable by, each of the D&O Indemnified Parties, their heirs and their representatives.

(g) In the event Parent or the Surviving Corporation or any of their respective successors or assigns (i) consolidates with or merges into any other Person and shall not be the continuing or surviving corporation or entity of such consolidation or merger, or (ii) transfers all or substantially all of its properties and assets to any Person, then, and in each such case, proper provision shall be made so that the successors and assigns of Parent or the Surviving Corporation, as the case may be, shall succeed to the obligations set forth in this Section 5.5. Parent shall cause the Surviving Corporation to perform all of the obligations of the Surviving Corporation under this Section 5.5.

**5.6 Additional Agreements.** The Parties shall use commercially reasonable efforts to cause to be taken all actions necessary to consummate the Contemplated Transactions. Without limiting the generality of the foregoing, each Party to this Agreement: (a) shall make all filings and other submissions (if any) and give all notices (if any) required to be made and given by such Party in connection with the Contemplated Transactions; (b) shall use reasonable best efforts to obtain each Consent (if any) reasonably required to be obtained (pursuant to any applicable Law or Contract, or otherwise) by such Party in connection with the Contemplated Transactions or for such Contract (with respect to Contracts set forth in Section 5.6 of the Company Disclosure Schedule) to remain in full force and effect; (c) shall use commercially reasonable efforts to lift any injunction prohibiting, or any other legal bar to, the Contemplated Transactions; and (d) shall use commercially reasonable efforts to satisfy the conditions precedent to the consummation of this Agreement.

5.7 **Disclosure.** The initial press release relating to this Agreement shall be a joint press release issued by the Company and Parent and thereafter Parent and the Company shall consult with each other before issuing any further press release(s) or otherwise making any public statement or making any announcement to Parent Associates or Company Associates (to the extent not previously issued or made in accordance with this Agreement) with respect to the Contemplated Transactions and shall not issue any such press release, public statement or announcement to Parent Associates or Company Associates without the other Party's written consent (which shall not be unreasonably withheld, conditioned or delayed). Notwithstanding the foregoing: (a) each Party may, without such consultation or consent, make any public statement in response to questions from the press, analysts, investors or those attending industry conferences, make internal announcements to employees and make disclosures in Parent SEC Documents, so long as such statements are consistent with previous press releases, public disclosures or public statements made jointly by the parties (or individually, if approved by the other Party); (b) a Party may, without the prior consent of the other Party hereto but subject to giving advance notice to the other Party, issue any such press release or make any such public announcement or statement as may be required by any Law; and (c) Parent need not consult with the Company in connection with such portion of any press release, public statement or filing to be issued or made pursuant to [Section 5.3\(f\)](#) or with respect to any Acquisition Proposal or Parent Board Adverse Recommendation Change.

5.8 **Listing.** Parent shall use its commercially reasonable efforts, (a) to maintain its existing listing on Nasdaq until the Effective Time and to obtain approval of the listing of the combined corporation on Nasdaq, (b) to the extent required by the rules and regulations of Nasdaq, to prepare and submit to Nasdaq a notification form for the listing of the shares of Parent Common Stock to be issued in connection with the Contemplated Transactions, and to cause such shares to be approved for listing (subject to official notice of issuance); (c) to effect the Nasdaq Reverse Split; and (d) to the extent required by Nasdaq Marketplace Rule 5110, to file an initial listing application for the Parent Common Stock on Nasdaq (the "**Nasdaq Listing Application**"), which Nasdaq Listing Application shall be prepared by the Company, and to cause such Nasdaq Listing Application to be conditionally approved prior to the Effective Time. The Parties will use commercially reasonable efforts to coordinate with respect to compliance with Nasdaq rules and regulations. Each Party will promptly inform the other Party of all verbal or written communications between Nasdaq and such Party or its representatives. All Nasdaq fees associated with the Nasdaq Listing Application and the Nasdaq Reverse Split, if any (the "**Nasdaq Fees**") shall be borne by the Company. The Company will cooperate with Parent as reasonably requested by Parent with respect to the Nasdaq Listing Application and promptly furnish to Parent all information concerning the Company and its stockholders that may be required or reasonably requested in connection with any action contemplated by this [Section 5.8](#).

5.9 **Tax Matters.**

(a) For United States federal income Tax purposes, (i) the Parties desire that the Merger qualify as a "reorganization" within the meaning of Section 368(a) of the Code (the "**Intended Tax Treatment**"), and (ii) this Agreement is intended to be, and is hereby adopted as, a "plan of reorganization" for purposes of Section 354 and 361 of the Code and Treasury Regulations Section 1.368-2(g) and 1.368-3(a), to which the Parent, Merger Sub and the Company are parties under Section 368(b) of the Code.

(b) The Parties acknowledge and agree that each has relied upon the advice of its own tax advisors in connection with the Merger and the Contemplated Transactions and that none of Parent, Company and Merger Sub makes any representation or warranty as to the Intended Tax Treatment.

(c) The Parties shall use their respective commercially reasonable efforts to cause the Merger to qualify, and will not take any action or cause any action to be taken which action would reasonably be expected to prevent the Merger from qualifying, for the Intended Tax Treatment.

5.10 **Legends.** Parent shall be entitled to place appropriate legends on the book entries and/or certificates evidencing any shares of Parent Common Stock to be received in the Merger by equity holders of the Company

who may be considered “affiliates” of Parent for purposes of Rules 144 and 145 under the Securities Act reflecting the restrictions set forth in Rules 144 and 145 and to issue appropriate stop transfer instructions to the transfer agent for Parent Common Stock.

**5.11 Directors and Officers.**

(a) The Parties shall use reasonable best efforts and take all necessary action so that immediately after the Effective Time, (a) the Parent Board is comprised of seven members, with seven such members designated by the Company, (b) the Persons listed in **Exhibit C** under the heading “Officers” are elected or appointed, as applicable, to the positions of officers of Parent and the Surviving Corporation, as set forth therein, to serve in such positions effective as of the Effective Time until successors are duly appointed and qualified in accordance with applicable Law and (c) Persons reasonably acceptable to Parent are elected or appointed, as applicable to the positions of officer of Parent set forth on **Exhibit C**. If any Person listed in **Exhibit C** is unable or unwilling to serve as an officer of Parent or the Surviving Corporation, as set forth therein, as of the Effective Time, the Parties shall mutually agree upon a successor. The Persons listed in **Exhibit C** under the heading “Board Designees — Company” shall be the Company’s designees pursuant to clause (a) of this Section 5.11 (which list may be changed by the Company at any time prior to the Closing by written notice to Parent to include different board designees who are reasonably acceptable to Parent).

**5.12 Termination of Certain Agreements and Rights.** The Company shall cause any Investor Agreements (excluding the Company Stockholder Support Agreements and Company Lock-up Agreements) to be terminated immediately prior to the Effective Time, without any liability being imposed on the part of Parent or the Surviving Corporation.

**5.13 Section 16 Matters.** Prior to the Effective Time, Parent and the Company shall take all such steps as may be required (to the extent permitted under applicable Laws) to cause any acquisitions of Parent Common Stock and any options to purchase Parent Common Stock in connection with the Contemplated Transactions, by each individual who is reasonably expected to become subject to the reporting requirements of Section 16(a) of the Exchange Act with respect to Parent, to be exempt under Rule 16b-3 promulgated under the Exchange Act. At least 30 calendar days prior to the Closing Date, the Company shall furnish the following information to Parent for each individual who, immediately after the Effective Time, will become subject to the reporting requirements of Section 16(a) of the Exchange Act with respect to Parent: (a) the number of shares of Company Common Stock owned by such individual and expected to be exchanged for shares of Parent Common Stock pursuant to the Merger, and (b) the number of other derivative securities (if any) with respect to Company Common Stock owned by such individual and expected to be converted into shares of Parent Common Stock, restricted stock awards to purchase Parent Common Stock or derivative securities with respect to Parent Common Stock in connection with the Merger.

**5.14 Cooperation.** Each Party shall cooperate reasonably with the other Party and shall provide the other Party with such assistance as may be reasonably requested for the purpose of facilitating the performance by each Party of its respective obligations under this Agreement and to enable the combined entity to continue to meet its obligations following the Effective Time.

**5.15 Allocation Certificates.**

(a) The Company will prepare and deliver to Parent at least five Business Days prior to the Closing Date a certificate signed by the Chief Executive Officer of the Company in a form reasonably acceptable to Parent setting forth (as of immediately prior to the Effective Time) (i) each holder of Company Common Stock, Company Options, and Company Warrants; (ii) such holder’s name and address; (iii) the number and type of Company Common Stock held and/or underlying the Company Options, and Company Warrants as of the immediately prior to the Effective Time for each such holder; and (iv) the number of shares of Parent Common Stock to be issued to such holder, or to underlie any Company Option or Company Warrant to be issued to such

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holder, pursuant to this Agreement in respect of the Company Common Stock, Company Options or Company Warrants held by such holder as of immediately prior to the Effective Time (the “**Allocation Certificate**”).

(b) Parent will prepare and deliver to the Company at least five Business Days prior to the Closing Date a certificate signed by the Interim Chief Financial Officer or President of Parent in a form reasonably acceptable to the Company, setting forth, as of immediately prior to the Effective Time (after giving effect to the conversion of the Company Converting Notes and the exercise of any Company Warrants in connection or as a result of the Merger) (i) each record holder of Parent Common Stock, Parent Options, or Parent Warrants; (ii) such record holder’s name and address; and (iii) the number of shares of Parent Common Stock held and/or underlying the Parent Options, or Parent Warrants as of the Effective Time for such holder (the “**Parent Outstanding Shares Certificate**”).

5.16 **Company Financial Statements.** As promptly as reasonably practicable following the date of this Agreement (i) and no later than May 1, 2019 the Company will furnish to Parent audited financial statements for the fiscal years ended 2017 and 2018 for inclusion in the Proxy Statement and the Registration Statement (the “**Company Audited Financial Statements**”) and (ii) the Company will furnish to Parent unaudited interim financial statements for each interim period completed prior to Closing that would be required to be included in the Registration Statement or any periodic report due prior to the Closing if the Company were subject to the periodic reporting requirements under the Securities Act or the Exchange Act (the “**Company Interim Financial Statements**”). Each of the Company Audited Financial Statements and the Company Interim Financial Statements will be suitable for inclusion in the Proxy Statement and the Registration Statement and prepared in accordance with GAAP as applied on a consistent basis during the periods involved (except in each case as described in the notes thereto) and on that basis will present fairly, in all material respects, the financial position and the results of operations, changes in stockholders’ equity, and cash flows of the Company as of the dates of and for the periods referred to in the Company Audited Financial Statements or the Company Interim Financial Statements, as the case may be.

5.17 **Takeover Statutes.** If any Takeover Statute is or may become applicable to the Contemplated Transactions, each of the Company, the Company Board, Parent and the Parent Board, as applicable, shall grant such approvals and take such actions as are necessary so that the Contemplated Transactions may be consummated as promptly as practicable on the terms contemplated by this Agreement and otherwise act to eliminate or minimize the effects of such statute or regulation on the Contemplated Transactions.

5.18 **Stockholder Litigation.** Parent shall conduct and control the settlement and defense of any stockholder litigation against Parent or any of its directors relating to this Agreement or the Contemplated Transactions. Without limiting the foregoing, prior to the Closing, Parent shall give the Company the opportunity to consult with Parent in connection with the defense of, and obtain the Company’s written consent prior to the settlement of, any such stockholder litigation, and Parent shall keep the Company apprised of any material developments in connection with any such stockholder litigation.

### 5.19 **Parent Options.**

(a) Prior to the Closing, the Parent Board shall have adopted appropriate resolutions and taken all other actions necessary and appropriate to provide that each unexpired and unexercised Parent Option, whether vested or unvested, shall be cancelled effective as of immediately prior to the Effective Time in accordance with the Parent Stock Plans.

(b) Prior to the Closing, Parent shall take all actions that may be necessary (under the Parent Stock Plans and otherwise) to effectuate the provisions of this [Section 5.19](#).

5.20 **Company Lock-Up.** The Company shall use commercially reasonable efforts to obtain execution of a Lock-Up Agreement and a Support Agreement by no less than 75% of the Company stockholders.

## **Section 6. CONDITIONS PRECEDENT TO OBLIGATIONS OF EACH PARTY**

The obligations of each Party to effect the Merger and otherwise consummate the Contemplated Transactions to be consummated at the Closing are subject to the satisfaction or, to the extent permitted by applicable Law, the written waiver by each of the Parties, at or prior to the Closing, of each of the following conditions:

6.1 **Effectiveness of Registration Statement.** The Registration Statement shall have become effective in accordance with the provisions of the Securities Act, and shall not be subject to any stop order or proceeding (or threatened proceeding by the SEC) seeking a stop order with respect to the Registration Statement that has not been withdrawn.

6.2 **No Restraints.** No temporary restraining order, preliminary or permanent injunction or other order preventing the consummation of the Contemplated Transactions shall have been issued by any court of competent jurisdiction or other Governmental Body of competent jurisdiction and remain in effect and there shall not be any Law which has the effect of making the consummation of the Contemplated Transactions illegal.

6.3 **Stockholder Approval.** (a) Parent shall have obtained the Required Parent Stockholder Vote and (b) the Company shall have obtained the Required Company Stockholder Vote.

6.4 **Listing.** The existing shares of Parent Common Stock shall have been continually listed on Nasdaq as of and from the date of this Agreement through the Closing Date, the approval of the listing of additional shares of Parent Common Stock on Nasdaq shall have been obtained and the shares of Parent Common Stock to be issued in the Merger pursuant to this Agreement shall have been approved for listing (subject to official notice of issuance) on Nasdaq as of the Closing.

## **Section 7. ADDITIONAL CONDITIONS PRECEDENT TO OBLIGATIONS OF PARENT AND MERGER SUB**

The obligations of Parent and Merger Sub to effect the Merger and otherwise consummate the transactions to be consummated at the Closing are subject to the satisfaction or the written waiver by Parent, at or prior to the Closing, of each of the following conditions:

7.1 **Accuracy of Representations.** The representations and warranties of the Company contained in this Agreement shall have been true and correct as of the date of this Agreement and shall be true and correct on and as of the Closing Date with the same force and effect as if made on the Closing Date except (a) in each case, or in the aggregate, where the failure to be true and correct would not reasonably be expected to have a Company Material Adverse Effect (without giving effect to any references therein to any Company Material Adverse Effect or other materiality qualifications), or (b) for those representations and warranties which address matters only as of a particular date (which representations shall have been true and correct, subject to the qualifications as set forth in the preceding clause (a), as of such particular date) (it being understood that, for purposes of determining the accuracy of such representations and warranties, any update of or modification to the Company Disclosure Schedule made or purported to have been made after the date of this Agreement shall be disregarded).

7.2 **Performance of Covenants.** The Company shall have performed or complied with in all material respects all agreements and covenants required to be performed or complied with by it under this Agreement at or prior to the Effective Time.

7.3 **Documents.** Parent shall have received the following documents, each of which shall be in full force and effect:

(a) a certificate executed by the Chief Executive Officer of the Company certifying (i) that the conditions set forth in [Sections 7.1, 7.2, 7.5, and 7.6](#) have been duly satisfied and (ii) that the information set forth in the Allocation Certificate delivered by the Company in accordance with [Section 5.15](#) is true and accurate in all respects as of the Closing Date; and

(b) the Allocation Certificate.

7.4 **FIRPTA Certificate.** Parent shall have received (i) an original signed statement from the Company that the Company is not, and has not been at any time during the applicable period specified in Section 897(c)(1)(A)(ii) of the Code, a “United States real property holding corporation,” as defined in Section 897(c)(2) of the Code, conforming to the requirements of Treasury Regulations Section 1.1445-2(c)(3) and 1.897-2(h), and (ii) an original signed notice to be delivered to the IRS in accordance with the provisions of Treasury Regulations Section 1.897-2(h)(2), together with written authorization for Parent to deliver such notice to the IRS on behalf of the Company following the Closing, each dated as of the Closing Date, duly executed by an authorized officer of the Company, and in form and substance reasonably acceptable to Parent.

7.5 **No Company Material Adverse Effect.** Since the date of this Agreement, there shall not have occurred any Company Material Adverse Effect that is continuing.

7.6 **Termination of Investor Agreements.** The Investor Agreements shall have been terminated.

7.7 **Company Lock-Up Agreements.** Parent shall have received the Company Lock-Up Agreements duly executed by each of the Company Signatories and each stockholder of the Company expected to own more than 5% of the outstanding Parent Common Stock after the Closing.

7.8 **Company Stockholder Written Consent.** The Company Stockholder Written Consent evidencing the Required Company Stockholder Vote shall be in full force and effect.

7.9 **Dissenting Shares.** No more than 10% of the Company Common Stock shall be Dissenting Shares.

## **Section 8. ADDITIONAL CONDITIONS PRECEDENT TO OBLIGATION OF THE COMPANY**

The obligations of the Company to effect the Merger and otherwise consummate the transactions to be consummated at the Closing are subject to the satisfaction or the written waiver by the Company, at or prior to the Closing, of each of the following conditions:

8.1 **Accuracy of Representations.** The representations and warranties of Parent and Merger Sub contained in this Agreement shall have been true and correct as of the date of this Agreement and shall be true and correct on and as of the Closing Date with the same force and effect as if made on the Closing Date except (a) in each case, or in the aggregate, where the failure to be true and correct would not reasonably be expected to have a Parent Material Adverse Effect (without giving effect to any references therein to any Parent Material Adverse Effect or other materiality qualifications), or (b) for those representations and warranties which address matters only as of a particular date (which representations shall have been true and correct, subject to the qualifications as set forth in the preceding clause (a), as of such particular date) (it being understood that, for purposes of determining the accuracy of such representations and warranties, any update of or modification to the Parent Disclosure Schedule made or purported to have been made after the date of this Agreement shall be disregarded).

8.2 **Performance of Covenants.** Parent and Merger Sub shall have performed or complied with in all material respects all of their agreements and covenants required to be performed or complied with by each of them under this Agreement at or prior to the Effective Time.

8.3 **Documents.** The Company shall have received the following documents, each of which shall be in full force and effect:

(a) a certificate executed by the President or Interim Chief Financial Officer of Parent (i) confirming that the conditions set forth in [Sections 8.1, 8.2, and 8.4](#) have been duly satisfied and (ii) certifying as to the Divestiture Transactions, including that the transactions contemplated thereby are anticipated to be consummated concurrently with the Closing and as to the amount of aggregate proceeds thereof.



(b) the Parent Outstanding Shares Certificate; and

(c) a written resignation, in a form reasonably satisfactory to the Company, dated as of the Closing Date and effective as of the Closing, executed by each of the officers and directors of Parent who are not to continue as officers or directors of Parent after the Closing pursuant to [Section 5.11](#) hereof.

8.4 **No Parent Material Adverse Effect.** Since the date of this Agreement, there shall not have occurred any Parent Material Adverse Effect.

8.5 **Parent Lock-Up Agreements.** The Company shall have received the Parent Lock-Up Agreements duly executed by each of the Parent Signatories, each of which shall be in full force and effect.

8.6 **Board of Directors.** Parent shall have caused the Parent Board to be constituted as set forth in [Section 5.11](#) of this Agreement effective as of the Effective Time.

## Section 9. TERMINATION

9.1 **Termination.** This Agreement may be terminated prior to the Effective Time (whether before or after adoption of this Agreement by the Company's stockholders and whether before or after approval of the Parent Stockholder Matters by Parent's stockholders, unless otherwise specified below):

(a) by mutual written consent of Parent and the Company;

(b) by either Parent or the Company if the Contemplated Transactions shall not have been consummated by July 31, 2019 (subject to possible extension as provided in this [Section 9.1\(b\)](#), the "**End Date**"); *provided, however*, that the right to terminate this Agreement under this [Section 9.1\(b\)](#) shall not be available to the Company, on the one hand, or to Parent, on the other hand, if such Party's action or failure to act has been a principal cause of the failure of the Contemplated Transactions to occur on or before the End Date and such action or failure to act constitutes a breach of this Agreement, *provided, further, however*, that, in the event that a request for additional information has been made by any Governmental Body, or in the event that the SEC has not declared effective under the Exchange Act the Registration Statement by the date which is 60 days prior to the End Date, then either the Company or Parent shall be entitled to extend the End Date for an additional 60 days by written notice to the other the Party; *provided, further, however*, that, in the event an adjournment or postponement of the Parent Stockholders' Meeting has occurred as permitted pursuant to [Section 5.3\(b\)](#) and such adjournment or postponement continues through the End Date, then the End Date shall automatically extend until the date that is 10 calendar days following such adjournment or postponement, or, in the event of an additional permitted adjournment or postponement, the date that is 10 calendar days following such permitted adjournment or postponement;

(c) by either Parent or the Company if a court of competent jurisdiction or other Governmental Body shall have issued a final and nonappealable order, decree or ruling, or shall have taken any other action, having the effect of permanently restraining, enjoining or otherwise prohibiting the Contemplated Transactions;

(d) by Parent if the Company Stockholder Written Consent evidencing the Required Company Stockholder Vote shall not have been obtained within the later of (i) 15 Business Days of the Registration Statement becoming effective in accordance with the provisions of the Securities Act and (ii) the date on which Parent obtains the Required Parent Stockholder Vote; *provided, however*, that once the Company Stockholder Written Consent evidencing the Required Company Stockholder Vote has been obtained, Parent may not terminate this Agreement pursuant to this [Section 9.1\(d\)](#);

(e) by either Parent or the Company if (i) the Parent Stockholders' Meeting (including, if applicable, following two adjournments or postponements thereof as permitted pursuant to [Section 5.3\(b\)](#)) shall have been

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held and completed and Parent's stockholders shall have taken a final vote on the Parent Stockholder Matters and (ii) the Parent Stockholder Matters shall not have been approved at the Parent Stockholders' Meeting (or at any adjournment or postponement thereof) by the Required Parent Stockholder Vote *provided, however*, that the right to terminate this Agreement under this Section 9.1(e) shall not be available to Parent where the failure to obtain the Required Parent Stockholder Vote has been caused by the action or failure to act of Parent or Merger Sub and such action or failure to act constitutes a material breach by Parent or Merger Sub of this Agreement;

(f) by the Company (at any time prior to the approval of the Parent Stockholder Matters by the Required Parent Stockholder Vote) if a Parent Triggering Event shall have occurred;

(g) by Parent (at any time prior to the Required Company Stockholder Vote being obtained) if a Company Triggering Event shall have occurred;

(h) by the Company, upon a breach of any representation, warranty, covenant or agreement set forth in this Agreement by Parent or Merger Sub or if any representation or warranty of Parent or Merger Sub shall have become inaccurate, in either case, such that the conditions set forth in Section 8.1 or Section 8.2 would not be satisfied as of the time of such breach or as of the time such representation or warranty shall have become inaccurate; *provided* that the Company is not then in material breach of any representation, warranty, covenant or agreement under this Agreement; *provided, further*, that if such inaccuracy in Parent's or Merger Sub's representations and warranties or breach by Parent or Merger Sub is curable by the End Date by Parent or Merger Sub, then this Agreement shall not terminate pursuant to this Section 9.1(h) as a result of such particular breach or inaccuracy until the expiration of a 15-day period commencing upon delivery of written notice from the Company to Parent or Merger Sub of such breach or inaccuracy and its intention to terminate pursuant to this Section 9.1(h) (it being understood that this Agreement shall not terminate pursuant to this Section 9.1(h) as a result of such particular breach or inaccuracy if such breach by Parent or Merger Sub is cured prior to such termination becoming effective); or

(i) by Parent, upon a breach of any representation, warranty, covenant or agreement set forth in this Agreement by the Company or if any representation or warranty of the Company shall have become inaccurate, in either case, such that the conditions set forth in Section 7.1 or Section 7.2 would not be satisfied as of the time of such breach or as of the time such representation or warranty shall have become inaccurate; *provided* that Parent is not then in material breach of any representation, warranty, covenant or agreement under this Agreement; *provided, further*, that if such inaccuracy in the Company's representations and warranties or breach by the Company is curable by the End Date by the Company then this Agreement shall not terminate pursuant to this Section 9.1(i) as a result of such particular breach or inaccuracy until the expiration of a 15-day period commencing upon delivery of written notice from Parent to the Company of such breach or inaccuracy and its intention to terminate pursuant to this Section 9.1(i) (it being understood that this Agreement shall not terminate pursuant to this Section 9.1(i) as a result of such particular breach or inaccuracy if such breach by the Company is cured prior to such termination becoming effective).

**9.2 Effect of Termination.** In the event of the termination of this Agreement as provided in Section 9.1(i), this Agreement shall be of no further force or effect; *provided, however*, that (a) this Section 9.2, Section 5.7, Section 9.3, Section 10 and the definitions of the defined terms in such Sections shall survive the termination of this Agreement and shall remain in full force and effect, and (b) the termination of this Agreement and the provisions of Section 9.3 shall not relieve any Party of any liability for fraud or for any willful and material breach of any representation, warranty, covenant, obligation or other provision contained in this Agreement.

### **9.3 Expenses; Termination Fees.**

(a) Except as set forth in this Section 9.3, whether or not the Merger is consummated, (i) all Parent Transaction Expenses shall be paid by Parent (or on behalf of Parent) at or prior to the Closing and (ii) all Company Transaction Expenses shall be paid by the Company.

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(b) If (i) this Agreement is terminated by the Company pursuant to Section 9.1(f), and (ii) an Acquisition Proposal with respect to Parent shall have been publicly announced or disclosed or otherwise communicated to Parent or the Parent Board after the date of this Agreement but prior to the termination of this Agreement, and (iii) within 12 months after the date of such termination, Parent enters into a definitive agreement with respect to any Subsequent Transaction, then Parent shall pay to the Company an amount equal to \$600,000, within five Business Days of such entry into a definitive agreement with respect to a Subsequent Transaction.

(c) If (i) this Agreement is terminated by Parent pursuant to Section 9.1(g), and (ii) an Acquisition Proposal with respect to the Company shall have been publicly announced or disclosed or otherwise communicated to the Company or the Company Board after the date of this Agreement but prior to the termination of this Agreement, and (iii) within 12 months after the date of such termination, the Company enters into a definitive agreement with respect to any Subsequent Transaction, then the Company shall pay to Parent an amount equal to \$700,000 within five Business Days of such entry into a definitive agreement with respect to a Subsequent Transaction.

(d) If this Agreement is terminated (i) by Parent pursuant to Section 9.1(d), or (ii) by the Company pursuant to Section 9.1(b) and the Company Stockholder Written Consent evidencing the Required Company Stockholder Vote has not been obtained by the Company, then the Company shall pay to Parent within five Business Days of such termination an amount equal to Parent's documented out-of-pocket expenses incurred in connection with this Agreement and the Contemplated Transactions up to an aggregate of \$300,000.

(e) If (i) this Agreement is terminated by either Parent or the Company pursuant to Section 9.1(e), or (ii) by Parent pursuant to Section 9.1(b) and the Required Parent Stockholder Vote has not been obtained by Parent, then Parent shall pay to the Company within five Business Days of such termination an amount equal to the Company's documented out-of-pocket expenses incurred in connection with this Agreement and the Contemplated Transactions up to an aggregate of \$300,000.

(f) If this Agreement is terminated (i) by the Company pursuant to Section 9.1(h), then Parent shall pay to the Company an amount equal to the Company's documented out-of-pocket expenses incurred in connection with this Agreement and the Contemplated Transactions up to an aggregate of \$300,000 within five Business Days of terminating this Agreement, (ii) by Parent pursuant to Section 9.1(i), then the Company shall pay to Parent an amount equal to Parent's documented out-of-pocket expenses incurred in connection with this Agreement and the Contemplated Transactions up to an aggregate of \$300,000 within five Business Days of terminating this Agreement.

(g) Any fee payable by the Company or Parent under Section 9.2 or this Section 9.3 shall be promptly paid within one Business Day by wire transfer pursuant to written instructions provided by the Party being paid. If a Party fails to pay when due any amount payable by it under Section 9.2 or this Section 9.3, then such Party shall pay to the other Party interest on such overdue amount (for the period commencing as of the date such overdue amount was originally required to be paid and ending on the date such overdue amount is actually paid to the other Party in full) at a rate per annum equal to the "prime rate" (as published in *The Wall Street Journal* or any successor thereto) in effect on the date such overdue amount was originally required to be paid.

(h) The Parties agree that, (i) subject to Section 9.2, any fee payable by Parent to the Company under this Section 9.3, in the circumstances in which it is owed in accordance with the terms of this Agreement, constitute the sole and exclusive remedy of the Company following the termination of this Agreement under the circumstances described in this Section 9.3, it being understood that in no event shall Parent be required to pay the amounts payable pursuant to this Section 9.3 on more than one occasion and (ii) following payment of any fee payable by Parent to the Company under this Section 9.3 (A) Parent shall have no further liability to the Company in connection with or arising out of this Agreement or the termination thereof, any breach of this Agreement by Parent giving rise to such termination, or the failure of the Contemplated Transactions to be

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consummated, (B) neither the Company nor any of its Affiliates shall be entitled to bring or maintain any other claim, action or proceeding against Parent or Merger Sub or seek to obtain any recovery, judgment or damages of any kind against such Parties (or any partner, member, stockholder, director, officer, employee, Subsidiary, Affiliate, agent or other Representative of such Parties) in connection with or arising out of this Agreement or the termination thereof, any breach by any such Parties giving rise to such termination or the failure of the Contemplated Transactions to be consummated and (C) the Company and its Affiliates shall be precluded from any other remedy against Parent, Merger Sub and their respective Affiliates, at law or in equity or otherwise, in connection with or arising out of this Agreement or the termination thereof, any breach by such Party giving rise to such termination or the failure of the Contemplated Transactions to be consummated; *provided, however*, that nothing in this [Section 9.3\(h\)](#) shall limit the rights of Parent and Merger Sub under [Section 10.11](#).

(i) The Parties agree that, (i) subject to [Section 9.2](#), any fee payable by the Company to Parent under this [Section 9.3](#) shall, in the circumstances in which it is owed in accordance with the terms of this Agreement, constitute the sole and exclusive remedy of Parent following the termination of this Agreement under the circumstances described in this [Section 9.3](#), it being understood that in no event shall the Company be required to pay the amounts payable pursuant to this [Section 9.3](#) on more than one occasion and (ii) following payment of any fee payable by the Company to Parent under this [Section 9.3](#) (A) the Company shall have no further liability to Parent in connection with or arising out of this Agreement or the termination thereof, any breach of this Agreement by the Company giving rise to such termination, or the failure of the Contemplated Transactions to be consummated, (B) neither Parent nor any of its Affiliates shall be entitled to bring or maintain any other claim, action or proceeding against the Company or seek to obtain any recovery, judgment or damages of any kind against such Parties (or any partner, member, stockholder, director, officer, employee, Subsidiary, Affiliate, agent or other Representative of such Parties) in connection with or arising out of this Agreement or the termination thereof, any breach by any such Parties giving rise to such termination or the failure of the Contemplated Transactions to be consummated and (C) Parent and its Affiliates shall be precluded from any other remedy against the Company and its Affiliates, at law or in equity or otherwise, in connection with or arising out of this Agreement or the termination thereof, any breach by such Party giving rise to such termination or the failure of the Contemplated Transactions to be consummated; *provided, however*, that nothing in this [Section 9.3\(i\)](#) shall limit the rights of the Company under [Section 10.11](#).

(j) Each of the Parties acknowledges that (i) the agreements contained in this [Section 9.3](#) are an integral part of the Contemplated Transactions, (ii) without these agreements, the Parties would not enter into this Agreement and (iii) any amount payable pursuant to this [Section 9.3](#) is not a penalty, but rather is liquidated damages in a reasonable amount that will compensate the Company in the circumstances in which such amount is payable.

## **Section 10. MISCELLANEOUS PROVISIONS**

**10.1 Non-Survival of Representations and Warranties.** The representations and warranties of the Company, Parent and Merger Sub contained in this Agreement or any certificate or instrument delivered pursuant to this Agreement shall terminate at the Effective Time, and only the covenants that by their terms survive the Effective Time and this [Section 10](#) shall survive the Effective Time.

**10.2 Amendment.** This Agreement may be amended with the approval of the respective boards of directors of the Company, Merger Sub and Parent at any time (whether before or after the adoption and approval of this Agreement by the Company's stockholders or before or after obtaining the Required Parent Stockholder Vote); *provided, however*, that after any such approval of this Agreement by a Party's stockholders, no amendment shall be made which by Law requires further approval of such stockholders without the further approval of such stockholders. This Agreement may not be amended except by an instrument in writing signed on behalf of each of the Company, Merger Sub and Parent.

**10.3 Waiver.**

(a) No failure on the part of any Party to exercise any power, right, privilege or remedy under this Agreement, and no delay on the part of any Party in exercising any power, right, privilege or remedy under this Agreement, shall operate as a waiver of such power, right, privilege or remedy; and no single or partial exercise of any such power, right, privilege or remedy shall preclude any other or further exercise thereof or of any other power, right, privilege or remedy.

(b) No Party shall be deemed to have waived any claim arising out of this Agreement, or any power, right, privilege or remedy under this Agreement, unless the waiver of such claim, power, right, privilege or remedy is expressly set forth in a written instrument duly executed and delivered on behalf of such Party and any such waiver shall not be applicable or have any effect except in the specific instance in which it is given.

**10.4 Entire Agreement; Counterparts; Exchanges by Electronic Transmission.** This Agreement and the other agreements referred to in this Agreement constitute the entire agreement and supersede all prior agreements and understandings, both written and oral, among or between any of the Parties with respect to the subject matter hereof and thereof; provided, however, that the Confidentiality Agreement shall not be superseded and shall remain in full force and effect in accordance with its terms. This Agreement may be executed in several counterparts, each of which shall be deemed an original and all of which shall constitute one and the same instrument. The exchange of a fully executed Agreement (in counterparts or otherwise) by all Parties by electronic transmission in .PDF format shall be sufficient to bind the Parties to the terms and conditions of this Agreement.

**10.5 Applicable Law; Jurisdiction.** This Agreement shall be governed by, and construed in accordance with, the Laws of the State of Delaware, regardless of the Laws that might otherwise govern under applicable principles of conflicts of laws. In any action or proceeding between any of the Parties arising out of or relating to this Agreement or any of the Contemplated Transactions, each of the Parties: (a) irrevocably and unconditionally consents and submits to the exclusive jurisdiction and venue of the Court of Chancery of the State of Delaware or, to the extent such court does not have subject matter jurisdiction, the United States District Court for the District of Delaware or, to the extent that neither of the foregoing courts has jurisdiction, the Superior Court of the State of Delaware; (b) agrees that all claims in respect of such action or proceeding shall be heard and determined exclusively in accordance with clause (a) of this [Section 10.5](#); (c) waives any objection to laying venue in any such action or proceeding in such courts; (d) waives any objection that such courts are an inconvenient forum or do not have jurisdiction over any Party; (e) agrees that service of process upon such Party in any such action or proceeding shall be effective if notice is given in accordance with [Section 10.8](#) of this Agreement; and (f) irrevocably and unconditionally waives the right to trial by jury.

**10.6 Attorneys' Fees.** In any action at law or suit in equity to enforce this Agreement or the rights of any of the Parties, the prevailing Party in such action or suit (as determined by a court of competent jurisdiction) shall be entitled to recover its reasonable out-of-pocket attorneys' fees and all other reasonable costs and expenses incurred in such action or suit.

**10.7 Assignability.** This Agreement shall be binding upon, and shall be enforceable by and inure solely to the benefit of, the Parties and their respective successors and permitted assigns; provided, however, that neither this Agreement nor any of a Party's rights or obligations hereunder may be assigned or delegated by such Party without the prior written consent of the other Party, and any attempted assignment or delegation of this Agreement or any of such rights or obligations by such Party without the other Party's prior written consent shall be void and of no effect.

**10.8 Notices.** All notices and other communications hereunder shall be in writing and shall be deemed to have been duly delivered and received hereunder (a) one Business Day after being sent for next Business Day delivery, fees prepaid, via a reputable international overnight courier service, (b) upon delivery in the case of

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delivery by hand, or (c) on the date delivered in the place of delivery if sent by email (with a written or electronic confirmation of delivery) prior to 5:00 p.m. New York time, otherwise on the next succeeding Business Day, in each case to the intended recipient as set forth below:

if to Parent or Merger Sub:

Histogenics Corporation  
830 Winter Street, 3<sup>rd</sup> Floor  
Waltham, Massachusetts  
Attention: President  
Email: agridley@histogenics.com

with a copy (which shall not constitute notice) to:

Gunderson Dettmer Stough Villeneuve Franklin & Hachigian, LLP  
One Marina Park Drive, Suite 900  
Boston, Massachusetts 02210  
Attention: Marc F. Dupré and Albert W. Vanderlaan  
Email: mdupre@gunder.com; avanderlaan@gunder.com

if to the Company:

Ocugen, Inc.  
5 Great Valley Parkway, Suite # 160  
Malvern, Pennsylvania 19355  
Attention: Shankar Musunuri  
Email: shankar.musunuri@ocugen.com

with a copy (which shall not constitute notice) to:

Morgan, Lewis & Bockius LLP  
1701 Market Street  
Philadelphia, Pennsylvania 19103  
Attention: Stephen A. Jannetta  
Email: stephen.jannetta@morganlewis.com

**10.9 Cooperation.** Each Party agrees to cooperate fully with the other Party and to execute and deliver such further documents, certificates, agreements and instruments and to take such other actions as may be reasonably requested by the other Party to evidence or reflect the Contemplated Transactions and to carry out the intent and purposes of this Agreement.

**10.10 Severability.** Any term or provision of this Agreement that is invalid or unenforceable in any situation in any jurisdiction shall not affect the validity or enforceability of the remaining terms and provisions of this Agreement or the validity or enforceability of the offending term or provision in any other situation or in any other jurisdiction. If a final judgment of a court of competent jurisdiction declares that any term or provision of this Agreement is invalid or unenforceable, the Parties agree that the court making such determination shall have the power to limit such term or provision, to delete specific words or phrases or to replace such term or provision with a term or provision that is valid and enforceable and that comes closest to expressing the intention of the invalid or unenforceable term or provision, and this Agreement shall be valid and enforceable as so modified. In the event such court does not exercise the power granted to it in the prior sentence, the Parties agree to replace such invalid or unenforceable term or provision with a valid and enforceable term or provision that will achieve, to the extent possible, the economic, business and other purposes of such invalid or unenforceable term or provision.

**10.11 Other Remedies; Specific Performance.** Except as otherwise provided herein, any and all remedies herein expressly conferred upon a Party will be deemed cumulative with and not exclusive of any other remedy conferred hereby, or by law or equity upon such Party, and the exercise by a Party of any one remedy

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will not preclude the exercise of any other remedy. The Parties agree that irreparable damage for which monetary damages, even if available, would not be an adequate remedy, would occur in the event that any Party does not perform the provisions of this Agreement (including failing to take such actions as are required of it hereunder to consummate this Agreement) in accordance with its specified terms or otherwise breaches such provisions. Accordingly, the Parties acknowledge and agree that the Parties shall be entitled to an injunction, specific performance and other equitable relief to prevent breaches of this Agreement and to enforce specifically the terms and provisions hereof, in addition to any other remedy to which they are entitled at law or in equity. Each of the Parties agrees that it will not oppose the granting of an injunction, specific performance or other equitable relief on the basis that any other Party has an adequate remedy at law or that any award of specific performance is not an appropriate remedy for any reason at law or in equity. Any Party seeking an injunction or injunctions to prevent breaches of this Agreement shall not be required to provide any bond or other security in connection with any such order or injunction.

10.12 **No Third Party Beneficiaries.** Nothing in this Agreement, express or implied, is intended to or shall confer upon any Person (other than the Parties and the D&O Indemnified Parties to the extent of their respective rights pursuant to [Section 5.5](#)) any right, benefit or remedy of any nature whatsoever under or by reason of this Agreement.

### 10.13 **Construction.**

(a) References to “cash,” “dollars” or “\$” are to U.S. dollars.

(b) For purposes of this Agreement, whenever the context requires: the singular number shall include the plural, and vice versa; the masculine gender shall include the feminine and neuter genders; the feminine gender shall include the masculine and neuter genders; and the neuter gender shall include masculine and feminine genders.

(c) The Parties have participated jointly in the negotiating and drafting of this Agreement and agree that any rule of construction to the effect that ambiguities are to be resolved against the drafting Party shall not be applied in the construction or interpretation of this Agreement, and no presumption or burden of proof shall arise favoring or disfavoring any Party by virtue of the authorship of any provision of this Agreement.

(d) As used in this Agreement, the words “include” and “including,” and variations thereof, shall not be deemed to be terms of limitation, but rather shall be deemed to be followed by the words “without limitation.”

(e) Except as otherwise indicated, all references in this Agreement to “Sections,” “Exhibits” and “Schedules” are intended to refer to Sections of this Agreement and Exhibits and Schedules to this Agreement, respectively.

(f) Any reference to legislation or to any provision of any legislation shall include any modification, amendment, re-enactment thereof, any legislative provision substituted therefore and all rules, regulations, and statutory instruments issued or related to such legislations.

(g) The bold-faced headings and table of contents contained in this Agreement are for convenience of reference only, shall not be deemed to be a part of this Agreement and shall not be referred to in connection with the construction or interpretation of this Agreement.

(h) The Parties agree that each of the Company Disclosure Schedule and the Parent Disclosure Schedule shall be arranged in sections and subsections corresponding to the numbered and lettered sections and subsections contained in this Agreement. The disclosures in any section or subsection of the Company Disclosure Schedule or the Parent Disclosure Schedule shall qualify other sections and subsections in this Agreement to the extent it is readily apparent on its face from a reading of the disclosure that such disclosure is applicable to such other sections and subsections.

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(i) Each of “delivered” or “made available” means, with respect to any documentation, that prior to 11:59 p.m. (New York time) on the date that is two Business Days prior to the date of this Agreement (i) a copy of such material has been posted to and made available by a Party to the other Party and its Representatives in the electronic data room maintained by such disclosing Party or (ii) such material is disclosed in the Parent SEC Documents filed with the SEC prior to the date hereof and publicly made available on the SEC’s Electronic Data Gathering Analysis and Retrieval system.

(j) Whenever the last day for the exercise of any privilege or the discharge of any duty hereunder shall fall upon a Saturday, Sunday, or any date on which banks in New York, New York are authorized or obligated by Law to be closed, the Party having such privilege or duty may exercise such privilege or discharge such duty on the next succeeding day which is a regular Business Day.

*(Remainder of page intentionally left blank)*









**EXHIBIT A**

**CERTAIN DEFINITIONS**

(a) For purposes of this Agreement (including this **Exhibit A**):

**“Acquisition Inquiry”** means, with respect to a Party, an inquiry, indication of interest or request for information (other than an inquiry, indication of interest or request for information made or submitted by the Company or any of its Affiliates, on the one hand, or Parent or any of its Affiliates, on the other hand, to the other Party) that would reasonably be expected to lead to an Acquisition Proposal.

**“Acquisition Proposal”** means, with respect to a Party, any offer or proposal, whether written or oral (other than an offer or proposal made or submitted by or on behalf of the Company or any of its Affiliates, on the one hand, or by or on behalf of Parent or any of its Affiliates, on the other hand, to the other Party) contemplating or otherwise relating to any Acquisition Transaction with such Party.

**“Acquisition Transaction”** means any transaction or series of related transactions involving:

(i) any merger, consolidation, amalgamation, share exchange, business combination, issuance of securities, acquisition of securities, reorganization, recapitalization, tender offer, exchange offer or other similar transaction: (i) in which a Party is a constituent entity; (ii) in which a Person or “group” (as defined in the Exchange Act and the rules promulgated thereunder) of Persons directly or indirectly acquires beneficial or record ownership of securities representing more than 20% of the outstanding securities of any class of voting securities of a Party or any of its Subsidiaries; or (iii) in which a Party or any of its Subsidiaries issues securities representing more than 20% of the outstanding securities of any class of voting securities of such Party or any of its Subsidiaries; or

(ii) any sale, lease, exchange, transfer, license, acquisition or disposition of any business or businesses or assets that constitute or account for 20% or more of the consolidated book value or the fair market value of the assets of a Party and its Subsidiaries, taken as a whole (excluding any Divestiture Transaction).

**“Affiliate”** of a Person means any other Person that directly or indirectly, through one or more intermediaries, controls, is controlled by, or is under common control with, such Person. The term “control” (including the terms “controlled by” and “under common control with”) means the possession, directly or indirectly, of the power to direct or cause the direction of the management and policies of a Person, whether through the ownership of voting securities, by contract or otherwise.

**“Agreement”** means the Agreement and Plan of Merger and Reorganization to which this **Exhibit A** is attached, as it may be amended from time to time.

**“Business Day”** means any day other than a Saturday, Sunday or other day on which banks in New York, New York are authorized or obligated by Law to be closed.

**“Cash and Cash Equivalents”** means all (a) cash and cash equivalents (excluding Restricted Cash) and (b) marketable securities, in each case determined in accordance with GAAP, consistently applied.

**“Code”** means the Internal Revenue Code of 1986, as amended.

**“Company Affiliate”** means any Person that is (or at any relevant time was) under common control with the Company or its Subsidiaries within the meaning of Sections 414(b), (c), (m) and (o) of the Code, and the regulations issued thereunder.

**“Company Associate”** means any current or former employee, independent contractor, officer or director of the Company or its Subsidiaries.

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“**Company Board**” means the board of directors of the Company.

“**Company Capital Stock**” means the Company Common Stock.

“**Company Change in Circumstance**” means a change in circumstances (other than an Acquisition Proposal) that affects the business, assets or operations of the Company and its Subsidiaries (taken as a whole) that occurs or arises after the date of this Agreement.

“**Company Common Stock**” means the Common Stock, \$0.0001 par value per share, of the Company.

“**Company Continuing Notes**” means those promissory notes issued by the Company which shall remain outstanding following the Effective Time.

“**Company Converting Notes**” means those promissory notes issued by the Company which shall be converted or exercised into Company Common Stock prior to the Effective Time.

“**Company Contract**” means any Contract: (a) to which the Company or any of its Subsidiaries is a Party; (b) by which the Company or any of its Subsidiaries or any Company IP or any other asset of the Company or its Subsidiaries is or may become bound or under which the Company or any of its Subsidiaries has, or may become subject to, any obligation; or (c) under which the Company or any of its Subsidiaries has or may acquire any right or interest.

“**Company ERISA Affiliate**” means any corporation or trade or business (whether or not incorporated) which is (or at any relevant time was) treated with the Company or any of its Subsidiaries as a single employer within the meaning of Section 414 of the Code.

“**Company IP**” means all Intellectual Property Rights that are owned or purported to be owned by, assigned to, or licensed by, the Company or its Subsidiaries.

“**Company Material Adverse Effect**” means any Effect that, considered together with all other Effects that have occurred prior to the date of determination of the occurrence of a Company Material Adverse Effect, has or would reasonably be expected to have a material adverse effect on the business, financial condition, assets, liabilities or results of operations of the Company or its Subsidiaries, taken as a whole; *provided, however*, that Effects arising or resulting from the following shall not be taken into account in determining whether there has been a Company Material Adverse Effect: (a) general business, economic or political conditions affecting the industry in which the Company and its Subsidiaries operate, (b) any natural disaster or any acts of war, armed hostilities or terrorism, (c) changes in financial, banking or securities markets, (d) the failure of the Company to meet internal or analysts’ expectations or projections or the results of operations of the Company, (e) any clinical trial programs or studies, including any adverse data, event or outcome arising out of or relating to any such programs or studies, (f) any change in, or any compliance with or action taken for the purpose of complying with, any Law or GAAP (or interpretations of any Law or GAAP), (g) resulting from the announcement of this Agreement or the pendency of the Contemplated Transactions, or (h) resulting from the taking of any action, or the failure to take any action, by the Company that is required to be taken by this Agreement; except in each case with respect to clauses (a) through (c), to the extent disproportionately affecting the Company and its Subsidiaries, taken as a whole, relative to other similarly situated companies in the industries in which the Company and its Subsidiaries operate.

“**Company Options**” means options or other rights to purchase shares of Company Common Stock issued by the Company.

“**Company Plans**” means the Ocugen, Inc. 2014 Stock Option Plan.

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**“Company Transaction Expenses”** means all fees and expenses incurred by the Company at or prior to the Effective Time in connection with the Contemplated Transactions and this Agreement, including (a) any fees and expenses of legal counsel and accountants, the maximum amount of fees and expenses payable to financial advisors, investment bankers, brokers, consultants, and other advisors of the Company, including, without limitation, for preparation of the Registration Statement, Proxy Statement, and any amendments and supplements thereto, preparing responses to any SEC comments, and drafting any charter amendments (and in each case, the related disclosure required in the Registration Statement and Proxy Statement); (b) 50% of (i) the fees paid to the SEC in connection with filing the Registration Statement, the Proxy Statement, and any amendments and supplements thereto with the SEC; (ii) the fees and expenses paid or payable to the Exchange Agent pursuant to the engagement agreement with the Exchange Agent; and (iii) any fees and expenses incurred by Broadridge Corporate Issuer Solutions, Inc., Parent’s transfer agent, and Innisfree M&A Incorporated, the proxy solicitor, in connection with the filing and distribution of the Registration Statement and any amendments and supplements thereto with the SEC (without duplication of the fees and expenses addressed in clause (b)(i) above); and (c) 100% of the Nasdaq Fees.

**“Company Triggering Event”** shall be deemed to have occurred if: (a) the Company shall have made a Company Board Adverse Recommendation Change; (b) the Company Board or any committee thereof shall have publicly approved, endorsed or recommended any Acquisition Proposal; (c) the Company shall have entered into any letter of intent or similar document relating to any Acquisition Proposal; or (d) the Company, or any director or officer of the Company, shall have willfully and intentionally breached the provisions set forth in Section 4.5.

**“Company Unaudited Interim Balance Sheet”** means the unaudited consolidated balance sheet of the Company and its consolidated Subsidiaries for the twelve month period ended December 31, 2018 provided to Parent prior to the date of this Agreement.

**“Company Warrant”** means the warrants to purchase capital stock of the Company listed on Section 2.6(a) of the Company Disclosure Schedule.

**“Concurrent Financing”** means financing in the form of debt or equity (whether convertible or otherwise) by the Company to occur after the date hereof and prior to the Closing.

**“Confidentiality Agreement”** means the non-disclosure and confidentiality agreement, dated as of March 15, 2019 between the Company and Parent.

**“Consent”** means any approval, consent, ratification, permission, waiver or authorization (including any Governmental Authorization).

**“Contemplated Transactions”** means the Merger, the Nasdaq Reverse Split, and the other transactions and actions contemplated by this Agreement.

**“Contract”** means, with respect to any Person, any written or oral agreement, contract, subcontract, lease (whether for real or personal property), mortgage, license, sublicense or other legally binding commitment or undertaking of any nature to which such Person is a party or by which such Person or any of its assets are bound or affected under applicable Law.

**“DGCL”** means the General Corporation Law of the State of Delaware.

**“Divestiture Transactions”** means sale and divestiture transactions pursuant to which Parent shall sell and divest assets (including rights under Contracts) pursuant to transaction documents (i) entered into and consummated prior to the Closing Date, or (ii) entered into prior to the Closing Date, as to which the only outstanding condition to the consummation thereof is the occurrence of the Merger on the Closing Date, and which are to be consummated effective upon the Merger on the Closing Date.

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“**Effect**” means any effect, change, event, circumstance, or development.

“**Encumbrance**” means any lien, pledge, hypothecation, charge, mortgage, security interest, lease, license, option, easement, reservation, servitude, adverse title, claim, infringement, interference, option, right of first refusal, preemptive right, community property interest or restriction or encumbrance of any nature (including any restriction on the voting of any security, any restriction on the transfer of any security or other asset, any restriction on the receipt of any income derived from any asset, any restriction on the use of any asset and any restriction on the possession, exercise or transfer of any other attribute of ownership of any asset).

“**Enforceability Exceptions**” means the (a) Laws of general application relating to bankruptcy, insolvency and the relief of debtors; and (b) rules of law governing specific performance, injunctive relief and other equitable remedies.

“**Entity**” means any corporation (including any non-profit corporation), partnership (including any general partnership, limited partnership or limited liability partnership), joint venture, estate, trust, company (including any company limited by shares, limited liability company or joint stock company), firm, society or other enterprise, association, organization or entity, and each of its successors.

“**Environmental Law**” means any federal, state, local or foreign Law relating to pollution or protection of human health or the environment (including ambient air, surface water, ground water, land surface or subsurface strata), including any Law or regulation relating to emissions, discharges, releases or threatened releases of Hazardous Materials, or otherwise relating to the manufacture, processing, distribution, use, treatment, storage, disposal, transport or handling of Hazardous Materials.

“**ERISA**” means the Employee Retirement Income Security Act of 1974, as amended.

“**Exchange Act**” means the Securities Exchange Act of 1934, as amended.

“**Exchange Ratio**” means, subject to Section 1.5(g), the following ratio (rounded to four decimal places): the quotient obtained by dividing (a) the Company Merger Shares by (b) the Company Outstanding Shares, in which:

- “**Company Allocation Percentage**” means (i) 90%, minus, (ii) the Parent Cash Adjustment Amount (if applicable).
- “**Company Merger Shares**” means the product of (i) the Post-Closing Parent Shares multiplied by (ii) the Company Allocation Percentage.
- “**Company Outstanding Shares**” means the total number of shares of Company Capital Stock outstanding immediately prior to the Effective Time, (i) including (a) the shares issuable upon exercise of all Company Options and Company Warrants, in each case, outstanding as of immediately prior to the Effective Time, (b) the shares of Company Capital Stock issuable in respect of all other outstanding options, restricted stock awards, warrants or rights to receive such shares, whether conditional or unconditional and including any outstanding options, warrants or rights triggered by or associated with the consummation of the Merger, and (c) the issuance of shares of Company Capital Stock issuable upon the conversion of the Company Converting Notes, but (ii) excluding (a) any other shares of Company Common Stock reserved for issuance under the Company Stock Plan and (b) any shares of Company Common Stock issuable upon the conversion of the Company Continuing Notes.
- “**Parent Allocation Percentage**” means (i) 10%, plus, (ii) the Parent Cash Adjustment Amount (if applicable).
- “**Parent Cash Adjustment Amount**” means an amount, express as a percentage, equal to (i) (A) the Parent Cash Amount, if positive, *plus* (B) the Company Continuing Note Amount, if any, *divided by* (b) \$50,000; *provided*, that, any fractional amount thereof shall be disregarded, *multiplied by* (ii) .05; *provided*, that in no event shall the Parent Cash Adjustment Amount be greater than 5.0%.

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- “**Parent Outstanding Shares**” means the total number of shares of Parent Common Stock outstanding immediately prior to the Effective Time, including the total number of shares of Parent Common Stock issuable in respect of all Parent Options, Parent Warrants and other outstanding options, warrants or rights to receive such shares, in each case, outstanding as of immediately prior to the Effective Time, but excluding any shares of Parent Common Stock reserved for issuance (other than shares of Parent Common Stock reserved for issuance pursuant to the Parent Stock Plans).
- “**Post-Closing Parent Shares**” means the quotient determined by dividing (i) the Parent Outstanding Shares by (ii) the Parent Allocation Percentage.

“**GAAP**” means generally accepted accounting principles and practices in effect from time to time within the United States applied consistently throughout the period involved.

“**Governmental Authorization**” means any: (a) permit, license, certificate, certification, franchise, permission, approval, exemption, variance, exception, order, clearance, registration, qualification or authorization issued, granted, given or otherwise made available by or under the authority of any Governmental Body or pursuant to any Law; or (b) right under any Contract with any Governmental Body.

“**Governmental Body**” means any: (a) nation, state, commonwealth, province, territory, county, municipality, district or other jurisdiction of any nature; (b) federal, state, local, municipal, foreign or other government; (c) governmental or quasi-governmental authority of any nature (including any governmental division, department, agency, commission, bureau, instrumentality, official, ministry, fund, foundation, center, organization, unit, body or Entity and any court or other tribunal, and for the avoidance of doubt, any taxing authority); or (d) self-regulatory organization (including Nasdaq).

“**Hazardous Materials**” means any pollutant, chemical, substance and any toxic, infectious, carcinogenic, reactive, corrosive, ignitable or flammable chemical, or chemical compound, or hazardous substance, material or waste, whether solid, liquid or gas, that is subject to regulation, control or remediation under any Environmental Law, including without limitation, crude oil or any fraction thereof, and petroleum products or by-products.

“**Intellectual Property Rights**” means and includes all past, present, and future rights of the following types, which may exist or be created under the laws of any jurisdiction in the world: (a) rights associated with works of authorship, including exclusive exploitation rights, copyrights, moral rights, software, databases, and mask works; (b) trademarks, service marks, trade dress, logos, trade names and other source identifiers, domain names and URLs and similar rights and any goodwill associated therewith; (c) rights associated with trade secrets, know how, inventions, invention disclosures, methods, processes, protocols, specifications, techniques and other forms of technology; (d) patents and industrial property rights; and (e) other similar proprietary rights in intellectual property of every kind and nature; (f) rights of privacy and publicity; and (g) all registrations, renewals, extensions, statutory invention registrations, provisionals, continuations, continuations-in-part, provisionals, divisions, or reissues of, and applications for, any of the rights referred to in clauses “(a)” through “(f)” above (whether or not in tangible form and including all tangible embodiments of any of the foregoing, such as samples, studies and summaries), along with all rights to prosecute and perfect the same through administrative prosecution, registration, recordation or other administrative proceeding, and all causes of action and rights to sue or seek other remedies arising from or relating to the foregoing.

“**IRS**” means the United States Internal Revenue Service.

“**Knowledge**” means, with respect to an individual, that such individual is actually aware of the relevant fact or such individual would reasonably be expected to know such fact in the ordinary course of the performance of such individual’s employment responsibilities. Any Person that is an Entity shall have Knowledge if any officer or director of such Person as of the date such knowledge is imputed has Knowledge of such fact or other matter.



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“**Law**” means any federal, state, national, foreign, material local or municipal or other law, statute, constitution, principle of common law, resolution, ordinance, code, edict, decree, rule, regulation, ruling or requirement issued, enacted, adopted, promulgated, implemented or otherwise put into effect by or under the authority of any Governmental Body (including under the authority of Nasdaq or the Financial Industry Regulatory Authority).

“**Legal Proceeding**” means any action, suit, litigation, arbitration, proceeding (including any civil, criminal, administrative, investigative or appellate proceeding), hearing, inquiry, audit, examination or investigation commenced, brought, conducted or heard by or before, or otherwise involving, any court or other Governmental Body or any arbitrator or arbitration panel.

“**Merger Sub Board**” means the board of directors of Merger Sub.

“**Nasdaq**” means The Nasdaq Stock Market, LLC, including The Nasdaq Capital Market or such other Nasdaq market on which shares of Parent Common Stock are then listed.

“**Nasdaq Reverse Split**” means a reverse stock split of all outstanding shares of Parent Common Stock at a reverse stock split ratio as mutually agreed to by Parent and the Company that is effected by Parent for the purpose of maintaining compliance with Nasdaq listing standards.

“**Ordinary Course of Business**” means, in the case of each of the Company and Parent, such actions taken in the ordinary course of its normal operations and consistent with its past practices.

“**Organizational Documents**” means, with respect to any Person (other than an individual), (a) the certificate or articles of association or incorporation or organization or limited partnership or limited liability company, and any joint venture, limited liability company, operating or partnership agreement and other similar documents adopted or filed in connection with the creation, formation or organization of such Person and (b) all bylaws, regulations and similar documents or agreements relating to the organization or governance of such Person, in each case, as amended or supplemented.

“**Parent Associate**” means any current or former employee, independent contractor, officer or director of Parent.

“**Parent Balance Sheet**” means the audited balance sheet of Parent as of December 31, 2018 (the “**Parent Balance Sheet Date**”), included in Parent’s Report on Form 10-K for the twelve month period ended December 31, 2018, as filed with the SEC.

“**Parent Board**” means the board of directors of Parent.

“**Parent Cash Amount**” (i) the sum of all Cash and Cash Equivalents, short-term investments, accrued investment interest receivable, and any prepaid refundable deposits listed on [Section 1.11\(a\)](#) of the Parent Disclosure Schedule, in each case, of Parent as of the Determination Date, calculated in accordance with [Section 1.11](#), plus (ii) the aggregate proceeds of all Divestiture Transactions, less (iii) all liabilities of Parent to any current or former Parent officer, director, employee, consultant or independent contractor, including change of control payments, retention payments, severance and other employee-, consultant- or independent contractor-related termination costs, or other payments triggered by the Contemplated Transactions or pursuant to any Parent Benefit Plan, including but not limited to payments of deferred compensation, accrued but unpaid bonuses and accrued but unpaid vacation or paid time off (including related employer employment taxes on all the foregoing), regardless of whether or not such amounts are accrued or due as of the Determination Date and regardless of when paid or payable and regardless of whether such amounts will be paid or are payable as a result of actions taken at, or immediately prior to or after the Effective Time, less (iv) the Parent Transaction Expenses.

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**“Parent Change in Circumstance”** means a change in circumstances (other than an Acquisition Proposal) that affects the business, assets or operations of Parent that occurs or arises after the date of this Agreement.

**“Parent Closing Price”** means the volume weighted average closing trading price of a share of Parent Common Stock on Nasdaq for the five consecutive trading days ending five trading days immediately prior to the date upon which the Merger becomes effective.

**“Parent Common Stock”** means the Common Stock, \$0.01 par value per share, of Parent.

**“Parent Contract”** means any Contract: (a) to which Parent or its Subsidiaries is a party; (b) by which Parent, its Subsidiaries, or any Parent IP or any other asset of Parent or its Subsidiaries is or may become bound or under which Parent or its Subsidiaries has, or may become subject to, any obligation; or (c) under which Parent or its Subsidiaries has or may acquire any right or interest.

**“Parent ERISA Affiliate”** means any corporation or trade or business (whether or not incorporated) which is (or at any relevant time was) treated with Parent or any of its Subsidiaries as a single employer within the meaning of Section 414 of the Code.

**“Parent Fully-Diluted Shares”** means the total number of shares of Parent Common Stock outstanding immediately prior to the Effective Time expressed on a fully-diluted basis, assuming the issuance of Parent Common Stock in respect of all Parent Options, and other outstanding options, warrants or rights to receive such shares, in each case, outstanding as of immediately prior to the Effective Time.

**“Parent IP”** means all Intellectual Property Rights that are owned or purported to be owned by, assigned to, or licensed by, Parent or its Subsidiaries.

**“Parent Material Adverse Effect”** means any Effect that, considered together with all other Effects that have occurred prior to the date of determination of the occurrence of a Parent Material Adverse Effect, has or would reasonably be expected to have a material adverse effect on the business, financial condition, assets, liabilities or results of operations of Parent; *provided, however*, that Effects arising or resulting from the following shall not be taken into account in determining whether there has been a Parent Material Adverse Effect: (a) general business, economic or political conditions affecting the industry in which Parent operates, (b) any natural disaster or any acts of war, armed hostilities or terrorism, (c) changes in financial, banking or securities markets, (d) the taking of any action required to be taken by this Agreement, (e) any change in the stock price or trading volume of Parent Common Stock (it being understood, however, that any Effect causing or contributing to any change in stock price or trading volume of Parent Common Stock may be taken into account in determining whether a Parent Material Adverse Effect has occurred, unless such Effects are otherwise excepted from this definition), (f) the failure of Parent to meet internal or analysts’ expectations or projections or the results of operations of Parent; (g) any clinical trial programs or studies, including any adverse data, event or outcome arising out of or related to any such programs or studies; (h) any change in, or any compliance with or action taken for the purpose of complying with, any Law or GAAP (or interpretations of any Law or GAAP); (i) resulting from the announcement of this Agreement or the pendency of the Contemplated Transactions; or (j) resulting from the taking of any action or the failure to take any action, by Parent that is required to be taken by this Agreement, except in each case with respect to clauses (a) through (c), to the extent disproportionately affecting Parent relative to other similarly situated companies in the industries in which Parent operates.

**“Parent Options”** means options or other rights to purchase shares of Parent Common Stock issued by Parent.

**“Parent Stock Plans”** means the Histogenics Corporation 2013 Equity Incentive Plan and the Histogenics Corporation Employee Stock Purchase Plan.

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“**Parent Target**” means \$0.

“**Parent Transaction Expenses**” means all fees and expenses incurred by Parent at or prior to the Effective Time in connection with the Contemplated Transactions and this Agreement, including (a) any fees and expenses of legal counsel and accountants, the maximum amount of fees and expenses payable to financial advisors, investment bankers, brokers, consultants, and other advisors of Parent, including, without limitation, for preparation of the Registration Statement, Proxy Statement, and any amendments and supplements thereto, preparing responses to any SEC comments, and drafting any charter amendments (and in each case, the related disclosure required in the Registration Statement and Proxy Statement); (b) 50% of (i) the fees paid to the SEC in connection with filing the Registration Statement, the Proxy Statement, and any amendments and supplements thereto with the SEC; (ii) the fees and expenses paid or payable to the Exchange Agent pursuant to the engagement agreement with the Exchange Agent; and (iii) any fees and expenses incurred by Broadridge Corporate Issuer Solutions, Inc., Parent’s transfer agent, and Innisfree M&A Incorporated, the proxy solicitor, in connection with the filing and distribution of the Registration Statement and any amendments and supplements thereto with the SEC (without duplication of the fees and expenses addressed in clause (b)(i) above); and (c) 100% of the D&O Tail Policy.

“**Parent Triggering Event**” shall be deemed to have occurred if: (a) Parent shall have failed to include in the Proxy Statement the Parent Board Recommendation or shall have made a Parent Board Adverse Recommendation Change; (b) the Parent Board or any committee thereof shall have publicly approved, endorsed or recommended any Acquisition Proposal; or (c) Parent shall have entered into any letter of intent or similar document relating to any Acquisition Proposal (other than a confidentiality agreement permitted pursuant to Section 4.4); or (d) Parent, or any director or officer of Parent, shall have willfully and intentionally breached the provisions set forth in Section 4.4.

“**Parent Warrants**” means the warrants to purchase capital stock of the Parent listed on Section 3.6(a) of the Parent Disclosure Schedule.

“**Party**” or “**Parties**” means the Company, Merger Sub and Parent.

“**Permitted Alternative Agreement**” means a definitive agreement that contemplates or otherwise relates to an Acquisition Transaction that constitutes a Superior Offer.

“**Permitted Encumbrance**” means: (a) any liens for current Taxes not yet due and payable or for Taxes that are being contested in good faith and for which adequate reserves have been made on the Company Unaudited Interim Balance Sheet or the Parent Balance Sheet, as applicable; (b) minor liens that have arisen in the Ordinary Course of Business and that do not (in any case or in the aggregate) materially detract from the value of the assets or properties subject thereto or materially impair the operations of the Company or any of its Subsidiaries or Parent, as applicable; (c) statutory liens to secure obligations to landlords, lessors or renters under leases or rental agreements; (d) deposits or pledges made in connection with, or to secure payment of, workers’ compensation, unemployment insurance or similar programs mandated by Law; (e) non-exclusive licenses of Intellectual Property Rights granted by the Company or any of its Subsidiaries or Parent, as applicable, in the Ordinary Course of Business and that do not (in any case or in the aggregate) materially detract from the value of the Intellectual Property Rights subject thereto; and (f) statutory liens in favor of carriers, warehousemen, mechanics and materialmen, to secure claims for labor, materials or supplies.

“**Person**” means any individual, Entity or Governmental Body.

“**Proxy Statement**” means the proxy statement to be sent to Parent’s stockholders in connection with the Parent Stockholders’ Meeting.

“**Reference Date**” means February 28, 2019.

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“**Registered IP**” means all Intellectual Property Rights that are registered or issued under the authority of any Governmental Body, including all patents, registered copyrights, registered mask works, and registered trademarks, service marks and trade dress, and all applications for any of the foregoing.

“**Registration Statement**” means the registration statement on Form S-4 (or any other applicable form under the Securities Act to register Parent Common Stock) to be filed with the SEC by Parent registering the public offering and sale of Parent Common Stock to some or all holders of Company Capital Stock in the Merger, including all shares of Parent Common Stock to be issued in exchange for all shares of Company Capital Stock in the Merger, as said registration statement may be amended prior to the time it is declared effective by the SEC.

“**Representatives**” means directors, officers, employees, agents, attorneys, accountants, investment bankers, advisors and representatives.

“**Restricted Cash**” means any cash or cash equivalents that are unavailable for dividend or distribution as a result of the requirements of applicable Law or the dividend or distribution of which is subject to Tax, including any withholding or other similar Tax, or the dividend or distribution of which would produce other adverse Tax consequences for Parent or its Affiliates.

“**Sarbanes-Oxley Act**” means the Sarbanes-Oxley Act of 2002.

“**SEC**” means the United States Securities and Exchange Commission.

“**Securities Act**” means the Securities Act of 1933, as amended.

“**Subsequent Transaction**” means any Acquisition Transaction (with all references to 20% in the definition of Acquisition Transaction being treated as references to 85% for these purposes).

“**Subsidiary**” means, with respect to a Person, another entity of which such Person directly or indirectly owns or purports to own, beneficially or of record, (a) an amount of voting securities or other interests that is sufficient to enable such Person to elect at least a majority of the members of such entity’s board of directors or other governing body, or (b) at least 50% of the outstanding equity, voting, beneficial or financial interests in such Entity.

“**Superior Offer**” means an unsolicited bona fide written Acquisition Proposal (with all references to 20% in the definition of Acquisition Transaction being treated as references to greater than 80% for these purposes) that: (a) was not obtained or made as a direct or indirect result of a breach of (or in violation of) this Agreement; and (b) is on terms and conditions that the Parent Board or the Company Board, as applicable, determines in good faith, based on such matters that it deems relevant (including the likelihood of consummation thereof), as well as any written offer by the other Party to this Agreement to amend the terms of this Agreement, and following consultation with its outside legal counsel and outside financial advisors, if any, are more favorable, from a financial point of view, to Parent’s stockholders or the Company’s stockholders, as applicable, than the terms of the Contemplated Transactions; provided, that any such offer shall not be deemed to be a “Superior Offer” if any financing required to consummate the transaction contemplated by such offer is not reasonably capable of being obtained by such third party.

“**Takeover Statute**” means any “fair price,” “moratorium,” “control share acquisition” or other similar anti-takeover Law.

“**Tax**” means any federal, state, local, foreign or other tax, including any income, capital gain, gross receipts, capital stock, profits, transfer, estimated, registration, stamp, premium, escheat, unclaimed property, customs duty, ad valorem, occupancy, occupation, alternative, add-on, windfall profits, value added, severance,

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property, business, production, sales, use, license, excise, franchise, employment, payroll, social security, disability, unemployment, workers' compensation, national health insurance, withholding or other taxes, duties, fees, assessments or governmental charges, surtaxes or deficiencies thereof of any kind whatsoever, however denominated, and including any fine, penalty, addition to tax or interest imposed by a Governmental Body with respect thereto.

**"Tax Return"** means any return (including any information return), report, statement, declaration, estimate, schedule, notice, notification, form, election, certificate or other document, and any amendment or supplement to any of the foregoing, filed with or submitted to, or required to be filed with or submitted to, any Governmental Body in connection with the determination, assessment, collection or payment of any Tax or in connection with the administration, implementation or enforcement of or compliance with any Law relating to any Tax.

**"Treasury Regulations"** means the United States Treasury regulations promulgated under the Code.

**"WARN Act"** means the Worker Adjustment Retraining and Notification Act of 1988, as amended, or any similar state or local plant closing mass layoff statute, rule or regulation.

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(b) Each of the following terms is defined in the Section set forth opposite such term:

<b>Term</b>	<b>Section</b>
Accounting Firm	1.11(e)
Allocation Certificate	5.15(a)
Anti-Bribery Laws	2.23
Anticipated Closing Date	1.11(a)
Business Associate Agreement	2.14(f)
Certificate of Merger	1.3
Certifications	3.7(a)
Closing	1.3
Closing Date	1.3
Company	Preamble
Company Audited Financial Statements	5.16
Company Benefit Plan	2.17(a)
Company Board Adverse Recommendation Change	5.2(d)
Company Board Recommendation	5.2(d)
Company Disclosure Schedule	Section 2
Company Financials	2.7(a)
Company In-bound Licenses	2.12(d)
Company Interim Financial Statements	5.16
Company Lock-Up Agreement	Recitals
Company Material Contract	2.13(a)
Company Out-bound Licenses	2.12(d)
Company Permits	2.14(b)
Company Real Estate Leases	2.11
Company Signatories	Recitals
Company Stock Certificate	1.6
Company Stockholders Agreement	2.4
Company Stockholder Matters	5.2(a)
Company Stockholder Support Agreement	Recitals
Company Stockholder Written Consent	2.4
Costs	5.5(a)
D&O Indemnified Parties	5.5(a)
D&O Tail Policy	5.5(d)
Determination Date	1.11(a)
Determination Notice	5.3(d)(i)
Dispute Notice	1.11(b)
Dissenting Shares	1.8(a)
Drug Regulatory Agency	2.14(a)
Effective Time	1.3
End Date	9.1(b)
Exchange Agent	1.7(a)
Exchange Fund	1.7(a)
FDA	2.14(a)
FDCA	2.14(a)
FLSA	2.17(p)
HIPAA	2.14(f)
Information Statement	5.2(a)
Intended Tax Treatment	5.9(a)
Investor Agreements	2.22(b)
Liability	2.9

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<b>Term</b>	<b>Section</b>
Merger	Recitals
Merger Consideration	1.5(a)(ii)
Merger Sub	Preamble
Nasdaq Fees	5.8
Nasdaq Listing Application	5.8
Parent	Preamble
Parent Benefit Plan	3.17(a)
Parent Board Adverse Recommendation Change	5.3(c)
Parent Board Recommendation	5.3(c)
Parent Cash Calculation	1.11(a)
Parent Cash Schedule	1.11(a)
Parent Disclosure Schedule	Section 3
Parent In-bound License	3.12(d)
Parent Lock-Up Agreement	Recitals
Parent Material Contract	3.13
Parent Out-bound License	3.12(d)
Parent Permits	3.14(b)
Parent Real Estate Leases	3.11
Parent SEC Documents	3.7(a)
Parent Signatories	Recitals
Parent Stockholder Matters	Recitals
Parent Stockholder Support Agreement	Recitals
Parent Stockholders' Meeting	Recitals
Pre-Closing Period	4.1(a)
Required Company Stockholder Vote	2.4
Required Parent Stockholder Vote	3.4
Response Date	1.11(b)
Sensitive Data	2.12(g)
Stockholder Notice	5.2(c)
Surviving Corporation	1.1

**Exhibit B-1**

Form of Company Stockholder Support Agreement

A-B-1-1



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**Exhibit B-2**

Form of Parent Stockholder Support Agreement

A-B-2-1

**Exhibit C**

***Officers***

<b>Name</b>	<b>Title</b>
Shankar Musunuri	Chief Executive Officer
Susan Drexler	Interim Chief Financial Officer
Dan Jorgensen	Secretary

***Board Designees — Company***

<b><u>Name</u></b>
Shankar Musunuri
Uday B. Kompella
Manish Potti
John Zhang
Frank N. Leo
Halit Suha Taspolatoglu
Martin M. Coyne

**Exhibit D**

Form of Lock-Up Agreement

A-D-1

**CONSENT AND AMENDMENT NO. 1 TO  
AGREEMENT AND PLAN OF MERGER AND REORGANIZATION**

THIS CONSENT AND AMENDMENT NO. 1 TO AGREEMENT AND PLAN OF MERGER AND REORGANIZATION (this "Amendment"), is made and entered into as of June 13, 2019 (the "First Amendment Effective Date"), by and among Histogenics Corporation, a Delaware corporation ("Parent"), Restore Merger Sub, Inc., a Delaware corporation and wholly owned subsidiary of Parent ("Merger Sub"), and Ocugen, Inc., a Delaware corporation (the "Company"). Capitalized terms used herein and not otherwise defined shall have the meanings assigned to such terms in that certain Agreement and Plan of Merger and Reorganization, made and entered into as of April 5, 2019, by and among Parent, Merger Sub and the Company (the "Merger Agreement").

**RECITALS**

- A. Section 10.02 of the Merger Agreement provides that the Merger Agreement may not be amended except by an instrument in writing signed on behalf of each of Parent, the Company and Merger Sub.
- B. The board of directors of each of the respective parties have determined that this Amendment is advisable and in the best interests of the respective entity and their respective stockholders.
- C. The parties wish to amend the Merger Agreement as set forth in this Amendment, such amendment to be effective as of the date hereof.

**AGREEMENT**

The parties to this Amendment, intending to be legally bound, hereby agree as follows:

- 1. **Amendments.**
  - 1.1 The phrase "time of calculating the Exchange Ratio" in Section 1.5(g) of the Merger Agreement shall be replaced in its entirety with the phrase "First Amendment Effective Date".
  - 1.2 Section 1.11 of the Merger Agreement and the defined term "Parent Cash Amount" in Exhibit A shall be deleted in their entirety.
  - 1.3 A new subsection (d) shall be added to Section 4.1 (Operation of Parent's Business) shall be added after subsection 4.1(c) of the Merger Agreement, which shall read as follows: "From the First Amendment Effective Date until the Effective Time, Parent shall not, without the consent of the Company, issue, or enter into any agreement to issue, any securities of any type (including, without limitation, common stock, preferred stock, warrants, options or promissory notes) to any Person, other than pursuant to the exercise, conversion or exchange pursuant to the terms of previously outstanding securities disclosed to the Company prior to the First Amendment Effective Date."
  - 1.4 A new subsection (d) shall be added to Section 4.2 (Operation of the Company's Business) shall be added after subsection 4.2(c) of the Merger Agreement, which shall read as follows: "From the First Amendment Effective Date until the Effective Time, the Company shall not, without the consent of Parent, issue, or enter into any agreement to issue, any equity securities of any type (including, without limitation, common stock, preferred stock, warrants, options or convertible promissory notes) to any Person, other than pursuant to the exercise, conversion or exchange pursuant to the terms of previously outstanding securities disclosed to Parent prior to the First Amendment Effective Date."

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- 1.5 The reference to “May 15, 2019” in Section 5.1(a) of the Merger Agreement pertaining to the date by which the Registration Statement shall have been prepared by the Company and caused by Parent to be filed with the SEC shall be amended and restated to read “June 17, 2019”.
- 1.6 The reference to “May 1, 2019” in Section 5.16 of the Merger Agreement pertaining to the date by which the Company shall have furnished to Parent audited financial statements for the fiscal years ended 2017 and 2018 shall be amended and restated to read “June 17, 2019”.
- 1.7 A new Section 5.21 (Amendment Related Payments) shall be added after Section 5.20 (Company Lock-Up) of the Merger Agreement, which shall read as follows: “The Company agrees to pay to Parent by wire transfer of immediately available United States funds to such Parent account as Parent shall direct by written notice delivered to the Company: (a) \$100,000 (less any earnest money payments made prior to the date hereof and acknowledged by the parties as such) on the date hereof; (b) \$30,000 on June 17, 2019; (c) \$200,000 on July 15, 2019; (d) \$200,000 on August 15, 2019; (e) \$100,000 on September 16, 2019; and (f) \$100,000 on September 30, 2019; *provided* that if the Effective Time has occurred prior to the respective dates set forth in subsections (c), (d), (e) or (f) of this Section 5.21, such payment shall no longer be payable on such date. In the event the Registration Statement is not filed with the SEC by 10:00 p.m. Eastern time on June 14, 2019 or any subsequent day thereafter, then the Company shall pay to Parent in immediately available United States funds to such Parent account as Parent shall direct by written notice delivered to the Company, no later than 9 a.m. Eastern time the following day, an amount equal to \$30,000. In the event a payment in the immediately preceding sentence is due on a weekend or bank holiday in New York City, then such payment shall be made on the next business day. If any payments required by this Section 5.21 are not made when due, then Parent shall have the right to terminate this Agreement at any time thereafter in accordance with the provisions of Section 9.1(i) without the need for any cure period or other condition otherwise required or contemplated by Section 9.1(i) or otherwise.”
- 1.8 A new Section 8.7 (Histogenics Asset Purchase Agreement) shall be added after Section 8.6 (Board of Directors) of the Merger Agreement, which shall read as follows: “That certain Asset Purchase Agreement, dated as of May 8, 2019, by and between Medavate Corp., a Colorado corporation, and Parent shall remain in full force and effect, and Parent shall not amend such agreement without the Company’s prior written consent (such consent not to be unreasonably withheld, conditioned or delayed), and the certificate delivered pursuant to Section 8.3(a) of the Merger Agreement shall certify that the aggregate proceeds to be received by Parent in connection with such Asset Purchase Agreement shall be no less than \$6,500,000, unless otherwise agreed to by the Company.”
- 1.9 The reference to “July 31, 2019” in Section 9.1(b) of the Merger Agreement, pertaining to the “End Date” by which the Contemplated Transactions shall have been consummated by shall be amended and restated to read “September 30, 2019”.
- 1.10 The defined term “Concurrent Financing” in Exhibit A to the Merger Agreement and the phrase “(including in connection with the Concurrent Financing)” in Sections 4.2(a) and 4.2(b) of the Merger Agreement shall be deleted in their entirety.
- 1.11 The definition of “Exchange Ratio” in Exhibit A to the Merger Agreement shall be amended and restated in its entirety to read as follows:

“**Exchange Ratio**” means, subject to Section 1.5(g), the following ratio (rounded to four decimal places): 28.7650.
- 1.12 A new definition shall be added to Exhibit A to the Merger Agreement, in alphabetical order, as follows:

“**Parent Cash Adjustment Amount**” shall mean 5.0%; provided, however, that for the avoidance of doubt, Parent Cash Adjustment Amount shall have no effect on either the Company Allocation Percentage or the Parent Allocation Percentage.

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- 1.13 The updated disclosures to the Company Disclosure Schedules for purposes of Section 3 of this Amendment are set forth on Schedule A hereto.
- 1.14 The Persons listed on Exhibit C under the heading “Officers” shall be amended and restated as set forth on Schedule B hereto.
2. **Calculation of Exchange Ratio.** Each of the Company and Parent represent and warrant to the other that the underlying capitalization of each respective party used for the calculation of the Exchange Ratio set forth on Schedule C hereto is true and correct in all respects as of the date hereof.
3. **Consent.** The Company hereby consents (a) pursuant to Section 4.1(b)(xi) of the Merger Agreement, to an amendment, on the date hereof and in the form previously presented to the Company, of that certain Engagement Letter, dated as of October 1, 2018, by and between Parent and Canaccord Genuity LLC (the “Canaccord Amendment”), and (b) pursuant to Section 4.1(b)(xii) of the Merger Agreement, to incurrance of Parent Transaction Expenses in connection with, and solely to the extent as set forth in, the Canaccord Amendment.
4. **Continuing Effectiveness; Entire Agreement.** Except as expressly modified by this Amendment, the Merger Agreement shall remain in full force and effect in accordance with its terms. The Company represents and warrants that the representations and warranties of the Company contained in Section 2 of the Merger Agreement are true and correct as of the date of this Amendment. This Amendment shall be deemed an amendment to the Merger Agreement and shall become effective when executed and delivered by the Parties. Upon the effectiveness of this Amendment, all references in the Merger Agreement to “the Agreement” or “this Agreement,” as applicable, shall refer to the Merger Agreement, as modified by this Amendment. This Amendment shall not constitute a release, waiver or discharge by Parent of any past, present or future claim, in law or in equity, asserted or unasserted, express or implied, known or unknown, matured or unmatured, contingent or vested, of any kind or nature or description whatsoever, that Parent had, presently has or may hereafter have or claim or assert to have against the Company, or Parent’s reliance on any specific facts or legal theories, all of which are hereby expressly reserved. This Amendment constitutes the entire agreement between and among the parties hereto with respect to the subject matter hereof, and supersedes in their entirety all prior negotiations and agreements with respect to such subject matter, whether written or oral.
5. **Governing Law.** This Amendment shall be governed by, and construed in accordance with, the Laws of the State of Delaware, regardless of the Laws that might otherwise govern under applicable principles of conflicts of laws. If any provision of this Amendment is determined by an arbitrator or court of competent jurisdiction to be illegal or unenforceable, such provision will be enforced to the maximum extent possible and the other provisions will remain effective and enforceable.
6. **Headings.** The bold-faced headings and table of contents contained in this Amendment are for convenience of reference only, shall not be deemed to be a part of this Amendment and shall not be referred to in connection with the construction or interpretation of this Amendment.
7. **Assignability.** This Amendment shall be binding upon, and shall be enforceable by and inure solely to the benefit of, the Parties and their respective successors and assigns.
8. **Counterparts; Exchanges by Facsimile.** This Amendment may be executed in several counterparts, each of which shall be deemed an original and all of which shall constitute one and the same instrument. The exchange of a fully executed Amendment (in counterparts or otherwise) by all Parties by electronic transmission in .PDF format shall be sufficient to bind the Parties to the terms and conditions of this Agreement.
9. **Miscellaneous.** Section 10 of the Merger Agreement is hereby incorporated into this Amendment *mutatis mutandis*.

IN WITNESS WHEREOF, the Parties have caused this Amendment to be executed as of the date first above written.

**HISTOGENICS CORPORATION**

By: /s/ Adam Gridley

Name: Adam Gridley

Title: President

**RESTORE MERGER SUB, INC.**

By:  /s/ Adam Gridley

Name: Adam Gridley

Title: President

SIGNATURE PAGE TO CONSENT AND AMENDMENT NO. 1 TO AGREEMENT AND PLAN OF  
MERGER AND REORGANIZATION



**OCUGEN, INC.**

By: /s/ Shankar Musunuri

Name: Shankar Musunuri

Title: Chief Executive Officer

SIGNATURE PAGE TO CONSENT AND AMENDMENT NO. 1 TO AGREEMENT AND PLAN OF  
MERGER AND REORGANIZATION

**SCHEDULE A**

UPDATED DISCLOSURES TO  
COMPANY DISCLOSURE SCHEDULES

A-1

**SCHEDULE B**

PERSONS LISTED AS OFFICERS  
ON EXHIBIT C

***Officers***

<b>Name</b>	<b>Title</b>
Shankar Musunuri, Ph.D., MBA	Chief Executive Officer
Daniel Jorgensen, M.D., M.P.H., MBA	Chief Medical Officer
Rasappa Arumugham, Ph.D.	Chief Scientific Officer
Vijay Tammara, Ph.D.	Vice President, Regulatory & Quality
Kelly Beck, MBA, SPHR, SHRM-SCP, PMP	Vice President, Investor Relations & Administration

**SCHEDULE C**

CALCULATION OF EXCHANGE RATIO

C-1



Canaccord Genuity LLC  
535 Madison Avenue  
New York, NY  
USA 10022

T1: 1.212.389.8000  
cgf.com

June 13, 2019

Board of Directors  
Histogenics Corporation  
830 Winter Street, 3<sup>rd</sup> Floor  
Waltham, Massachusetts 02451

Members of the Board:

You have requested our opinion as to the fairness, from a financial point of view, to Histogenics Corporation, a Delaware corporation ("Parent"), of the Exchange Ratio pursuant to the Agreement and Plan of Merger and Reorganization, dated as of April 5, 2019, by and among Parent, Restore Merger Sub, Inc., a Delaware corporation and wholly owned subsidiary of Parent ("Merger Sub"), and Ocugen, Inc., a Delaware corporation (the "Company"), as proposed to be amended as of the date hereof by that certain Consent and Amendment No. 1 to Agreement and Plan of Merger and Reorganization (as amended, the "Merger Agreement"). The Merger Agreement provides for, among other things, the merger (the "Merger") of Merger Sub with and into the Company pursuant to which the Company will become a wholly-owned subsidiary of Parent, and except as otherwise provided in the Merger Agreement, each outstanding share of common stock, par value \$0.0001 per share, of the Company (each, a "Company Share") (excluding Company Shares held in treasury or held by the Company, any subsidiary of the Company, or Merger Sub, or any Dissenting Shares) will be converted into the right to receive a number of shares of common stock, par value \$0.01 per share, of Parent ("Parent Common Stock") equal to the Exchange Ratio, such that, following consummation of the Merger, the holders of shares of Parent Common Stock on a fully-diluted basis immediately prior to the Merger shall hold approximately 17% of the shares of Parent Common Stock outstanding on a fully-diluted basis immediately following the Merger, without giving effect to the proposed financing (the "Pre-Merger Financing") contemplated by that certain Securities Purchase Agreement, dated as of June 13, 2019, by and among Parent, the Company and certain investors (the "Securities Purchase Agreement"). For purposes of this opinion, the term "Exchange Ratio" refers to the exchange ratio of 28.7650 set forth in the Merger Agreement but without giving effect to the Pre-Merger Financing. The terms and conditions of the Merger are more fully set forth in the Merger Agreement and capitalized terms used but not defined herein shall have the meanings ascribed to such terms in the Merger Agreement.

Canaccord Genuity LLC ("Canaccord Genuity"), as part of its investment banking activities, is regularly engaged in the valuation of businesses and their securities in connection with

Member FINRA/SIPC

mergers and acquisitions, negotiated underwritings, secondary distributions of listed and unlisted securities, private placements and valuations for corporate and other purposes. In the ordinary course of business, we and our affiliates may acquire, hold or sell, for our and our affiliates' own accounts and the accounts of customers, equity, debt and other securities and financial instruments (including bank loans and other obligations) of Parent. Other than as related to the Merger and as set forth below, we have provided no investment banking or other financial services of a material nature to either Parent or the Company during the two years preceding the date of this opinion. As you are aware, we (i) acted as sole book-running manager for an approximately \$5.5 million registered direct equity offering of Parent in January 2018, (ii) acted as underwriter for an approximately \$17.0 million follow-on equity offering of Parent in October 2018, and (iii) are party to an Equity Distribution Agreement with Parent with respect to at-the-market offerings, for which services we received an aggregate amount of approximately \$1.2 million in the past two years. We have acted as financial advisor to the Board of Directors of Parent in connection with the Merger. We received a fee upon signing our engagement letter, and also will receive fees for our services in connection with the Merger, a portion of which was payable in connection with the delivery of our opinion dated April 5, 2019 and the public announcement of the proposed Merger, a portion of which is payable upon the delivery of this opinion, and a significant portion of which is contingent upon the consummation of the Merger. In addition, Parent has agreed to reimburse certain of our expenses and indemnify us for liabilities relating to or arising out of our engagement.

In connection with our review of the proposed Merger and developing our opinion, we have:

- (i) reviewed certain publicly available historical business and financial information concerning Parent;
- (ii) reviewed certain internal historical financial statements and other historical financial and operating data concerning Parent and the Company provided to us by management of Parent and the Company, and certain projected cash balances of Parent prepared by management of Parent;
- (iii) conducted discussions with members of management of Parent and the Company regarding the past and current operations and financial condition and the prospects of Parent and the Company;
- (iv) reviewed financial and stock market data for certain companies, the securities of which are publicly traded, that we deemed to be relevant to the Company;
- (v) reviewed certain financial terms of certain initial public offerings executed by certain companies that we deemed to be relevant to the Company;
- (vi) reviewed certain financial terms of certain business combination transactions that we deemed to be relevant to Parent;
- (vii) reviewed the terms of the Merger Agreement provided to us by Parent, including the Consent and Amendment No. 1 thereto in substantially final form provided to

us on June 12, 2019, which we have assumed, with your permission, to be identical in all material respects to the amendment executed by the parties; and

- (viii) reviewed such other financial studies and analyses, performed such other investigations, and took into account such other matters as we deemed necessary, including an assessment of general securities, economic, market and monetary conditions.

In connection with our review and arriving at our opinion, we have not independently verified any of the foregoing information, have relied on such information, have assumed that all such information is complete and accurate in all material respects, and have relied on assurances of management of Parent that they are not aware of any facts that would make such information misleading. With respect to the projected cash balances of Parent prepared by management of Parent and any related forward-looking information reviewed by us, we have assumed, with your permission, that such information has been reasonably prepared on bases reflecting the best currently available estimates and judgments of management as to the matters covered thereby, and we have relied, with your permission, on such information for purposes of our analysis and this opinion. We express no view or opinion as to such information or the assumptions on which it is based. We have also assumed that (i) the Merger will be consummated upon the terms set forth in the Merger Agreement, without any adjustment to the Exchange Ratio or any waiver, modification or amendment of any material term, condition or agreement therein which would be in any way meaningful to our analysis and (ii) in the course of obtaining necessary governmental, regulatory and third party approvals and consents for the Merger, no modification, delay, limitation, restriction or conditions will be imposed which would have an adverse effect on Parent or the Company or be in any way meaningful to our analysis.

This opinion has been approved by a fairness committee of Canaccord Genuity in accordance with FINRA Rule 5150. Our opinion is rendered on the basis of securities, economic, market and monetary conditions prevailing as of the date hereof and on the prospects, financial and otherwise, of Parent and the Company, known to us as of the date hereof. It should be understood that (i) subsequent developments may affect the conclusions expressed in this opinion if this opinion were rendered as of a later date, and (ii) Canaccord Genuity disclaims any obligation to advise any person of any change in any manner affecting this opinion that may come to our attention after the date of this opinion. We have not undertaken to reaffirm or revise this opinion or otherwise comment upon any events occurring after the date hereof and do not have any obligation to update, revise or reaffirm this opinion. We have not been requested to conduct and we have not conducted, nor have we relied upon, any independent valuation or appraisal of any of the assets or liabilities (contingent, derivative, off-balance sheet or otherwise) of Parent or the Company. We also have not evaluated and do not express any opinion as to the solvency of any party to the Merger Agreement, or the ability of Parent or the Company to pay its obligations when they become due, or as to the impact of the Merger on such matters, under any state, federal or other laws relating to bankruptcy, insolvency or similar matters.

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This opinion is limited to and addresses only the fairness, from a financial point of view, as of the date hereof, to Parent of the Exchange Ratio. We do not express any view on, and our opinion does not address, any other term or aspect of any other agreements or arrangements contemplated by the Merger Agreement or entered into in connection with the Merger, including, without limitation, (i) the Securities Purchase Agreement and (ii) that certain Asset Purchase Agreement, dated as of May 8, 2019, by and between Parent and Medavate Corp. We also express no opinion as to the fairness of the Merger to the holders of any class of securities, creditors or other constituencies of Parent or any value that the holders of Dissenting Shares may be entitled to receive. Our opinion does not address the relative merits of the Merger as compared to other business strategies or transactions that might be available to Parent, nor does it address the underlying business decision of Parent to proceed with the Merger or any view on another term or aspect of the Merger, including, without limitation, the structure or form of the Merger. We also note that we are not legal, accounting, regulatory or tax experts and have relied on the assessments made by Parent and its advisors with respect to such matters. We have not considered, and we express no opinion as to, the fairness of the amount or nature of the compensation to any of the officers, directors or employees of Parent or any other party, or class of such persons. Further, we express no opinion as to in the future what the value of Parent Common Stock or any other securities actually will be when issued or the price or range of prices at which Parent Common Stock or any other securities may trade or otherwise be transferable at any time, including following announcement or consummation of the Merger.

It is agreed between the Board of Directors of Parent and Canaccord Genuity that this opinion, as set forth in this letter form, is directed to and for the information of the Board of Directors only (in its capacity as such) in connection with its evaluation of the Merger and does not constitute advice or a recommendation to the Board of Directors or any other person as to how the Board of Directors or such person should vote with respect to the Merger or otherwise act on any other matter with respect to the Merger.

Based upon and subject to the foregoing, it is our opinion that, as of the date hereof, the Exchange Ratio is fair, from a financial point of view, to Parent.

Sincerely,

/s/ CANACCORD GENUITY LLC

CANACCORD GENUITY LLC



**GENERAL CORPORATION LAW OF THE STATE OF DELAWARE REGARDING APPRAISAL RIGHTS**

**SECTION 262 OF THE GENERAL CORPORATION LAW OF THE STATE OF DELAWARE**

**§ 262. Appraisal rights.**

(a) Any stockholder of a corporation of this State who holds shares of stock on the date of the making of a demand pursuant to subsection (d) of this section with respect to such shares, who continuously holds such shares through the effective date of the merger or consolidation, who has otherwise complied with subsection (d) of this section and who has neither voted in favor of the merger or consolidation nor consented thereto in writing pursuant to § 228 of this title shall be entitled to an appraisal by the Court of Chancery of the fair value of the stockholder's shares of stock under the circumstances described in subsections (b) and (c) of this section. As used in this section, the word "stockholder" means a holder of record of stock in a corporation; the words "stock" and "share" mean and include what is ordinarily meant by those words; and the words "depository receipt" mean a receipt or other instrument issued by a depository representing an interest in 1 or more shares, or fractions thereof, solely of stock of a corporation, which stock is deposited with the depository.

(b) Appraisal rights shall be available for the shares of any class or series of stock of a constituent corporation in a merger or consolidation to be effected pursuant to § 251 (other than a merger effected pursuant to § 251(g) of this title), § 252, § 254, § 255, § 256, § 257, § 258, § 263 or § 264 of this title:

(1) Provided, however, that, except as expressly provided in § 363(b) of this title, no appraisal rights under this section shall be available for the shares of any class or series of stock, which stock, or depository receipts in respect thereof, at the record date fixed to determine the stockholders entitled to receive notice of the meeting of stockholders to act upon the agreement of merger or consolidation (or, in the case of a merger pursuant to § 251(h), as of immediately prior to the execution of the agreement of merger), were either: (i) listed on a national securities exchange or (ii) held of record by more than 2,000 holders; and further provided that no appraisal rights shall be available for any shares of stock of the constituent corporation surviving a merger if the merger did not require for its approval the vote of the stockholders of the surviving corporation as provided in § 251(f) of this title.

(2) Notwithstanding paragraph (b)(1) of this section, appraisal rights under this section shall be available for the shares of any class or series of stock of a constituent corporation if the holders thereof are required by the terms of an agreement of merger or consolidation pursuant to §§ 251, 252, 254, 255, 256, 257, 258, 263 and 264 of this title to accept for such stock anything except:

- a. Shares of stock of the corporation surviving or resulting from such merger or consolidation, or depository receipts in respect thereof;
- b. Shares of stock of any other corporation, or depository receipts in respect thereof, which shares of stock (or depository receipts in respect thereof) or depository receipts at the effective date of the merger or consolidation will be either listed on a national securities exchange or held of record by more than 2,000 holders;
- c. Cash in lieu of fractional shares or fractional depository receipts described in the foregoing paragraphs (b)(2)a. and b. of this section; or
- d. Any combination of the shares of stock, depository receipts and cash in lieu of fractional shares or fractional depository receipts described in the foregoing paragraphs (b)(2)a., b. and c. of this section.

(3) In the event all of the stock of a subsidiary Delaware corporation party to a merger effected under § 253 or § 267 of this title is not owned by the parent immediately prior to the merger, appraisal rights shall be available for the shares of the subsidiary Delaware corporation.

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(4) In the event of an amendment to a corporation's certificate of incorporation contemplated by § 363(a) of this title, appraisal rights shall be available as contemplated by § 363(b) of this title, and the procedures of this section, including those set forth in subsections (d) and (e) of this section, shall apply as nearly as practicable, with the word "amendment" substituted for the words "merger or consolidation," and the word "corporation" substituted for the words "constituent corporation" and/or "surviving or resulting corporation."

(c) Any corporation may provide in its certificate of incorporation that appraisal rights under this section shall be available for the shares of any class or series of its stock as a result of an amendment to its certificate of incorporation, any merger or consolidation in which the corporation is a constituent corporation or the sale of all or substantially all of the assets of the corporation. If the certificate of incorporation contains such a provision, the provisions of this section, including those set forth in subsections (d), (e), and (g) of this section, shall apply as nearly as is practicable.

(d) Appraisal rights shall be perfected as follows:

(1) If a proposed merger or consolidation for which appraisal rights are provided under this section is to be submitted for approval at a meeting of stockholders, the corporation, not less than 20 days prior to the meeting, shall notify each of its stockholders who was such on the record date for notice of such meeting (or such members who received notice in accordance with § 255(c) of this title) with respect to shares for which appraisal rights are available pursuant to subsection (b) or (c) of this section that appraisal rights are available for any or all of the shares of the constituent corporations, and shall include in such notice a copy of this section and, if 1 of the constituent corporations is a nonstock corporation, a copy of § 114 of this title. Each stockholder electing to demand the appraisal of such stockholder's shares shall deliver to the corporation, before the taking of the vote on the merger or consolidation, a written demand for appraisal of such stockholder's shares. Such demand will be sufficient if it reasonably informs the corporation of the identity of the stockholder and that the stockholder intends thereby to demand the appraisal of such stockholder's shares. A proxy or vote against the merger or consolidation shall not constitute such a demand. A stockholder electing to take such action must do so by a separate written demand as herein provided. Within 10 days after the effective date of such merger or consolidation, the surviving or resulting corporation shall notify each stockholder of each constituent corporation who has complied with this subsection and has not voted in favor of or consented to the merger or consolidation of the date that the merger or consolidation has become effective; or

(2) If the merger or consolidation was approved pursuant to § 228, § 251(h), § 253, or § 267 of this title, then either a constituent corporation before the effective date of the merger or consolidation or the surviving or resulting corporation within 10 days thereafter shall notify each of the holders of any class or series of stock of such constituent corporation who are entitled to appraisal rights of the approval of the merger or consolidation and that appraisal rights are available for any or all shares of such class or series of stock of such constituent corporation, and shall include in such notice a copy of this section and, if 1 of the constituent corporations is a nonstock corporation, a copy of § 114 of this title. Such notice may, and, if given on or after the effective date of the merger or consolidation, shall, also notify such stockholders of the effective date of the merger or consolidation. Any stockholder entitled to appraisal rights may, within 20 days after the date of mailing of such notice or, in the case of a merger approved pursuant to § 251(h) of this title, within the later of the consummation of the offer contemplated by § 251(h) of this title and 20 days after the date of mailing of such notice, demand in writing from the surviving or resulting corporation the appraisal of such holder's shares. Such demand will be sufficient if it reasonably informs the corporation of the identity of the stockholder and that the stockholder intends thereby to demand the appraisal of such holder's shares. If such notice did not notify stockholders of the effective date of the merger or consolidation, either (i) each such constituent corporation shall send a second notice before the effective date of the merger or consolidation notifying each of the holders of any class or series of stock of such constituent corporation that are entitled to appraisal rights of the effective date of the merger or consolidation or (ii) the surviving or resulting corporation shall send such a second notice to all such holders on or within 10 days after such effective date; provided, however, that if such second notice is sent more than 20 days following the sending of the first notice or, in the case of a merger approved pursuant to § 251(h) of this

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title, later than the later of the consummation of the offer contemplated by § 251(h) of this title and 20 days following the sending of the first notice, such second notice need only be sent to each stockholder who is entitled to appraisal rights and who has demanded appraisal of such holder's shares in accordance with this subsection. An affidavit of the secretary or assistant secretary or of the transfer agent of the corporation that is required to give either notice that such notice has been given shall, in the absence of fraud, be prima facie evidence of the facts stated therein. For purposes of determining the stockholders entitled to receive either notice, each constituent corporation may fix, in advance, a record date that shall be not more than 10 days prior to the date the notice is given, provided, that if the notice is given on or after the effective date of the merger or consolidation, the record date shall be such effective date. If no record date is fixed and the notice is given prior to the effective date, the record date shall be the close of business on the day next preceding the day on which the notice is given.

(e) Within 120 days after the effective date of the merger or consolidation, the surviving or resulting corporation or any stockholder who has complied with subsections (a) and (d) of this section hereof and who is otherwise entitled to appraisal rights, may commence an appraisal proceeding by filing a petition in the Court of Chancery demanding a determination of the value of the stock of all such stockholders. Notwithstanding the foregoing, at any time within 60 days after the effective date of the merger or consolidation, any stockholder who has not commenced an appraisal proceeding or joined that proceeding as a named party shall have the right to withdraw such stockholder's demand for appraisal and to accept the terms offered upon the merger or consolidation. Within 120 days after the effective date of the merger or consolidation, any stockholder who has complied with the requirements of subsections (a) and (d) of this section hereof, upon written request, shall be entitled to receive from the corporation surviving the merger or resulting from the consolidation a statement setting forth the aggregate number of shares not voted in favor of the merger or consolidation (or, in the case of a merger approved pursuant to § 251(h) of this title, the aggregate number of shares (other than any excluded stock (as defined in § 251(h)(6)d. of this title)) that were the subject of, and were not tendered into, and accepted for purchase or exchange in, the offer referred to in § 251(h)(2)), and, in either case, with respect to which demands for appraisal have been received and the aggregate number of holders of such shares. Such written statement shall be mailed to the stockholder within 10 days after such stockholder's written request for such a statement is received by the surviving or resulting corporation or within 10 days after expiration of the period for delivery of demands for appraisal under subsection (d) of this section hereof, whichever is later. Notwithstanding subsection (a) of this section, a person who is the beneficial owner of shares of such stock held either in a voting trust or by a nominee on behalf of such person may, in such person's own name, file a petition or request from the corporation the statement described in this subsection.

(f) Upon the filing of any such petition by a stockholder, service of a copy thereof shall be made upon the surviving or resulting corporation, which shall within 20 days after such service file in the office of the Register in Chancery in which the petition was filed a duly verified list containing the names and addresses of all stockholders who have demanded payment for their shares and with whom agreements as to the value of their shares have not been reached by the surviving or resulting corporation. If the petition shall be filed by the surviving or resulting corporation, the petition shall be accompanied by such a duly verified list. The Register in Chancery, if so ordered by the Court, shall give notice of the time and place fixed for the hearing of such petition by registered or certified mail to the surviving or resulting corporation and to the stockholders shown on the list at the addresses therein stated. Such notice shall also be given by 1 or more publications at least 1 week before the day of the hearing, in a newspaper of general circulation published in the City of Wilmington, Delaware or such publication as the Court deems advisable. The forms of the notices by mail and by publication shall be approved by the Court, and the costs thereof shall be borne by the surviving or resulting corporation.

(g) At the hearing on such petition, the Court shall determine the stockholders who have complied with this section and who have become entitled to appraisal rights. The Court may require the stockholders who have demanded an appraisal for their shares and who hold stock represented by certificates to submit their certificates of stock to the Register in Chancery for notation thereon of the pendency of the appraisal proceedings; and if any stockholder fails to comply with such direction, the Court may dismiss the proceedings as to such stockholder. If immediately before the merger or consolidation the shares of the class or series of stock of the constituent

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corporation as to which appraisal rights are available were listed on a national securities exchange, the Court shall dismiss the proceedings as to all holders of such shares who are otherwise entitled to appraisal rights unless (1) the total number of shares entitled to appraisal exceeds 1% of the outstanding shares of the class or series eligible for appraisal, (2) the value of the consideration provided in the merger or consolidation for such total number of shares exceeds \$1 million, or (3) the merger was approved pursuant to § 253 or § 267 of this title.

(h) After the Court determines the stockholders entitled to an appraisal, the appraisal proceeding shall be conducted in accordance with the rules of the Court of Chancery, including any rules specifically governing appraisal proceedings. Through such proceeding the Court shall determine the fair value of the shares exclusive of any element of value arising from the accomplishment or expectation of the merger or consolidation, together with interest, if any, to be paid upon the amount determined to be the fair value. In determining such fair value, the Court shall take into account all relevant factors. Unless the Court in its discretion determines otherwise for good cause shown, and except as provided in this subsection, interest from the effective date of the merger through the date of payment of the judgment shall be compounded quarterly and shall accrue at 5% over the Federal Reserve discount rate (including any surcharge) as established from time to time during the period between the effective date of the merger and the date of payment of the judgment. At any time before the entry of judgment in the proceedings, the surviving corporation may pay to each stockholder entitled to appraisal an amount in cash, in which case interest shall accrue thereafter as provided herein only upon the sum of (1) the difference, if any, between the amount so paid and the fair value of the shares as determined by the Court, and (2) interest theretofore accrued, unless paid at that time. Upon application by the surviving or resulting corporation or by any stockholder entitled to participate in the appraisal proceeding, the Court may, in its discretion, proceed to trial upon the appraisal prior to the final determination of the stockholders entitled to an appraisal. Any stockholder whose name appears on the list filed by the surviving or resulting corporation pursuant to subsection (f) of this section and who has submitted such stockholder's certificates of stock to the Register in Chancery, if such is required, may participate fully in all proceedings until it is finally determined that such stockholder is not entitled to appraisal rights under this section.

(i) The Court shall direct the payment of the fair value of the shares, together with interest, if any, by the surviving or resulting corporation to the stockholders entitled thereto. Payment shall be so made to each such stockholder, in the case of holders of uncertificated stock forthwith, and the case of holders of shares represented by certificates upon the surrender to the corporation of the certificates representing such stock. The Court's decree may be enforced as other decrees in the Court of Chancery may be enforced, whether such surviving or resulting corporation be a corporation of this State or of any state.

(j) The costs of the proceeding may be determined by the Court and taxed upon the parties as the Court deems equitable in the circumstances. Upon application of a stockholder, the Court may order all or a portion of the expenses incurred by any stockholder in connection with the appraisal proceeding, including, without limitation, reasonable attorney's fees and the fees and expenses of experts, to be charged pro rata against the value of all the shares entitled to an appraisal.

(k) From and after the effective date of the merger or consolidation, no stockholder who has demanded appraisal rights as provided in subsection (d) of this section shall be entitled to vote such stock for any purpose or to receive payment of dividends or other distributions on the stock (except dividends or other distributions payable to stockholders of record at a date which is prior to the effective date of the merger or consolidation); provided, however, that if no petition for an appraisal shall be filed within the time provided in subsection (e) of this section, or if such stockholder shall deliver to the surviving or resulting corporation a written withdrawal of such stockholder's demand for an appraisal and an acceptance of the merger or consolidation, either within 60 days after the effective date of the merger or consolidation as provided in subsection (e) of this section or thereafter with the written approval of the corporation, then the right of such stockholder to an appraisal shall cease. Notwithstanding the foregoing, no appraisal proceeding in the Court of Chancery shall be dismissed as to any stockholder without the approval of the Court, and such approval may be conditioned upon such terms as the Court deems just; provided, however that this provision shall not affect the right of any stockholder who has not

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commenced an appraisal proceeding or joined that proceeding as a named party to withdraw such stockholder's demand for appraisal and to accept the terms offered upon the merger or consolidation within 60 days after the effective date of the merger or consolidation, as set forth in subsection (e) of this section.

(l) The shares of the surviving or resulting corporation to which the shares of such objecting stockholders would have been converted had they assented to the merger or consolidation shall have the status of authorized and unissued shares of the surviving or resulting corporation.

**CERTIFICATE OF AMENDMENT  
OF THE SIXTH AMENDED AND RESTATED CERTIFICATE OF  
INCORPORATION  
OF  
HISTOGENICS CORPORATION**

Histogenics Corporation (the “**Corporation**”), a corporation organized and existing under and by virtue of the provisions of the General Corporation Law of the State of Delaware (the “**General Corporation Law**”):

**DOES HEREBY CERTIFY:**

**FIRST:** That the name of this Corporation is Histogenics Corporation. The original certificate of incorporation of this Corporation was originally filed with the office of the Secretary of State of the State of Delaware on July 14, 2006 under the name Histogenics Corporation.

**SECOND:** That the Board of Directors duly adopted resolutions proposing to amend the Sixth Amended and Restated Certificate of Incorporation (the “**Restated Certificate**”) of this Corporation, declaring said amendment to be advisable and in the best interests of this Corporation and its stockholders, and authorizing the appropriate officers of this Corporation to solicit the consent of the stockholders therefor, which resolutions setting forth the proposed amendments are as follows:

**RESOLVED,** that Article IV of the Restated Certificate be amended by adding a new paragraph immediately prior to Paragraph A which reads as follows:

“Effective as of immediately upon the filing of this Certificate of Amendment to the Sixth Amended and Restated Certificate of Incorporation with the office of the Secretary of State of the State of Delaware (the “**Effective Time**”), each \* issued shares of each series of Preferred Stock and Common Stock shall be combined and changed into 1 share of such series of Preferred Stock or Common Stock, as applicable (the “**Reverse Stock Split**”), which shares shall be fully paid and nonassessable. The Corporation shall not issue to any holder a fractional share of Common Stock on account of the Reverse Stock Split. Rather, any fractional share of Common Stock resulting from such change shall be rounded upward to the nearest whole share of Common Stock. Share interests issued due to rounding are given solely to save the expense and inconvenience of issuing fractional shares of Common Stock and do not represent separately bargained for consideration. Such Reverse Stock Split shall occur whether or not certificates representing any stockholder’s shares held prior to the Reverse Stock Split are surrendered for cancellation.”

\*Number between thirty (30) and forty (40) as determined by the Board of Directors in its sole discretion.

**THIRD:** The foregoing amendment was approved by the holders of the requisite number of shares of this Corporation in accordance with Sections 211 and 242 of the General Corporation Law.

**FOURTH:** Other than as set forth in this Certificate of Amendment, the Sixth Amended and Restated Certificate of Incorporation shall remain in full force and effect, without modification, amendment or change.

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**IN WITNESS WHEREOF**, the Corporation has caused this Certificate of Amendment to be signed this    day of                    ,                    .

HISTOGENICS CORPORATION

By: \_\_\_\_\_  
Adam Gridley, President

**CERTIFICATE OF AMENDMENT  
OF THE SIXTH AMENDED AND RESTATED CERTIFICATE OF  
INCORPORATION  
OF  
HISTOGENICS CORPORATION**

Histogenics Corporation (the “**Corporation**”), a corporation organized and existing under and by virtue of the provisions of the General Corporation Law of the State of Delaware (the “**General Corporation Law**”):

**DOES HEREBY CERTIFY:**

**FIRST:** That the name of this Corporation is Histogenics Corporation. The original certificate of incorporation of this Corporation was originally filed with the office of the Secretary of State of the State of Delaware on July 14, 2006 under the name Histogenics Corporation.

**SECOND:** That the Board of Directors duly adopted resolutions proposing to amend the Sixth Amended and Restated Certificate of Incorporation (the “**Restated Certificate**”) of this Corporation, declaring said amendment to be advisable and in the best interests of this Corporation and its stockholders, and authorizing the appropriate officers of this Corporation to solicit the consent of the stockholders therefor, which resolutions setting forth the proposed amendments are as follows:

**RESOLVED**, that Article I of the Restated Certificate be amended and restated in its entirety as follows:

“The name of this corporation is Ocugen, Inc. (the “**Corporation**”)”

**THIRD:** The foregoing amendment was approved by the holders of the requisite number of shares of this Corporation in accordance with Sections 211 and 242 of the General Corporation Law.

**FOURTH:** Other than as set forth in this Certificate of Amendment, the Sixth Amended and Restated Certificate of Incorporation shall remain in full force and effect, without modification, amendment or change.

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**IN WITNESS WHEREOF**, the Corporation has caused this Certificate of Amendment to be signed this    day of                    ,                    .

HISTOGENICS CORPORATION

By: \_\_\_\_\_  
Adam Gridley, President

**CERTIFICATE OF AMENDMENT  
OF THE SIXTH AMENDED AND RESTATED CERTIFICATE OF  
INCORPORATION  
OF  
HISTOGENICS CORPORATION**

Histogenics Corporation (the “**Corporation**”), a corporation organized and existing under and by virtue of the provisions of the General Corporation Law of the State of Delaware (the “**General Corporation Law**”):

**DOES HEREBY CERTIFY:**

**FIRST:** That the name of this Corporation is Histogenics Corporation. The original certificate of incorporation of this Corporation was originally filed with the office of the Secretary of State of the State of Delaware on July 14, 2006 under the name Histogenics Corporation.

**SECOND:** That the Board of Directors duly adopted resolutions proposing to amend the Sixth Amended and Restated Certificate of Incorporation (the “**Restated Certificate**”) of this Corporation, declaring said amendment to be advisable and in the best interests of this Corporation and its stockholders, and authorizing the appropriate officers of this Corporation to solicit the consent of the stockholders therefor, which resolutions setting forth the proposed amendments are as follows:

**RESOLVED**, that Article IV of the Restated Certificate be amended by amending and restating Paragraph A in its entirety as follows:

“A. The total number of shares of all classes of stock which the Corporation shall have authority to issue is two hundred and ten million (210,000,000), consisting of two hundred million (200,000,000) shares of Common Stock, par value \$0.01 per share (the “Common Stock”), and ten million (10,000,000) shares of Preferred Stock, par value \$0.01 per share (the “Preferred Stock”).”

**THIRD:** The foregoing amendment was approved by the holders of the requisite number of shares of this Corporation in accordance with Sections 211 and 242 of the General Corporation Law.

**FOURTH:** Other than as set forth in this Certificate of Amendment, the Sixth Amended and Restated Certificate of Incorporation shall remain in full force and effect, without modification, amendment or change.

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**IN WITNESS WHEREOF**, the Corporation has caused this Certificate of Amendment to be signed this    day of                    ,                    .

HISTOGENICS CORPORATION

By: \_\_\_\_\_  
Adam Gridley, President

**PART II**

**INFORMATION NOT REQUIRED IN PROXY STATEMENT/PROSPECTUS/INFORMATION STATEMENT**

**Item 20—Indemnification and Officers**

Subsection (a) of Section 145 of the General Corporation Law of the State of Delaware (the “DGCL”) empowers a corporation to indemnify any person who was or is a party or who is threatened to be made a party to any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative (other than an action by or in the right of the corporation) by reason of the fact that the person is or was a director, officer, employee or agent of the corporation, or is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise, against expenses (including attorneys’ fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by the person in connection with such action, suit or proceeding if the person acted in good faith and in a manner the person reasonably believed to be in or not opposed to the best interests of the corporation, and, with respect to any criminal action or proceeding, had no reasonable cause to believe the person’s conduct was unlawful.

Subsection (b) of Section 145 empowers a corporation to indemnify any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action or suit by or in the right of the corporation to procure a judgment in its favor by reason of the fact that the person acted in any of the capacities set forth above, against expenses (including attorneys’ fees) actually and reasonably incurred by the person in connection with the defense or settlement of such action or suit if the person acted in good faith and in a manner the person reasonably believed to be in or not opposed to the best interests of the corporation, except that no indemnification shall be made in respect of any claim, issue or matter as to which such person shall have been adjudged to be liable to the corporation unless and only to the extent that the Court of Chancery or the court in which such action or suit was brought shall determine upon application that, despite the adjudication of liability but in view of all the circumstances of the case, such person is fairly and reasonably entitled to indemnity for such expenses which the Court of Chancery or such other court shall deem proper.

Section 145 further provides that to the extent a director or officer of a corporation has been successful on the merits or otherwise in the defense of any action, suit or proceeding referred to in subsections (a) and (b) of Section 145, or in defense of any claim, issue or matter therein, such person shall be indemnified against expenses (including attorneys’ fees) actually and reasonably incurred by such person in connection therewith; that indemnification provided for by Section 145 shall not be deemed exclusive of any other rights to which the indemnified party may be entitled; and the indemnification provided for by Section 145 shall, unless otherwise provided when authorized or ratified, continue as to a person who has ceased to be a director, officer, employee or agent and shall inure to the benefit of such person’s heirs, executors and administrators. Section 145 also empowers the corporation to purchase and maintain insurance on behalf of any person who is or was a director, officer, employee or agent of the corporation, or is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise against any liability asserted against such person and incurred by such person in any such capacity, or arising out of his status as such, whether or not the corporation would have the power to indemnify such person against such liabilities under Section 145.

Section 102(b)(7) of the DGCL provides that a corporation’s certificate of incorporation may contain a provision eliminating or limiting the personal liability of a director to the corporation or its stockholders for monetary damages for breach of fiduciary duty as a director, provided that such provision shall not eliminate or limit the liability of a director (i) for any breach of the director’s duty of loyalty to the corporation or its stockholders, (ii) for acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law, (iii) under Section 174 of the DGCL or (iv) for any transaction from which the director derived an improper personal benefit.

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Histogenics' sixth amended and restated certificate of incorporation provides that to the fullest extent permitted by the DGCL, a director of Histogenics shall not be personally liable to Histogenics or its stockholders for monetary damages for breach of fiduciary duty as a director. Histogenics' amended and restated bylaws provide that to the fullest extent permitted by applicable law as it presently exists or may hereafter be amended, any person who was or is made or is threatened to be made a party or is otherwise involved in any action, suit or proceeding, whether civil, criminal administrative or investigative, by reason of the fact that the person is or was a director, officer, employee or agent of the corporation, is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation or of a partnership, joint venture, trust, or other enterprise, against all expense, liability and loss actually and reasonably incurred or suffered by such person in connection with such action, suit or proceeding.

Histogenics entered into indemnification agreements with its directors and executive officers, in addition to the indemnification provided for in its sixth amended and restated certificate of incorporation and amended and restated bylaws, and intends to enter into indemnification agreements with any new directors and executive officers in the future.

Histogenics has purchased and intends to maintain insurance on behalf of any person who is or was a director or officer of Histogenics against any loss arising from any claim asserted against him or her and incurred by him or her in any such capacity, subject to certain inclusions.

Pursuant to the terms of the Merger Agreement, from the Effective Time through the sixth anniversary of the date on which the Effective Time occurs, Histogenics must indemnify and hold harmless each person who is now, or has been at any time prior to the date thereof, or who becomes prior to the Effective Time, a director or officer of Histogenics or Ocugen, respectively, against all claims, losses, liabilities, damages, judgments, fines and reasonable fees, costs and expenses, including attorney's fees and disbursements, incurred in connection with any claim, action, suit, proceeding or investigation, whether civil or criminal, administrative or investigative, arising out of or pertaining to the fact that the director or officer is or was a director or officer of Histogenics or of Ocugen, whether asserted or claimed prior to, at or after the Effective time, in each case, to the fullest extent permitted under the DGCL. Each such person will also be entitled to advancement of expenses incurred in the defense of any such claim, action, suit, proceeding or investigation, provided that such person provides an undertaking required by the DGCL, to repay such advances if it is ultimately determined that such person is not entitled to indemnification. From and after the Effective Time, Histogenics must maintain directors' and officers' liability insurance policies, with an effective date as of the closing date of the merger, on commercially available terms and conditions and with coverage limits customary for U.S. public companies similarly situated to Histogenics. In addition, Histogenics shall purchase, prior to the Effective Time, a six-year prepaid "tail policy" for the non-cancellable extension of the directors' and officers' liability coverage of Histogenics' existing directors' and officers' insurance policies for a claims reporting or discovery period of at least six years from and after the Effective time with respect to any claim related to any period of time at or prior to the Effective Time.

Further, pursuant to the terms of the Merger Agreement, the provisions of the sixth amended and restated certificate of incorporation and amended and restated bylaws of Histogenics with respect to indemnification, advancement of expenses and exculpation of present and former directors and officers of Histogenics shall not be amended, modified or repealed for a period of six years from the Effective Time in a manner that would adversely affect the rights thereunder of individuals who, at or prior to the Effective Time, were officers or directors of Histogenics.

### **Item 21—Exhibits**

#### ***(a) Exhibit Index***

A list of exhibits filed with this registration statement on Form S-4 is set forth on the Exhibit Index and is incorporated herein by reference.

**(b) Financial Statements**

The financial statements filed with this registration statement on Form S-4 are set forth on the Financial Statement Index and are incorporated herein by reference.

**Item 22—Undertakings**

(a) The undersigned registrant hereby undertakes as follows:

(1) To deliver or cause to be delivered with the prospectus, to each person to whom the prospectus is sent or given, the latest annual report to security holders that is incorporated by reference in the prospectus and furnished pursuant to and meeting the requirements of Rule 14a-3 or Rule 14c-3 under the Securities Exchange Act of 1934; and, where interim financial information required to be presented by Article 3 of Regulation S-X are not set forth in the prospectus, to deliver, or cause to be delivered to each person to whom the prospectus is sent or given, the latest quarterly report that is specifically incorporated by reference in the prospectus to provide such interim financial information.

(2) That prior to any public reoffering of the securities registered hereunder through use of a proxy statement/prospectus/information statement which is a part of this registration statement, by any person or party who is deemed to be an underwriter within the meaning of Rule 145(c), the issuer undertakes that such reoffering proxy statement/prospectus/information statement will contain the information called for by the applicable registration form with respect to reofferings by persons who may be deemed underwriters, in addition to the information called for by the other Items of the applicable form.

(3) That every proxy statement/prospectus/information statement (i) that is filed pursuant to paragraph (a)(1) immediately preceding, or (ii) that purports to meet the requirements of Section 10(a)(3) of the Securities Act and is used in connection with an offering of securities subject to Rule 415, will be filed as a part of an amendment to the registration statement and will not be used until such amendment is effective, and that, for purposes of determining any liability under the Securities Act, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

(b) The undersigned registrant hereby undertakes to respond to requests for information that is incorporated by reference into the prospectus pursuant to Items 4, 10(b), 11, or 13 of this Form, within one business day of receipt of such request, and to send the incorporated documents by first class mail or other equally prompt means. This includes information contained in documents filed subsequent to the effective date of the registration statement through the date of responding to the request.

(c) The undersigned registrant hereby undertakes to supply by means of a post-effective amendment all information concerning a transaction, and the company being acquired involved therein, that was not the subject of and included in the registration statement when it became effective.

(d) Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

INDEX TO EXHIBITS

<u>Exhibit</u>	<u>Description</u>
2.1	<a href="#">Agreement and Plan of Merger and Reorganization, dated April 5, 2019, by and among the Registrant, Ocugen, Inc. and Restore Merger Sub, Inc. (filed as Exhibit 2.1 to the Registrant's Current Report on Form 8-K as filed on April 8, 2019, and incorporated herein by reference)</a>
2.2	<a href="#">Consent and Amendment No. 1 to Agreement and Plan of Merger and Reorganization, dated June 13, 2019, by and among the Registrant, Ocugen, Inc. and Restore Merger Sub, Inc. (filed as Exhibit 2.1 to the Registrant's Current Report on Form 8-K as filed on June 14, 2019, and incorporated herein by reference)</a>
2.3	<a href="#">Form of the Registrant's Voting Agreement, dated April 5, 2019, by and between the Registrant, Ocugen, Inc. and each of the parties named in each agreement therein (filed as Exhibit 2.2 to the Registrant's Current Report on Form 8-K as filed on April 8, 2019, and incorporated herein by reference)</a>
2.4	<a href="#">Form of Ocugen, Inc.'s Voting Agreement, dated April 5, 2019, by and between Ocugen, Inc., the Registrant and each of the parties named in each agreement therein (filed as Exhibit 2.3 to the Registrant's Current Report on Form 8-K as filed on April 8, 2019, and incorporated herein by reference)</a>
2.5	<a href="#">Form of Lock-Up Agreement, dated April 5, 2019, by each of the parties named in each agreement therein (filed as Exhibit 2.4 to the Registrant's Current Report on Form 8-K as filed on April 8, 2019, and incorporated herein by reference)</a>
3.1	<a href="#">Sixth Amended and Restated Certificate of Incorporation (filed as Exhibit 3.1 to the Registrant's Current Report on Form 8-K as filed on December 8, 2014, and incorporated herein by reference)</a>
3.2	<a href="#">Amended and Restated Bylaws (filed as Exhibit 3.4 to the Registrant's Registration Statement on Form S-1 (SEC File No. 333-199202), as filed on October 7, 2014, and incorporated herein by reference)</a>
3.3	<a href="#">Certificate of Designation of Preferences, Rights and Limitations of Series A Convertible Preferred Stock of Histogenics Corporation (filed as Exhibit 3.3 to the Registrant's Current Report on Form 8-K as filed on September 16, 2016, and incorporated herein by reference)</a>
4.1	<a href="#">Specimen stock certificate evidencing the shares of common stock (filed as Exhibit 4.1 to Amendment No. 3 to the Registrant's Registration Statement on Form S-1 (SEC File No. 333-199202), as filed on November 26, 2014, and incorporated herein by reference)</a>
4.2	<a href="#">Second Amended and Restated Investors' Rights Agreement dated as of December 18, 2013 (filed as Exhibit 4.2 to the Registrant's Registration Statement on Form S-1 (SEC File No. 333-199202), as filed on October 7, 2014, and incorporated herein by reference)</a>
4.3	<a href="#">Second Amended and Restated Stockholders' Agreement dated as of December 18, 2013 (filed as Exhibit 4.3 to the Registrant's Registration Statement on Form S-1 (SEC File No. 333-199202), as filed on October 7, 2014, and incorporated herein by reference)</a>
4.4	<a href="#">Warrant to Purchase Common Stock dated July 9, 2014 issued to Silicon Valley Bank (filed as Exhibit 4.4 to the Registrant's Registration Statement on Form S-1 (SEC File No. 333-199202), as filed on October 7, 2014, and incorporated herein by reference)</a>
4.5	<a href="#">Amended and Restated Royalty Agreement dated as of October 14, 2014 (filed as Exhibit 4.5 to Amendment No. 1 to the Registrant's Registration Statement on Form S-1 (SEC File No. 333-199202), as filed on November 7, 2014, and incorporated herein by reference)</a>
4.6	<a href="#">Registration Rights Agreement dated September 29, 2016 (filed as Exhibit 10.35 to the Registrant's Current Report on Form 8-K as filed on September 29, 2016, and incorporated herein by reference)</a>

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<u>Exhibit</u>	<u>Description</u>
4.8	<a href="#"><u>Warrant to Purchase Common Stock of Histogenics Corporation issued to H.C. Wainwright &amp; Co., LLC dated September 29, 2016 (filed as Exhibit 4.7 to the Registrant's Current Report on Form 8-K as filed on September 29, 2016, and incorporated herein by reference)</u></a>
4.9	<a href="#"><u>Form of Series A/B Investor Warrants (filed as Exhibit 4.1 to the Registrant's Current Report on Form 8-K as filed on June 14, 2019, and incorporated herein by reference)</u></a>
4.10	<a href="#"><u>Form of Series C Investor Warrants (filed as Exhibit 4.2 to the Registrant's Current Report on Form 8-K as filed on June 14, 2019, and incorporated herein by reference)</u></a>
4.11	<a href="#"><u>Registration Rights Agreement, dated June 13, 2019, by and among the Registrant and certain investors named therein (filed as Exhibit 4.3 to the Registrant's Current Report on Form 8-K as filed on June 14, 2019, and incorporated herein by reference)</u></a>
5.1	<a href="#"><u>Opinion of Gunderson Dettmer Stough Villeneuve Franklin &amp; Hachigian, LLP regarding the validity of the securities (filed as Exhibit 5.1 to the Registrant's Registration Statement on Form S-4 (SEC File No. 333-232147), as filed on June 14, 2019, and incorporated herein by reference)</u></a>
10.1	<a href="#"><u>Form of Indemnity Agreement for directors and officers (filed as Exhibit 10.1 to the Registrant's Registration Statement on Form S-1 (SEC File No. 333-199202), as filed on October 7, 2014, and incorporated herein by reference)</u></a>
10.2	<a href="#"><u>2012 Equity Incentive Plan, as amended, and form of option agreement thereunder (filed as Exhibit 10.6 to the Registrant's Registration Statement on Form S-1 (SEC File No. 333-199202), as filed on October 7, 2014, and incorporated herein by reference)</u></a>
10.3	<a href="#"><u>2013 Equity Incentive Plan (filed as Exhibit 10.3 to the Registrant's Current Report on Form 8-K as filed on May 4, 2016, and incorporated herein by reference)</u></a>
10.3A	<a href="#"><u>Amendment No. 1 to 2013 Equity Incentive Plan (filed as Exhibit 10.3A to the Registrant's Registration Statement on Form S-8 (SEC File No. 333-212358), as filed on June 30, 2016, and incorporated herein by reference)</u></a>
10.4	<a href="#"><u>2013 Employee Stock Purchase Plan (filed as Exhibit 10.4 to the Registrant's Current Report on Form 8-K as filed on May 4, 2016, and incorporated herein by reference)</u></a>
10.5†	<a href="#"><u>License Agreement dated as of May 12, 2005 among the Registrant and Angiotech Pharmaceuticals (US), Inc. and Angiodevice International GmbH (filed as Exhibit 10.10 to the Registrant's Registration Statement on Form S-1 (SEC File No. 333-199202), as filed on October 7, 2014, and incorporated herein by reference)</u></a>
10.6†	<a href="#"><u>Amendment to License Agreement dated as of August 31, 2007 among the Registrant and Angiotech Pharmaceuticals (US), Inc. and Angiodevice International GmbH (filed as Exhibit 10.11 to the Registrant's Registration Statement on Form S-1 (SEC File No. 333-199202), as filed on October 7, 2014, and incorporated herein by reference)</u></a>
10.7†	<a href="#"><u>Second Amendment to License Agreement dated as of January 1, 2008 among the Registrant and Angiotech Pharmaceuticals (US), Inc. and Angiodevice International GmbH (filed as Exhibit 10.12 to the Registrant's Registration Statement on Form S-1 (SEC File No. 333-199202), as filed on October 7, 2014, and incorporated herein by reference)</u></a>
10.8†	<a href="#"><u>Third Amendment to License Agreement dated as of April 15, 2008 among the Registrant and Angiotech Pharmaceuticals (US), Inc. and Angiodevice International GmbH (filed as Exhibit 10.13 to the Registrant's Registration Statement on Form S-1 (SEC File No. 333-199202), as filed on October 7, 2014, and incorporated herein by reference)</u></a>
10.9†	<a href="#"><u>Fourth Amendment to License Agreement dated as of November 1, 2008 among the Registrant and Angiotech Pharmaceuticals (US), Inc. and Angiodevice International GmbH (filed as Exhibit 10.14 to the Registrant's Registration Statement on Form S-1 (SEC File No. 333-199202), as filed on October 7, 2014, and incorporated herein by reference)</u></a>



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<u>Exhibit</u>	<u>Description</u>
10.10†	<a href="#"><u>Fifth Amendment to License Agreement dated as of August 6, 2010 among the Registrant and Angiotech Pharmaceuticals (US), Inc. and Angiodevice International GmbH (filed as Exhibit 10.15 to the Registrant's Registration Statement on Form S-1 (SEC File No. 333-199202), as filed on October 7, 2014, and incorporated herein by reference)</u></a>
10.11†	<a href="#"><u>Reinstatement Agreement and Sixth Amendment to License Agreement dated as of February 8, 2011 among the Registrant and Angiotech Pharmaceuticals (US), Inc. and Angiodevice International GmbH (filed as Exhibit 10.16 to the Registrant's Registration Statement on Form S-1 (SEC File No. 333-199202), as filed on October 7, 2014, and incorporated herein by reference)</u></a>
10.12†	<a href="#"><u>Seventh Amendment to License Agreement dated as of March 31, 2011 among the Registrant and Angiotech Pharmaceuticals (US), Inc. and Angiodevice International GmbH (filed as Exhibit 10.17 to the Registrant's Registration Statement on Form S-1 (SEC File No. 333-199202), as filed on October 7, 2014, and incorporated herein by reference)</u></a>
10.13†	<a href="#"><u>Eighth Amendment to License Agreement dated as of June 29, 2012 among the Registrant and Angiotech Pharmaceuticals (US), Inc. and Angiodevice International GmbH (filed as Exhibit 10.18 to the Registrant's Registration Statement on Form S-1 (SEC File No. 333-199202), as filed on October 7, 2014, and incorporated herein by reference)</u></a>
10.14†	<a href="#"><u>Paid-up License Agreement dated as of March 6, 2013 between the Registrant and Koken Co., Ltd. (filed as Exhibit 10.19 to the Registrant's Registration Statement on Form S-1 (SEC File No. 333-199202), as filed on October 7, 2014, and incorporated herein by reference)</u></a>
10.15†	<a href="#"><u>Agreement dated as of June 22, 2012 between the Registrant and Purpose Co., Ltd. f/k/a Takagi Sangyo Co. Ltd. and f/k/a Takagi Industrial Co., Ltd. (filed as Exhibit 10.20 to the Registrant's Registration Statement on Form S-1 (SEC File No. 333-199202), as filed on October 7, 2014, and incorporated herein by reference)</u></a>
10.16†	<a href="#"><u>Exclusive Agreement dated as of April 15, 2001 between the Registrant and The Board of Trustees of The Leland Stanford Junior University (filed as Exhibit 10.21 to the Registrant's Registration Statement on Form S-1 (SEC File No. 333-199202), as filed on October 7, 2014, and incorporated herein by reference)</u></a>
10.17	<a href="#"><u>First Amendment to Exclusive Agreement dated as of October 26, 2005 between the Registrant and The Board of Trustees of The Leland Stanford Junior University (filed as Exhibit 10.22 to the Registrant's Registration Statement on Form S-1 (SEC File No. 333-199202), as filed on October 7, 2014, and incorporated herein by reference)</u></a>
10.18†	<a href="#"><u>Second Amendment to Exclusive Agreement dated as of January 15, 2006 between the Registrant and The Board of Trustees of The Leland Stanford Junior University (filed as Exhibit 10.23 to the Registrant's Registration Statement on Form S-1 (SEC File No. 333-199202), as filed on October 7, 2014, and incorporated herein by reference)</u></a>
10.19†	<a href="#"><u>Amendment No. 3 to the License Agreement Effective 4/15/2001 dated as of May 1, 2009 between the Registrant and The Board of Trustees of The Leland Stanford Junior University (filed as Exhibit 10.24 to the Registrant's Registration Statement on Form S-1 (SEC File No. 333-199202), as filed on October 7, 2014, and incorporated herein by reference)</u></a>
10.20	<a href="#"><u>Amendment No. 4 to the License Agreement Effective 4/15/2001 dated as of April 29, 2010 between the Registrant and The Board of Trustees of The Leland Stanford Junior University (filed as Exhibit 10.25 to the Registrant's Registration Statement on Form S-1 (SEC File No. 333-199202), as filed on October 7, 2014, and incorporated herein by reference)</u></a>
10.21	<a href="#"><u>Lease Agreement dated of June 9, 2006 between the Registrant and Intercontinental Fund III 830 Winter Street LLC (filed as Exhibit 10.28 to the Registrant's Registration Statement on Form S-1 (SEC File No. 333-199202), as filed on October 7, 2014, and incorporated herein by reference)</u></a>

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<u>Exhibit</u>	<u>Description</u>
10.22	<a href="#"><u>First Amendment to Lease dated as of October 1, 2009 between the Registrant and Intercontinental Fund III 830 Winter Street LLC (filed as Exhibit 10.29 to the Registrant's Registration Statement on Form S-1 (SEC File No. 333-199202), as filed on October 7, 2014, and incorporated herein by reference)</u></a>
10.23†	<a href="#"><u>Collagen Technology Transfer Agreement dated as of April 15, 2014 between the Registrant and Advanced BioMatrix, Inc. (filed as Exhibit 10.31 to the Registrant's Registration Statement on Form S-1 (SEC File No. 333-199202), as filed on October 7, 2014, and incorporated herein by reference)</u></a>
10.24†	<a href="#"><u>First Amendment to License Agreement, dated May 9, 2016, between the Registrant and Purpose Co., Ltd., f/k/a Takagi Sangyo Co. Ltd. (filed as Exhibit 10.33 to the Registrant's Quarterly Report on Form 10-Q as filed on August 11, 2016, and incorporated herein by reference)</u></a>
10.25†	<a href="#"><u>License and Commercialization Agreement dated as of December 21, 2017 between the Registrant and MEDINET Co., Ltd. (filed as Exhibit 10.33 to the Registrant's Annual Report on Form 10-K as filed on March 15, 2018, and incorporated herein by reference)</u></a>
10.26	<a href="#"><u>Consulting Agreement, effective December 21, 2018, between the Registrant and Danforth Advisors, LLC (filed as Exhibit 10.2 to the Registrant's Current Report on Form 8-K as filed on December 21, 2018, and incorporated herein by reference)</u></a>
10.27	<a href="#"><u>Separation Agreement dated January 23, 2019 between the Registrant and Donald Haut, Ph.D. (filed as Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q as filed on May 15, 2019, and incorporated herein by reference)</u></a>
10.28	<a href="#"><u>Separation Agreement dated March 18, 2019 between the Registrant and Adam Gridley (filed as Exhibit 10.3 to the Registrant's Quarterly Report on Form 10-Q as filed on May 15, 2019, and incorporated herein by reference)</u></a>
10.29	<a href="#"><u>Separation Agreement dated March 19, 2019 between the Registrant and Stephen Kennedy (filed as Exhibit 10.4 to the Registrant's Quarterly Report on Form 10-Q as filed on May 15, 2019, and incorporated herein by reference)</u></a>
10.30	<a href="#"><u>Ocugen, Inc. 2014 Stock Option Plan (filed as Exhibit 10.30 to the Registrant's Registration Statement on Form S-4 (SEC File No. 333-232147), as filed on June 14, 2019, and incorporated herein by reference)</u></a>
10.31	<a href="#"><u>Form of Incentive Stock Option Agreement under Ocugen, Inc. 2014 Stock Option Plan (filed as Exhibit 10.31 to the Registrant's Registration Statement on Form S-4 (SEC File No. 333-232147), as filed on June 14, 2019, and incorporated herein by reference)</u></a>
10.32	<a href="#"><u>Form of Nonstatutory Stock Option Agreement under Ocugen, Inc. 2014 Stock Option Plan (filed as Exhibit 10.32 to the Registrant's Registration Statement on Form S-4 (SEC File No. 333-232147), as filed on June 14, 2019, and incorporated herein by reference)</u></a>
10.33††	<a href="#"><u>Exclusive License Agreement, effective as of March 3, 2014, between The Regents of the University of Colorado and Ocugen, Inc. (filed as Exhibit 10.33 to the Registrant's Registration Statement on Form S-4 (SEC File No. 333-232147), as filed on June 14, 2019, and incorporated herein by reference)</u></a>
10.34††	<a href="#"><u>First Amendment to the Exclusive License Agreement, dated as of January 3, 2017, by and between The Regents of the University of Colorado and Ocugen, Inc. (filed as Exhibit 10.34 to the Registrant's Registration Statement on Form S-4 (SEC File No. 333-232147), as filed on June 14, 2019, and incorporated herein by reference)</u></a>

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<u>Exhibit</u>	<u>Description</u>
10.35	<a href="#"><u>Letter of Understanding, dated November 8, 2017, between The Regents of the University of Colorado and Ocugen, Inc. (filed as Exhibit 10.35 to the Registrant's Registration Statement on Form S-4 (SEC File No. 333-232147), as filed on June 14, 2019, and incorporated herein by reference)</u></a>
10.36††	<a href="#"><u>Exclusive License Agreement, effective as of February 3, 2016, between The Board of Trustees of the University of Illinois and Ocugen, Inc. (filed as Exhibit 10.36 to the Registrant's Registration Statement on Form S-4 (SEC File No. 333-232147), as filed on June 14, 2019, and incorporated herein by reference)</u></a>
10.37††	<a href="#"><u>Exclusive License Agreement, effective as of December 19, 2017, between The Schepens Eye Research Institute, Inc and Ocugen, Inc. (filed as Exhibit 10.37 to the Registrant's Registration Statement on Form S-4 (SEC File No. 333-232147), as filed on June 14, 2019, and incorporated herein by reference)</u></a>
10.38	<a href="#"><u>Lease Agreement, dated December 19, 2016, by and between Ocugen, Inc. and WPT Land 2 LP (filed as Exhibit 10.38 to the Registrant's Registration Statement on Form S-4 (SEC File No. 333-232147), as filed on June 14, 2019, and incorporated herein by reference)</u></a>
10.38A	<a href="#"><u>First Amendment to Lease Agreement, dated November 27, 2017, by and between the Registrant and WPT Land 2 LP (filed as Exhibit 10.38A to the Registrant's Registration Statement on Form S-4 (SEC File No. 333-232147), as filed on June 14, 2019, and incorporated herein by reference)</u></a>
10.38B	<a href="#"><u>Second Amendment to Lease Agreement, dated November 16, 2018, by and between Ocugen, Inc. and WPT Land 2 LP (filed as Exhibit 10.38B to the Registrant's Registration Statement on Form S-4 (SEC File No. 333-232147), as filed on June 14, 2019, and incorporated herein by reference)</u></a>
10.39	<a href="#"><u>Executive Employment Agreement, dated as of January 1, 2018, by and between Ocugen, Inc. and Shankar Musunuri (filed as Exhibit 10.39 to the Registrant's Registration Statement on Form S-4 (SEC File No. 333-232147), as filed on June 14, 2019, and incorporated herein by reference)</u></a>
10.40	<a href="#"><u>Executive Employment Agreement, dated as of April 3, 2016, by and between Ocugen, Inc. and Daniel Jorgensen (filed as Exhibit 10.40 to the Registrant's Registration Statement on Form S-4 (SEC File No. 333-232147), as filed on June 14, 2019, and incorporated herein by reference)</u></a>
10.41	<a href="#"><u>Executive Employment Agreement, dated December 21, 2016, by and between Ocugen, Inc. and Rasappa Arumugham (filed as Exhibit 10.41 to the Registrant's Registration Statement on Form S-4 (SEC File No. 333-232147), as filed on June 14, 2019, and incorporated herein by reference)</u></a>
10.41A	<a href="#"><u>Amendment to Employment Agreement, dated March 1, 2018, by and between Ocugen, Inc. and Rasappa Arumugham (filed as Exhibit 10.41A to the Registrant's Registration Statement on Form S-4 (SEC File No. 333-232147), as filed on June 14, 2019, and incorporated herein by reference)</u></a>
10.42	<a href="#"><u>Loan and Security Agreement, effective as of September 12, 2016, by and between EB5 Life Sciences, LP and the Registrant (filed as Exhibit 10.42 to the Registrant's Registration Statement on Form S-4/A (SEC File No. 333-232147), as filed on July 23, 2019, and incorporated herein by reference)</u></a>
10.43	<a href="#"><u>Asset Purchase Agreement dated May 8, 2019 by and between the Restistrant and Medavate Corp. (filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K as filed on May 13, 2019, and incorporated herein by reference)</u></a>
10.44	<a href="#"><u>Securities Purchase Agreement, dated as of June 13, 2019, by and among Ocugen, Inc., the Registrant and the investors party thereto (filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K as filed on June 14, 2019, and incorporated herein by reference)</u></a>
10.45	<a href="#"><u>Form of Lock-Up Agreement (filed as Exhibit 10.2 to the Registrant's Current Report on Form 8-K as filed on June 14, 2019, and incorporated herein by reference)</u></a>

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<u>Exhibit</u>	<u>Description</u>
10.46	<a href="#"><u>Securities Purchase Agreement, dated as of May 21, 2019, by and among Ocugen, Inc. and the investors party thereto (filed as Exhibit 10.47 to the Registrant's Registration Statement on Form S-4 (SEC File No. 333-232147), as filed on June 14, 2019, and incorporated herein by reference)</u></a>
10.47	<a href="#"><u>Form of Senior Secured Convertible Note, dated as of May 21, 2019, by Ocugen, Inc. to each of the investors party to the Securities Purchase Agreement, dated as of May 21, 2019 (filed as Exhibit 10.48 to the Registrant's Registration Statement on Form S-4 (SEC File No. 333-232147), as filed on June 14, 2019, and incorporated herein by reference)</u></a>
10.48	<a href="#"><u>Security Agreement, dated as of May 21, 2019, by Ocugen, Inc. in favor of HB Fund LLC, in its capacity as collateral agent for the investors party to the Securities Purchase Agreement, dated as of May 21, 2019 (filed as Exhibit 10.49 to the Registrant's Registration Statement on Form S-4 (SEC File No. 333-232147), as filed on June 14, 2019, and incorporated herein by reference)</u></a>
10.49	<a href="#"><u>Form of Amendment to Securities Purchase Agreement, dated as of June 28, 2019, by and among Histogenics Corporation, Ocugen, Inc. and the investor named therein (filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K as filed on June 14, 2019, and incorporated herein by reference)</u></a>
21.1	<a href="#"><u>List of Subsidiaries (filed as Exhibit 21.1 to the Registrant's Annual Report on Form 10-K as filed on March 27, 2015, and incorporated herein by reference)</u></a>
23.1+	<a href="#"><u>Consent of Grant Thornton LLP, Independent Registered public Accounting Firm to the Registrant</u></a>
23.2+	<a href="#"><u>Consent of Ernst &amp; Young LLP, Independent Registered public Accounting Firm to Ocugen, Inc.</u></a>
24.1	<a href="#"><u>Power of Attorney (filed as Exhibit 24.1 to the Registrant's Registration Statement on Form S-4 (SEC File No. 333-232147), as filed on June 14, 2019, and incorporated herein by reference)</u></a>
99.1	<a href="#"><u>Opinion of Canaccord Genuity LLC, financial advisor to Histogenics Corporation, dated June 13, 2019 (included as Annex B to the proxy statement/prospectus/information statement forming part of this Registration Statement)</u></a>
99.2	<a href="#"><u>Consent of Canaccord Genuity LLC, financial advisor to Histogenics Corporation (filed as Exhibit 99.2 to the Registrant's Registration Statement on Form S-4 (SEC File No. 333-232147), as filed on June 14, 2019, and incorporated herein by reference)</u></a>
99.3	<a href="#"><u>Proposed Restated Certificate of Incorporation of Histogenics Corporation (included as Annex D to the proxy statement/prospectus/information statement forming a part of this Registration Statement)</u></a>
99.4	<a href="#"><u>Proposed Restated Certificate of Incorporation of Histogenics Corporation (included as Annex E to the proxy statement/prospectus/information statement forming a part of this Registration Statement)</u></a>
99.5	<a href="#"><u>Consent of Shankar Musunuri, Ph.D., MBA to be named as a Director (filed as Exhibit 99.5 to the Registrant's Registration Statement on Form S-4 (SEC File No. 333-232147), as filed on June 14, 2019, and incorporated herein by reference)</u></a>
99.6	<a href="#"><u>Consent of Ramesh Kumar, Ph.D. to be named as a Director (filed as Exhibit 99.6 to the Registrant's Registration Statement on Form S-4/A (SEC File No. 333-232147), as filed on July 23, 2019, and incorporated herein by reference)</u></a>
99.7	<a href="#"><u>Consent of Uday Kampella, Ph.D. to be named as a Director (filed as Exhibit 99.7 to the Registrant's Registration Statement on Form S-4 (SEC File No. 333-232147), as filed on June 14, 2019, and incorporated herein by reference)</u></a>
99.8	<a href="#"><u>Consent of Frank Leo to be named as a Director (filed as Exhibit 99.8 to the Registrant's Registration Statement on Form S-4 (SEC File No. 333-232147), as filed on June 14, 2019, and incorporated herein by reference)</u></a>
99.9	<a href="#"><u>Consent of Manish Potti to be named as a Director (filed as Exhibit 99.9 to the Registrant's Registration Statement on Form S-4 (SEC File No. 333-232147), as filed on June 14, 2019, and incorporated herein by reference)</u></a>

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<u>Exhibit</u>	<u>Description</u>
99.10	<a href="#"><u>Consent of Suha Taspolatoglu, M.D. to be named as a Director (filed as Exhibit 99.10 to the Registrant's Registration Statement on Form S-4 (SEC File No. 333-232147), as filed on June 14, 2019, and incorporated herein by reference)</u></a>
99.11	<a href="#"><u>Consent of Junge Zhang to be named as a Director (filed as Exhibit 99.11 to the Registrant's Registration Statement on Form S-4 (SEC File No. 333-232147), as filed on June 14, 2019, and incorporated herein by reference)</u></a>
<hr/>	
+	Filed herewith.
†	Confidential treatment has been granted with respect to certain portions of this exhibit.
††	Portions of this exhibit (indicated by asterisks) have been omitted as the Registrant has determined that (i) the omitted information is not material, and (ii) the omitted information would likely cause competitive harm to the Registrant if publicly disclosed.

**SIGNATURES**

Pursuant to the requirements of the Securities Act of 1933, as amended, the registrant has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized in the City of Boston, Commonwealth of Massachusetts, on the 2nd day of August, 2019.

**Histogenics Corporation**

By: /s/ Adam Gridley

Adam Gridley  
President

Pursuant to the requirements of the Securities Act of 1933, as amended, this registration statement has been signed by the following persons on behalf of the Registrant and in the capacities and on the dates indicated.

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ Adam Gridley</u> Adam Gridley	President and Director ( <i>Principal Executive Officer</i> )	August 2, 2019
<u>/s/ Jonathan Lieber</u> Jonathan Lieber	Interim Chief Financial Officer ( <i>Principal Financial and Accounting Officer</i> )	August 2, 2019
* <u>Joshua Baltzell</u>	Chairman of the Board of Directors	August 2, 2019
<u>/s/ David C. Hood</u> David C. Hood	Director	August 2, 2019
* <u>Susan Washer</u>	Director	August 2, 2019
*By: <u>/s/ Adam Gridley</u> Adam Gridley Attorney-in-fact		

**CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

We have issued our report dated March 21, 2019, with respect to the consolidated financial statements of Histogenics Corporation contained in the Registration Statement and Prospectus. We consent to the use of the aforementioned report in the Registration Statement and Prospectus, and to the use of our names as it appears under the caption "Experts".

/s/ GRANT THORNTON LLP

Hartford, Connecticut  
August 2, 2019

**Consent of Independent Registered Public Accounting Firm**

We consent to the reference to our firm under the caption “Experts” and to the use of our report dated June 14, 2019, with respect to the consolidated financial statements of Ocugen, Inc. included in the Proxy Statement of Histogenics Corporation that is made a part of Amendment No. 2 to the Registration Statement (Form S-4 No. 333-232147) and related Prospectus of Histogenics Corporation dated August 2, 2019.

/s/ Ernst & Young LLP

Philadelphia, Pennsylvania  
August 2, 2019