As filed with the Securities and Exchange Commission on October 7, 2019

Registration No. 333-

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM S-3
REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

OCUGEN, INC.
(Exact name of registrant as specified in its charter)

Delaware	**04-3522315**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

5 Great Valley Parkway, Suite 160
Malvern, PA 19355
(484) 328-4701
(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

Shankar Musunuri, Ph.D., MBA
Chief Executive Officer and Chairman
Ocugen, Inc.
5 Great Valley Parkway, Suite 160
Malvern, PA 19355
(484) 328-4701
(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies to:

James W. McKenzie, Jr.
Jacquelynne M. Hamilton
Morgan, Lewis & Bockius LLP
1701 Market Street
Philadelphia, PA 19103
(215) 963-5000

Approximate date of commencement of proposed sale to the public: From time to time after this registration statement becomes effective

If the only securities being registered on this form are being offered pursuant to dividend or interest reinvestment plans, please check the following box. o

If any of the securities being registered on this form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, other than securities offered only in connection with dividend or interest reinvestment plans, check the following box. ☒

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

If this Form is a post-effective amendment filed pursuant to Rule 462(c) 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. o

If this Form is a registration statement pursuant to General Instruction I.D. or a post-effective amendment thereto that shall become effective upon filing with the Commission pursuant to Rule 462(e) under the Securities Act, check the following box. o

If this Form is a post-effective amendment to a registration statement filed pursuant to General Instruction I.D. filed to register additional securities or additional classes of securities pursuant to Rule 413(b) under the Securities Act, check the following box. o

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a 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 o	Accelerated filer o	Non-accelerated filer o	Smaller reporting company ☒ Emerging growth company ☒

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. o

CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities to be Registered	Amount to be Registered(1)	Proposed Maximum Offering Price Per Share(2)	Proposed Maximum Aggregate Offering Price	Amount of Registration Fee
Common Stock, par value $0.01 per share, issuable upon exercise of warrants	111,540,825(3)	$1.93	$215,273,792.25	$27,942.54

(1) Pursuant to Rule 416(a) under the Securities Act of 1933, as amended, this Registration Statement shall also cover any additional shares of the Registrant's Common Stock that become issuable by reason of any stock dividend, stock split, recapitalization or other similar transaction effected without receipt of consideration.

(2) Estimated solely for the purpose of calculating the amount of the registration fee pursuant to Rule 457(c) under the Securities Act of 1933, as amended. The offering price per share and aggregate offering price are based upon the average of the high and low prices for the Registrant's Common Stock as reported on the Nasdaq Capital Market on October 3, 2019, a date within five business days prior to the filing of this Registration Statement.

(3) All 111,540,825 shares of Common Stock issuable upon exercise of the warrants are to be offered by certain of the selling stockholders named herein, which warrants were issued on October 4, 2019 to such selling stockholders pursuant to that certain Securities Purchase Agreement, dated as of June 13, 2019, by and among the Registrant, Ocugen OpCo, Inc. (formerly known as Ocugen, Inc.), a Delaware corporation and the investors listed on the Schedule of Buyers attached thereto, as amended.

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 which 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.

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The information in this prospectus is not complete and may be changed. These securities may not be sold until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

Subject to Completion, dated October 7, 2019

PROSPECTUS

Ocugen, Inc.

111,540,825 Shares of Common Stock

This prospectus of Ocugen, Inc. (formerly known as Histogenics Corporation), a Delaware corporation ("Ocugen"), relates solely to the resale by the investors listed in the section of this prospectus entitled "Selling Stockholders" (the "Selling Stockholders"), of up to 111,540,825 shares of our common stock, par value $0.01 per share ("Common Shares"). The 111,540,825 Common Shares consist solely of Common Shares issuable upon exercise of outstanding warrants to purchase Common Shares (the "Warrants") issued by us on October 4, 2019, pursuant to that certain Securities Purchase Agreement, dated as of June 13, 2019, by and among Ocugen, Ocugen Opco, Inc., a Delaware corporation (formerly known as Ocugen, Inc.) ("Old Ocugen"), and the investors listed on the Schedule of Buyers attached thereto (the "Investors"), as amended (the "Securities Purchase Agreement"). The Warrants are comprised of three series of warrants, the Series A Warrants to Purchase Common Stock (the "Series A Warrants"), the Series B Warrants to Purchase Common Stock (the "Series B Warrants") and the Series C Warrants to Purchase Common Stock (the "Series C Warrants").

The Series A Warrants have an exercise price of $7.13, were exercisable upon issuance and have a term of 60 months from the date of issuance. The Series B Warrants have an exercise price of $0.01, were exercisable upon issuance and will expire on the day following the later to occur of (i) the 45th trading day immediately following 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 Series B Warrants without restriction or limitation pursuant to Rule 144 under the Securities Act of 1933, as amended (the "Securities Act"), and without the requirement to be in compliance with Rule 144(c)(1) and (b) October 4, 2020, 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 C Warrants have an exercise price of $7.13, were exercisable upon issuance 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) October 4, 2020. We are registering the resale of the Common Shares underlying the Warrants (the "Warrant Shares") as required by the Registration Rights Agreement we entered into with the Selling Stockholders on June 13, 2019 (the "Registration Rights Agreement").

Our registration of the Warrant Shares covered by this prospectus does not mean that the Selling Stockholders will offer or sell any of the Warrant Shares. The Selling Stockholders may sell the Warrant Shares covered by this prospectus in a number of different ways and at varying prices. For additional information on the possible methods of sale that may be used by the Selling Stockholders, you should refer to the section of this prospectus entitled "Plan of Distribution" of this prospectus. We will not receive any of the proceeds from the Warrant Shares sold by the Selling Stockholders, other than any proceeds from any cash exercise of the Warrants.

No underwriter or other person has been engaged to facilitate the sale of the Warrant Shares in this offering. The Selling Stockholders may, individually but not severally, be deemed to be an "underwriter" within the meaning of the Securities Act, of the Warrant Shares that they are offering pursuant to this prospectus. We will bear all costs, expenses and fees in connection with the registration of the Warrant Shares. The Selling Stockholders will bear all commissions and discounts, if any, attributable to their respective sales of the Warrant Shares.

You should read this prospectus, any applicable prospectus supplement and any related free writing prospectus carefully before you invest.

Investing in our Common Shares involves a high degree of risk. You should review carefully the risks and uncertainties described under the heading "Risk Factors" contained on page 6 of this prospectus, any applicable prospectus supplement and in any applicable free writing prospectuses, and under similar headings in the documents that are incorporated by reference into this prospectus.

Our Common Shares are currently listed on the Nasdaq Capital Market under the symbol "OCGN". On October 2, 2019, the last reported sales price for our Common Shares was $1.91 per share.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The date of this prospectus is , 2019.

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ABOUT THIS PROSPECTUS

You should rely only on the information we have provided or incorporated by reference into this prospectus, any applicable prospectus supplement and any related free writing prospectus. We have not authorized anyone to provide you with information different from that contained in this prospectus, any applicable prospectus supplement or any related free writing prospectus. No dealer, salesperson or other person is authorized to give any information or to represent anything not contained in this prospectus, any applicable prospectus supplement or any related free writing prospectus. You must not rely on any unauthorized information or representation. This prospectus is an offer to sell only the Warrant Shares offered hereby, but only under circumstances and in jurisdictions where it is lawful to do so. You should assume that the information in this prospectus, any applicable prospectus supplement or any related free writing prospectus is accurate only as of the date on the front of the document and that any information we have incorporated by reference is accurate only as of the date of the document incorporated by reference, regardless of the time of delivery of this prospectus or any sale of a security.

The Selling Stockholders are offering the Warrant Shares only in jurisdictions where such issuances are permitted. The distribution of this prospectus and the issuance of the Warrant Shares in certain jurisdictions may be restricted by law. Persons outside the United States who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to, the issuance of the Warrant Shares and the distribution of this prospectus outside the United States. This prospectus does not constitute, and may not be used in connection with, an offer to sell, or a solicitation of an offer to buy, the Warrant Shares offered by this prospectus by any person in any jurisdiction in which it is unlawful for such person to make such an offer or solicitation.

This prospectus is part of a registration statement that we filed with the Securities and Exchange Commission (the "SEC"), under which the Selling Stockholders may offer from time to time up to an aggregate of 111,540,825 Common Shares in one or more offerings. If required, each time a Selling Stockholder offers Common Shares, in addition to this prospectus, we will provide you with a prospectus supplement that will contain specific information about the terms of that offering. We may also authorize one or more free writing prospectuses to be provided to you that may contain material information relating to that offering. We may also use a prospectus supplement and any related free writing prospectus to add, update or change any of the information contained in this prospectus or in documents we have incorporated by reference. This prospectus, together with any applicable prospectus supplements, any related free writing prospectuses and the documents incorporated by reference into this prospectus, includes all material information relating to this offering. To the extent that any statement that we make in a prospectus supplement is inconsistent with statements made in this prospectus, the statements made in this prospectus will be deemed modified or superseded by those made in a prospectus supplement. Please carefully read both this prospectus and any prospectus supplement together with the additional information described below under "Important Information Incorporated by Reference".

SUMMARY

This summary highlights selected information contained elsewhere in this prospectus or incorporated by reference in this prospectus, and does not contain all of the information that you need to consider in making your investment decision. You should carefully read the entire prospectus, any applicable prospectus supplement and any related free writing prospectus, including the risks of investing in our Common Shares discussed under the heading "Risk Factors" contained in this prospectus, any applicable prospectus supplement and any related free writing prospectus, and under similar headings in the other documents that are incorporated by reference into this prospectus. You should also carefully read the information incorporated by reference into this prospectus, including our financial statements, and the exhibits to the registration statement of which this prospectus forms a part. Unless otherwise mentioned or unless the context requires otherwise, all references in this prospectus to "Ocugen", "the Company", "we", "us", "our" or similar references mean Ocugen, Inc. and its subsidiaries.

The Company

Ocugen is a 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.1

The Merger, Reverse Stock Split and Name Change

On September 27, 2019, Ocugen (formerly known as Histogenics Corporation), completed its business combination with Ocugen Opco, Inc. (formerly known as Ocugen, Inc.) ("Old Ocugen"), in accordance with the terms of the Agreement and Plan of Merger and Reorganization, dated as of April 5, 2019, as amended, by and among Ocugen, Old Ocugen and a wholly-owned subsidiary of Ocugen ("Merger Sub") (the "Merger Agreement"), pursuant to which Merger Sub merged with and into Old Ocugen, with Old Ocugen surviving as a wholly owned subsidiary of Ocugen (the "Merger").

In connection with, and immediately prior to the completion of, the Merger, Ocugen effected a reverse stock split of the Common Shares, at a ratio of 1-for-60 (the "Reverse Stock Split"). Under the terms of the Merger Agreement, Ocugen issued Common Shares to Old Ocugen's stockholders at an exchange rate of 0.4794 Common Shares, after taking into account the Reverse Stock Split, for each share of Old Ocugen's common stock outstanding immediately prior to the Merger. Immediately after completion of the Merger, Ocugen changed its name from "Histogenics Corporation" to "Ocugen, Inc." and the business conducted by Ocugen became the business conducted by Old Ocugen.

Private Placement of Common Shares and Warrants

On September 27, 2019, Ocugen and Old Ocugen completed a previously announced private placement transaction with the Investors for an aggregate purchase price of approximately $25.0 million (the "Purchase Price") whereby, among other things, Old Ocugen issued to the Investors shares of Old Ocugen common stock immediately prior to the Merger (the "Pre-Merger Financing"), pursuant the Securities Purchase Agreement.

At the closing of the Pre-Merger Financing, (i) Old Ocugen issued and sold to the Investors shares of Old Ocugen's common stock (the "Initial Shares" and, as converted pursuant to the exchange rate in the Merger, after giving effect to the Reverse Stock Split, approximately 2.2 million Common Shares, the "Converted Initial Shares"), and (ii) Old Ocugen deposited additional shares of Old Ocugen's common stock (as converted pursuant to the exchange rate in the Merger, after giving effect to the Reverse Stock Split, approximately 2.2 million Common Shares, the "Converted Additional Shares") into escrow for the benefit of the Investors.

On October 4, 2019, the Converted Additional Shares were released from escrow to the Investors because 80% of the volume-weighted average trading price of a share of Ocugen's common stock as quoted on the Nasdaq Capital Market for the first three trading days immediately following the closing date of the Pre-Merger Financing was lower than the price paid by the Investors for the Initial Shares. Also on October 4, 2019, pursuant to the Securities Purchase Agreement, Ocugen issued the Series A Warrants, the Series B Warrants and the Series C Warrants. For a description of the Warrants, see "Description of Capital Stock—Outstanding Warrants."

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 Ocugen common stock up to the amount issuable upon consummation of the merger in exchange for 200% of 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, purchased by the holder.

Series B Warrants

The Series B Warrants have an exercise price per share of $0.01, were exercisable upon issuance and will expire on the day following the later to occur of (i) the 45th trading day immediately following 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 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 (b) October 4, 2020, 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 Ocugen 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 Ocugen 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 45th 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, and (b) April 4, 2020 (such earlier date, the "Six Month Reset Date") and (iii) in the event of a Public Information Failure (as defined in the Securities Purchase Agreement) 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) October 4, 2020 (such 45 trading day period, the "Reset Period" and each such 45th 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 Ocugen 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 are exercisable for up to 50 million Common Shares at an exercise price of $7.13, were exercisable upon issuance 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) October 4, 2020, 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 Ocugen 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 Ocugen common stock equal to the number of Series C Warrants.

RISK FACTORS

Investing in shares of Ocugen common stock involves a high degree of risk. Before making an investment decision, you should carefully consider the risks described below and under "Risk Factors" in any applicable prospectus supplement and in our most recent Annual Report on Form 10-K, or any updates in our Quarterly Reports on Form 10-Q or our Current Reports on Form 8-K, together with all of the other information appearing in or incorporated by reference into this prospectus and any applicable prospectus supplement, before deciding whether to purchase any of the Common Shares being offered. Our business, financial condition or results of operations could be materially adversely affected by any of these risks. The trading price of the Common Shares could decline due to any of these risks, and you may lose all or part of your investment.

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 $9.9 million for the six months ended June 30, 2019, $18.2 million for the year ended December 31, 2018, and $7.8 million for the year ended December 31, 2017. As of June 30, 2019, Ocugen had an accumulated deficit of $41.1 million, a cash and cash equivalents balance of $0.7 million and a working capital deficit of $5.6 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;
- 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 incorporated by reference in this prospectus. 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 June 30, 2019, Ocugen had cash and cash equivalents of approximately $0.7 million. Ocugen believes that its cash and cash equivalents and $25.0 million in funds raised as a result of the private placement transaction completed during September 2019, 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, 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.

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 June 30, 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.

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.

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 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;

- 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;
- 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 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 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;
- 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.

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.

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 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 that 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;
- 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. 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;
- 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 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 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 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;
- 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.

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.

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 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 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, and 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

The trading price of the shares of the Ocugen's common stock could be highly volatile, and purchasers of the Common Shares could incur substantial losses.

Ocugen'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 Ocugen's common stock may be influenced by those factors discussed in this "Risk Factors" section and many others, including:

- Ocugen's ability to enroll subjects in its ongoing and planned clinical trials;
- results of Ocugen's clinical trials and preclinical studies, and the results of trials of Ocugen's competitors or those of other companies in Ocugen's market sector;
- regulatory approval of Ocugen'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 Ocugen's efforts to acquire, license or develop additional product candidates;
- innovations or new products developed by Ocugen or its competitors;
- announcements by Ocugen or its competitors of significant acquisitions, strategic partnerships, joint ventures or capital commitments;
- manufacturing, supply or distribution delays or shortages;
- any changes to Ocugen's relationship with any manufacturers, suppliers, licensors, future collaborators or other strategic partners;
- achievement of expected product sales and profitability;
- variations in Ocugen's financial results or those of companies that are perceived to be similar to Ocugen;
- market conditions in the biopharmaceutical sector and issuance of securities analysts' reports or recommendations;
- trading volume of Ocugen's common stock;
- an inability to obtain additional funding;
- sales of Ocugen's stock by insiders and stockholders;
- general economic, industry and market conditions other events or factors, many of which are beyond Ocugen's control;
- additions or departures of key personnel; and
- intellectual property, product liability or other litigation against Ocugen.

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 Ocugen, could cause Ocugen to incur substantial costs and divert management's attention and resources, which could have a material adverse effect on Ocugen's business, financial condition and results of operations.

Ocugen's failure to meet the continued listing requirements of the Nasdaq could result in a delisting of the Common Shares.

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

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

Ocugen has never declared or paid any cash dividend on the Common Shares. Ocugen currently anticipates that it will retain future earnings for the development, operation and expansion of its

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 Ocugen from paying dividends. Any return to stockholders will therefore be limited to the appreciation of their stock. There is no guarantee that the Common Shares will appreciate in value or even maintain the price at which stockholders have purchased their shares.

Sales of a substantial number of Common Shares by Ocugen's stockholders in the public market could cause Ocugen's stock price to fall.

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

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.

Ocugen began operating as a public company as a result of the Merger. As a public company, Ocugen will incur significant legal, accounting and other expenses that Ocugen did not incur as a private company prior to the Merger. Ocugen is subject to the reporting requirements of the Exchange Act, which require, among other things, that Ocugen files with the U.S. Securities and Exchange Commission (the "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 Ocugen's business, Ocugen's stock price and trading volume could decline.

The trading market for Ocugen's common stock will depend in part on the research and reports that securities or industry analysts publish about Ocugen, 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 Ocugen, the trading price for Ocugen's stock would be negatively impacted. In the event Ocugen obtains securities or industry analyst coverage, if one or more of the analysts who covers Ocugen downgrades its stock, Ocugen's stock price would likely decline. If one or more of these analysts ceases to cover Ocugen or fails to regularly publish reports on Ocugen, interest in Ocugen's stock could decrease, which could cause Ocugen's stock price or trading volume to decline.

If Ocugen 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 Ocugen's financial reporting and the trading price of Ocugen's common stock may decline.

Pursuant to Section 404 of Sarbanes-Oxley, Ocugen's management will be required to report upon the effectiveness of Ocugen's internal control over financial reporting beginning with the annual report for Ocugen's fiscal year ending December 31, 2019. Additionally, if Ocugen reaches an accelerated filer threshold, Ocugen's independent registered public accounting firm will be required to attest to the effectiveness of Ocugen's internal control over financial reporting. The rules governing the standards that must be met for management to assess Ocugen'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, Ocugen 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 Ocugen or, if required, its auditors are unable to conclude that Ocugen's internal control over financial reporting is effective, investors may lose confidence in Ocugen's financial reporting and the trading price of Ocugen's common stock may decline.

Ocugen cannot assure you that there will not be material weaknesses or significant deficiencies in Ocugen's internal control over financial reporting in the future. Any failure to maintain internal control over financial reporting could severely inhibit Ocugen's ability to accurately report its financial condition, results of operations or cash flows. If Ocugen is unable to conclude that its internal control over financial reporting is effective, or if Ocugen's independent registered public accounting firm determines Ocugen has a material weakness or significant deficiency in Ocugen's internal control over financial reporting once that firm begin its Section 404 reviews, investors may lose confidence in the accuracy and completeness of Ocugen's financial reports, the market price of Ocugen's common stock could decline, and Ocugen could be subject to sanctions or investigations by Nasdaq, the SEC or other regulatory authorities. Failure to remedy any material weakness in Ocugen's internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also restrict Ocugen's future access to the capital markets.

Provisions in Ocugen'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 Ocugen that will be in effect immediately after consummation of the merger will contain provisions that could significantly reduce the value of Ocugen's shares to a potential acquiror or delay or prevent changes in control or changes in Ocugen's management without the consent of Ocugen's board of directors. The provisions in Ocugen'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 Ocugen'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 Ocugen'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 Ocugen's board of directors;

- the prohibition on removal of directors without cause due to the classified board of directors;

- the ability of Ocugen'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 Ocugen'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 Ocugen's amended and restated bylaws or repeal certain provisions of Ocugen'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 Ocugen's stockholders to force consideration of a proposal or to take action, including the removal of directors; and

- advance notice procedures that stockholders must comply with in order to nominate candidates to Ocugen'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 Ocugen.

Ocugen 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.

Ocugen's amended and restated bylaws provide that the Court of Chancery of the State of Delaware is the exclusive forum for substantially all disputes between Ocugen and its stockholders, which could limit Ocugen's stockholders' ability to obtain a favorable judicial forum for disputes with Ocugen or its directors, officers or employees.

Ocugen's amended and restated bylaws provide that the Court of Chancery of the State of Delaware is the exclusive forum for any derivative action or proceeding brought on Ocugen's behalf, any action asserting a breach of fiduciary duty, any action asserting a claim against Ocugen arising pursuant to the Delaware General Corporation Law, Ocugen's amended and restated certificate of incorporation or Ocugen's amended and restated bylaws, or any action asserting a claim against Ocugen 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 Ocugen or its directors, officers or other employees, which may discourage such lawsuits against Ocugen and its directors, officers and other employees. By agreeing to this provision, however, stockholders will not be deemed to have waived Ocugen'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 Ocugen's amended and restated bylaws to be inapplicable or unenforceable in an action, Ocugen may incur additional costs associated with resolving such action in other jurisdictions, which could adversely affect Ocugen's business and financial condition.

Ocugen 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 Ocugen, because biotechnology and pharmaceutical companies have experienced significant stock price volatility in recent years. If Ocugen faces such litigation, it could result in substantial costs and a diversion of management's attention and resources, which could harm Ocugen's business.

Ocugen may never pay dividends on its common stock so any returns would be limited to the appreciation of Ocugen's stock.

Ocugen currently anticipates that it will retain future earnings for the development, operation and expansion of Ocugen's business and does 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.

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 combined organization's common stock after closing and in the event of certain dilutive issuances by the combined organization. Even if Ocugen's stock increases in value, the number of shares of Ocugen's common stock issuable upon exercise of the Investor Warrants may still increase. The circumstances under which the number of shares of Ocugen'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 "Description of Capital Stock—Outstanding Warrants," in this prospectus.

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. 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 Shares (including the Common Shares 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 Ocugen's 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.

DISCLOSURE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus and the documents incorporated by reference into this prospectus may contain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), about Ocugen and its subsidiaries. These forward-looking statements are intended to be covered by the safe harbor for forward-looking statements provided by the Private Securities Litigation Reform Act of 1995. Forward-looking statements are not statements of historical fact, and can be identified by the use of forward-looking terminology such as "believes", "expects", "may", "will", "could", "should", "projects", "plans", "goal", "targets", "potential", "estimates", "pro forma", "seeks", "intends" or "anticipates" or the negative thereof or comparable terminology. Forward-looking statements include discussions of strategy, financial projections, guidance and estimates (including their underlying assumptions), statements regarding plans, objectives, expectations or consequences of various transactions, and statements about the future performance, operations, products and services of Ocugen and its subsidiaries. We caution our stockholders and other readers not to place undue reliance on such statements.

You should read this prospectus and the documents incorporated by reference completely and with the understanding that our actual future results may be materially different from what we currently expect. Our business and operations are and will be subject to a variety of risks, uncertainties and other factors. Consequently, actual results and experience may materially differ from those contained in any forward-looking statements. Such risks, uncertainties and other factors that could cause actual results and experience to differ from those projected include, but are not limited to, the risk factors discussed under the heading "Risk Factors" contained in this prospectus, any applicable prospectus supplement and any related free writing prospectus, and under similar headings in the other documents that are incorporated by reference into this prospectus.

You should assume that the information appearing in this prospectus, any accompanying prospectus supplement, any related free writing prospectus and any document incorporated herein by reference is accurate as of its date only. Because the risk factors referred to above could cause actual results or outcomes to differ materially from those expressed in any forward-looking statements made by us or on our behalf, you should not place undue reliance on any forward-looking statements. Further, any forward-looking statement speaks only as of the date on which it is made. New factors emerge from time to time, and it is not possible for us to predict which factors will arise. In addition, we cannot assess the impact of each factor on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements. All written or oral forward-looking statements attributable to us or any person acting on our behalf made after the date of this prospectus are expressly qualified in their entirety by the risk factors and cautionary statements contained in and incorporated by reference into this prospectus. Unless legally required, we do not undertake any obligation to release publicly any revisions to such forward-looking statements to reflect events or circumstances after the date of this prospectus or to reflect the occurrence of unanticipated events.

USE OF PROCEEDS

We will receive no proceeds from the sale of the Securities by the Selling Stockholders. We may, however, receive cash proceeds equal to up to the total exercise price of the Warrants to the extent that the Warrants are exercised for cash. The exercise price of the Series A Warrants is $7.13 per Common Share, the exercise price of the Series B Warrants is $0.01 per Common Share, and the exercise price of the Series C Warrants is $7.13 per Common Share. The exercise price and the number of Common Shares issuable upon exercise of the Warrants may be adjusted in certain circumstances, including stock splits, dividends or distributions, or other similar transactions. However, the Warrants contain a "cashless exercise" feature that allows the holders to exercise the Warrants without making a cash payment to us. In the case of the Series A Warrants, the "cashless exercise" feature is available only in the event that there is no registration statement registering the Warrant Shares for resale. There can be no assurance that any of these Warrants will be exercised by the Selling Stockholders at all or that the Warrants will be exercised for cash rather than pursuant to the "cashless exercise" feature. To the extent we receive proceeds from the cash exercise of the Warrants, we intend to use such proceeds to provide capital support or for general corporate purposes, which may include, without limitation, supporting asset growth and engaging in acquisitions or other business combinations. We do not have any specific plans for acquisitions or other business combinations at this time. Our management will retain broad discretion in the allocation of the net proceeds from the exercise of the Warrants for cash.

The Selling Stockholders will pay any underwriting discounts and commissions and any similar expenses they incur in disposing of the Securities. We will bear all other costs, fees and expenses incurred in effecting the registration of the Securities covered by this prospectus. These may include, without limitation, all registration and filing fees, printing fees and fees and expenses of our counsel and accountants and the fees and disbursements of legal counsel for the Selling Stockholders in connection with the registration of the Warrant Shares covered by this prospectus, in an amount not to exceed $25,000.

SELLING STOCKHOLDERS

The shares of common stock being offered by the Selling Stockholders are those issuable to the Selling Stockholders, upon exercise of the warrants. For additional information regarding the issuances of those shares of common stock and the warrants, see "Summary—Private Placement of Common Shares and Warrants" above. We are registering the Common Stock in order to permit the Selling Stockholders to offer the shares for resale from time to time. Except for the ownership of the shares of common stock and the warrants, the Selling Stockholders have not had any material relationship with us within the past three years.

The table below lists the Selling Stockholders and other information regarding the beneficial ownership of the shares of common stock by each of the Selling Stockholders. The second column lists the number of shares of common stock beneficially owned by each Selling Stockholder, based on its ownership of the shares of common stock and the warrants, as of October 4, 2019, assuming exercise of the warrants held by the Selling Stockholders on that date, without regard to any limitations on exercises.

The third column lists the shares of common stock being offered by this prospectus by the Selling Stockholders.

In accordance with the terms of a registration rights agreement with the Selling Stockholders (the "Registration Rights Agreement"), this prospectus generally covers the resale of the maximum number of shares of common stock issuable upon exercise of the related warrants, determined as if the outstanding warrants were exercised in full as of the trading day immediately preceding the date this registration statement was initially filed with the SEC, each as of the trading day immediately preceding the applicable date of determination and all subject to adjustment as provided in the registration right agreement, without regard to any limitations on the exercise of the warrants and until the earlier to occur of (I) the date the Holder can sell all Underlying Securities pursuant to Rule 144 without restriction or limitation and without the requirement to be in compliance with Rule 144(c)(1) and (II) October 4, 2020. This registration statement registers a number of shares of common stock issued and issuable pursuant to the Series A Warrants, Series B Warrants and Series C Warrants equal to 900% of the sum of (x) the number of Initial Common Shares (as adjusted for stock splits, stock dividends, recapitalizations, reorganizations, reclassification, combinations, reverse stock splits or other similar events occurring after June 13, 2019), (y) the number of Additional Vested Common Shares (as defined in the Registration Rights Agreement) (as adjusted for stock splits, stock dividends, recapitalizations, reorganizations, reclassification, combinations, reverse stock splits or other similar events occurring after the applicable date the Additional Vested Common Shares are delivered), delivered or deliverable to the Buyers pursuant to the Securities Purchase Agreement and (z) the Initial Maximum Eligibility Number (as defined in the Registration Rights Agreement) (as adjusted for stock splits, stock dividends, recapitalizations, reorganizations, reclassification, combinations, reverse stock splits or other similar events occurring after the Closing Date (as defined in the Registration Rights Agreement)) without giving effect to any limitation on exercise set forth in the Warrants or in Section 1(c)(iv) of the Securities Purchase Agreement. The fourth column assumes the sale of all of the shares offered by the Selling Stockholders pursuant to this prospectus.

Under the terms of the warrants, a Selling Stockholder may not exercise the warrants to the extent such exercise would cause such Selling Stockholder, together with its affiliates, to beneficially own a number of shares of common stock which would exceed 4.99% or 9.99%, as the case may be, of our then outstanding common stock following such exercise, excluding for purposes of such determination common stock issuable upon exercise of the warrants which have not been exercised. The number of

shares in the second column does not reflect this limitation. The Selling Stockholders may sell all, some or none of their shares in this offering. See "Plan of Distribution."

Name of Selling Stockholder	Number of Shares of Common Stock Owned Prior to Offering	Maximum Number of Shares of Common Stock to be Sold Pursuant to this Prospectus	Number of Shares of Common Stock Owned After Offering
Hudson Bay Master Fund Ltd.	16,564,681(1)	26,769,789	537,631
CVI Investments, Inc.	18,502,994(2)	29,000,619	1,140,350
Empery Asset Master LTD	936,580(3)	1,516,959	28,380
Empery Tax Efficient, LP	234,138(4)	379,233	7,095
Empery Debt Opportunity Fund, LP	22,243,773(5)	36,027,684	674,029
Alto Opportunity Master Fund, SPC—Segregated Master Portfolio B	11,386,462(6)	17,846,541	701,754

(1) The number of shares consists of (i) 537,631 Common Shares held directly by the Selling Stockholder and (ii) 16,027,050 Common Shares issuable upon exercise of the Warrants, without giving effect to the blocker provision described above. Hudson Bay Capital Management, L.P., the investment manager of Hudson Bay Master Fund Ltd., has voting and investment power over these securities. Sander Gerber is the managing member of Hudson Bay Capital GP LLC, which is the general partner of Hudson Bay Capital Management, L.P. Each of Hudson Bay Master Fund Ltd. and Sander Gerber disclaims beneficial ownership over these securities.

(2) The number of shares consists of (i) 1,140,350 Common Shares held directly by the Selling Stockholder, and (ii) 17,362,644 Common Shares issuable upon exercise of the Warrants, without giving effect to the blocker provision described above. Heights Capital Management, Inc., the authorized agent of CVI Investments, Inc. ("CVI"), has discretionary authority to vote and dispose of the shares held by CVI and may be deemed to be the beneficial owner of these shares. Martin Kobinger, in his capacity as Investment Manager of Heights Capital Management, Inc., may also be deemed to have investment discretion and voting power over the shares held by CVI. Mr. Kobinger disclaims any such beneficial ownership of the shares. CVI Investments, Inc. is affiliated with one or more FINRA member, none of whom are currently expected to participate in the sale pursuant to the prospectus contained in the registration statement of Common Shares purchased by the Selling Stockholder in this offering.

(3) The number of shares consists of (i) 28,380 Common Shares held directly by the Selling Stockholder and (ii) 908,200 Common Shares issuable upon exercise of the Warrants, without giving effect to the blocker provision described above. Empery Asset Management LP, the authorized agent of Empery Asset Master Ltd ("EAM"), has discretionary authority to vote and dispose of the shares held by EAM and may be deemed to be the beneficial owner of these shares. Martin Hoe and Ryan Lane, in their capacity as investment managers of Empery Asset Management LP, may also be deemed to have investment discretion and voting power over the shares held by EAM. EAM, Mr. Hoe and Mr. Lane each disclaim any beneficial ownership of these shares.

(4) The number of shares consists of (i) 7,095 Common Shares held directly by the Selling Stockholder and (ii) 227,043 Common Shares issuable upon exercise of the Warrants, without giving effect to the blocker provision described above. Empery Asset Management LP, the authorized agent of Empery Tax Efficient, LP ("ETE"), has discretionary authority to vote and dispose of the shares held by ETE and may be deemed to be the beneficial owner of these shares. Martin Hoe and Ryan Lane, in their capacity as investment managers of Empery Asset Management LP, may also be deemed to have investment discretion and voting power over the shares held by ETE. ETE, Mr. Hoe and Mr. Lane each disclaim any beneficial ownership of these shares.

(5) The number of shares consists of (i) 674,029 Common Shares held directly by the Selling Stockholder and (ii) 21,569,744 Common Shares issuable upon exercise of the Warrants, without giving effect to the blocker provision described above. Empery Asset Management LP, the authorized agent of Empery Debt Opportunity Fund, LP ("EDOF"), has discretionary authority to vote and dispose of the shares held by EDOF and may be deemed to be the beneficial owner of these shares. Martin Hoe and Ryan Lane, in their capacity as investment managers of Empery Asset Management LP, may also be deemed to have investment discretion and voting power over the shares held by EDOF. EDOF, Mr. Hoe and Mr. Lane each disclaim any beneficial ownership of these shares.

(6) The number of shares consists of (i) 701,754 Common Shares held directly by the Selling Stockholder and (ii) 10,684,708 Common Shares issuable upon exercise of the Warrants, without giving effect to the blocker provision described above. Ayrton Capital LLC, the investment manager to Alto Opportunity Master Fund, SPC—Segregated Master Portfolio B, has discretionary authority to vote and dispose of the shares held by Alto Opportunity Master Fund, SPC—Segregated Master Portfolio B and may be deemed to be the beneficial owner of these shares. Waqas Khatri, in his capacity as Managing Member of Ayrton Capital LLC, may also be deemed to have investment discretion and voting power over the shares held by Alto Opportunity Master Fund, SPC—Segregated Master Portfolio B. Alto Opportunity Master Fund, SPC—Segregated Master Portfolio B and Mr. Khatri each disclaim any beneficial ownership of these shares. The address of Ayrton Capital LLC is 222 Broadway, 19th Fl, New York, NY 10038.

PLAN OF DISTRIBUTION

We are registering the shares of common stock issued and issuable upon exercise of the warrants to permit the resale of these shares of common stock by the holders of the common stock warrants from time to time after the date of this prospectus. We will not receive any of the proceeds from the sale by the Selling Stockholders of the shares of common stock. We will bear all fees and expenses incident to our obligation to register the shares of common stock.

The Selling Stockholders may sell all or a portion of the shares of common stock beneficially owned by them and offered hereby from time to time directly or through one or more underwriters, broker-dealers or agents. If the shares of common stock are sold through underwriters or broker-dealers, the Selling Stockholders will be responsible for underwriting discounts or commissions or agent's commissions. The shares of common stock may be sold in one or more transactions at fixed prices, at prevailing market prices at the time of the sale, at varying prices determined at the time of sale, or at negotiated prices. These sales may be effected in transactions, which may involve crosses or block transactions,

- on any national securities exchange or quotation service on which the securities may be listed or quoted at the time of sale;
- in the over-the-counter market;
- in transactions otherwise than on these exchanges or systems or in the over-the-counter market;
- through the writing of options, whether such options are listed on an options exchange or otherwise;
- ordinary brokerage transactions and transactions in which the broker-dealer solicits purchasers;
- block trades in which the broker-dealer will attempt to sell the shares as agent but may position and resell a portion of the block as principal to facilitate the transaction;
- purchases by a broker-dealer as principal and resale by the broker-dealer for its account;
- an exchange distribution in accordance with the rules of the applicable exchange;
- privately negotiated transactions;
- short sales;
- sales pursuant to Rule 144;
- broker-dealers may agree with the selling securityholders to sell a specified number of such shares at a stipulated price per share;
- a combination of any such methods of sale; and
- any other method permitted pursuant to applicable law.

If the Selling Stockholders effect such transactions by selling shares of common stock to or through underwriters, broker-dealers or agents, such underwriters, broker-dealers or agents may receive commissions in the form of discounts, concessions or commissions from the Selling Stockholders or commissions from purchasers of the shares of common stock for whom they may act as agent or to whom they may sell as principal (which discounts, concessions or commissions as to particular underwriters, broker-dealers or agents may be in excess of those customary in the types of transactions involved). In connection with sales of the shares of common stock or otherwise, the Selling Stockholders may enter into hedging transactions with broker-dealers, which may in turn engage in short sales of the shares of common stock in the course of hedging in positions they assume. The Selling Stockholders may also sell shares of common stock short and deliver shares of common stock

covered by this prospectus to close out short positions and to return borrowed shares in connection with such short sales. The Selling Stockholders may also loan or pledge shares of common stock to broker-dealers that in turn may sell such shares.

The Selling Stockholders may pledge or grant a security interest in some or all of the warrants or shares of common stock owned by them and, if they default in the performance of their secured obligations, the pledgees or secured parties may offer and sell the shares of common stock from time to time pursuant to this prospectus or any amendment to this prospectus under Rule 424(b)(3) or other applicable provision of the Securities Act of 1933, as amended, amending, if necessary, the list of Selling Stockholders to include the pledgee, transferee or other successors in interest as Selling Stockholders under this prospectus. The Selling Stockholders also may transfer and donate the shares of common stock in other circumstances in which case the transferees, donees, pledgees or other successors in interest will be the selling beneficial owners for purposes of this prospectus.

The Selling Stockholders and any broker-dealer participating in the distribution of the shares of common stock may be deemed to be "underwriters" within the meaning of the Securities Act, and any commission paid, or any discounts or concessions allowed to, any such broker-dealer may be deemed to be underwriting commissions or discounts under the Securities Act. At the time a particular offering of the shares of common stock is made, a prospectus supplement, if required, will be distributed which will set forth the aggregate amount of shares of common stock being offered and the terms of the offering, including the name or names of any broker-dealers or agents, any discounts, commissions and other terms constituting compensation from the Selling Stockholders and any discounts, commissions or concessions allowed or reallowed or paid to broker-dealers.

Under the securities laws of some states, the shares of common stock may be sold in such states only through registered or licensed brokers or dealers. In addition, in some states the shares of common stock may not be sold unless such shares have been registered or qualified for sale in such state or an exemption from registration or qualification is available and is complied with.

There can be no assurance that any Selling Stockholder will sell any or all of the shares of common stock registered pursuant to the registration statement, of which this prospectus forms a part.

The Selling Stockholders and any other person participating in such distribution will be subject to applicable provisions of the Securities Exchange Act of 1934, as amended, and the rules and regulations thereunder, including, without limitation, Regulation M of the Exchange Act, which may limit the timing of purchases and sales of any of the shares of common stock by the Selling Stockholders and any other participating person. Regulation M may also restrict the ability of any person engaged in the distribution of the shares of common stock to engage in market-making activities with respect to the shares of common stock. All of the foregoing may affect the marketability of the shares of common stock and the ability of any person or entity to engage in market-making activities with respect to the shares of common stock.

We will pay all expenses of the registration of the shares of common stock pursuant to the registration rights agreement, estimated to be $137,942.54 in total, including, without limitation, Securities and Exchange Commission filing fees and expenses of compliance with state securities or "blue sky" laws; provided, however, that a Selling Stockholder will pay all underwriting discounts and selling commissions, if any. We will indemnify the Selling Stockholders against liabilities, including some liabilities under the Securities Act, in accordance with the registration rights agreements, or the Selling Stockholders will be entitled to contribution. We may be indemnified by the Selling Stockholders against civil liabilities, including liabilities under the Securities Act, that may arise from any written information furnished to us by the Selling Stockholder specifically for use in this prospectus, in accordance with the related registration rights agreement, or we may be entitled to contribution.

Once sold under the registration statement, of which this prospectus forms a part, the shares of common stock will be freely tradable in the hands of persons other than our affiliates.

DESCRIPTION OF CAPITAL STOCK

The following description of our capital stock is not complete and may not contain all the information you should consider before investing in our capital stock. This description is summarized from, and qualified in its entirety by reference to, our Amended and Restated Articles of Incorporation, as amended, which have been publicly filed with the SEC. See "Where You Can Find More Information."

Ocugen's authorized capital stock consists of 210,000,000 shares, with a par value of $0.01 per share, of which:

- 200,000,000 shares are designated as common stock; and
- 10,000,000 shares are designated as preferred stock.

Common Stock

General

Each holder of common stock is entitled to one vote per share on all matters submitted to a vote of stockholders. Ocugen 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 Ocugen common stock are entitled to receive dividends out of assets legally available at the times and in the amounts that Ocugen's board of directors may determine from time to time. Upon Ocugen's 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 Ocugen common stock.

Stock Exchange Listing

Ocugen common stock is listed on The Nasdaq Capital Market under the symbol "OCGN."

Transfer Agent and Registrar

The transfer agent and registrar for Ocugen common stock is Broadridge Corporate Issuer Solutions, Inc.

Preferred Stock

Ocugen's sixth amended and restated certificate of incorporation, as amended, authorizes the issuance of up to 10,000,000 shares of preferred stock, 30,000 of which have been designated as Series A Convertible Preferred Stock, and 400.4910 of which are issued and outstanding as of June 30, 2019. Ocugen may issue, from time to time in one or more series, the terms of which may be determined at the time of issuance by Ocugen's board of directors, without further action by Ocugen's 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 Ocugen, which could depress the market price of the Common Shares.

Outstanding Warrants

2016 Warrants

As part of a private placement of Series A Convertible Preferred Stock in September 2016, Ocugen issued warrants to purchase Common Shares (the "2016 Warrants"). The 2016 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 June 30, 2019, 2016 Warrants to purchase up to 8,495 Common Shares were outstanding. The 2016 Warrants are exercisable, at the option of each holder, at any time or from time to time for shares of Ocugen common stock at an exercise price of $135.00, except that, subject to certain limited exceptions, no holder may exercise the 2016 Warrants if, after giving effect to the exercise, the holder and all affiliated persons would own beneficially more than 4.99% of Ocugen 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 $135.00 is subject to appropriate adjustment in the event of a stock split, stock dividend, combination or other recapitalization affecting the Common Shares.

Series A Warrants

The Series A Warrants were issued on October 4, 2019 at an initial exercise price of $7.13, were immediately exercisable upon issuance and have a term of 60 months from the date of issuance.

The Series A Warrants provide that if Ocugen issues or sells, enters into a definitive, binding agreement pursuant to which Ocugen is required to issue or sell or is deemed, pursuant to the provisions of the Series A Warrants, to have issued or sold, any Common Shares for a price per share lower than the exercise price then in effect (a "Dilutive Issuance"), subject to 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 Common Shares determined by multiplying (a) the exercise price in effect immediately prior to such Dilutive Issuance by (b) the number of Common Shares 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.

Pursuant to the Series A Warrants, Ocugen has agreed 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 Ocugen's assets, tender offer or exchange offer, or reclassification of the Common Shares (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) October 4, 2020 (the "Reservation Date"). Thereafter, Ocugen 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 Ocugen under the Series A Warrants and the other Pre-Merger Financing documents, upon which the Series A Warrants shall become exercisable for Common Shares, 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, Ocugen 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 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 are 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 Shares 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 Shares (including the Common Shares issuable upon such exercise), as such percentage ownership is determined in accordance with the terms of the Series A Warrants.

If Ocugen fails to issue to a holder of Series A Warrants the number of Common Shares to which such holder is entitled upon such holder's exercise of the Series A Warrants, then Ocugen 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 the Common Shares selected by the holder while the failure is continuing and if the holder purchases Common Shares in connection with such failure ("Series A Buy-In Shares"), then Ocugen 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, in the event that Ocugen 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 Ocugen to pay an amount equal to the product of (i) the number of shares that Ocugen is unable to deliver and (ii) the highest volume-weighted average price of a share of Ocugen common stock as quoted on Nasdaq during the period beginning on the date of such attempted exercise and ending on the date that Ocugen makes the applicable payment.

Series B Warrants

The Series B Warrants have an exercise price of $0.01, were exercisable upon issuance and will expire on the day following the later to occur of (i) the 45th trading day immediately following 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 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 (b) October 4, 2020, 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 by a holder for an amount of Ocugen 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 Ocugen 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 45th 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, and (b) April 4, 2020 (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) October 4, 2020 (such 45 trading day period, the "Reset Period" and each such 45th 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 Ocugen 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).

Pursuant to the Series B Warrants, Ocugen has also agreed not to enter into, allow or be party to a Fundamental Transaction until the Reservation Date. Thereafter, Ocugen has 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 Ocugen under the Series B Warrants and the other Pre-Merger Financing documents, upon which the Series B Warrants shall become exercisable for Common Shares, 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 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 are 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 Ocugen 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 Shares (including the Common Shares issuable upon such exercise).

If Ocugen fails to issue to a holder of Series B Warrants the number of Common Shares to which such holder is entitled upon such holder's exercise of the Series B Warrants, then Ocugen 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 Ocugen common stock selected by the holder while the failure is continuing and if the holder purchases Common Shares in connection with such failure ("Series B Buy-In Shares"), then Ocugen 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 Ocugen 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 Ocugen to pay an amount equal to the product of (i) the number of shares that Ocugen is unable to deliver and (ii) the highest volume-weighted average price of a share of Ocugen common stock as quoted on Nasdaq during the period beginning on the date of such attempted exercise and ending on the date that Ocugen makes the applicable payment.

Series C Warrants

The Series C Warrants are exercisable for up to 50 million Common Shares at an exercise price of $7.13, were exercisable upon issuance 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) October 4, 2020, provided that if such date falls on a Holiday, then the next day that is not a Holiday (the "Series C Expiration Date").

If the volume-weighted average trading price of a share of Ocugen 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 Common Shares equal to the number of Series C Warrants.

Pursuant to the Series C Warrants, Ocugen has also agreed not to enter into, allow or be party to a Fundamental Transaction until the Reservation Date. Thereafter, Ocugen 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 Ocugen under the Series C Warrants and the other Pre-Merger Financing documents, upon which the Series C Warrants shall become exercisable for Common Shares, 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 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 are 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 Common Shares 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 Shares (including the shares of common stock issuable upon such exercise).

If Ocugen fails to issue to a holder of Series C Warrants the number of Common Shares to which such holder is entitled upon such holder's exercise of the Series C Warrants, then Ocugen 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 Ocugen common stock selected by the holder while the failure is continuing and if the holder purchases Common Shares in connection with such failure ("Series C Buy-In Shares"), then Ocugen 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 Ocugen 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 Ocugen to pay an amount equal to the product of (i) the number of shares that Ocugen is unable to deliver and (ii) the highest volume-weighted average price of a share of Ocugen common stock as quoted on Nasdaq during the period beginning on the date of such attempted exercise and ending on the date that Ocugen makes the applicable payment.

Registration Rights

In connection with the Pre-Merger Financing, Ocugen entered into the Registration Rights Agreement with the Investors. Pursuant to the Registration Rights Agreement, Ocugen is required to file an initial resale registration statement with respect to shares of Ocugen capital stock (the "Registrable Securities"), held by or issuable to the Investors, within 10 days of the closing of the Pre-Merger Financing. Additionally, Ocugen 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. Ocugen 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 Ocugen 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 Ocugen 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 Ocugen's 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.

Anti-Takeover Effects of Delaware Law and Provisions of our Sixth Amended and Restated Articles of Incorporation, as amended, and Amended and Restated Bylaws, as amended

Certain provisions of Delaware law and our Sixth Amended and Restated Articles of Incorporation, as amended, and Amended and Restated Bylaws, as amended, could make the following more difficult:

- acquisition of us by means of a tender offer;
- acquisition of us by means of a proxy contest or otherwise; or
- removal of our incumbent officers and directors.

These provisions, summarized below, could have the effect of discouraging certain types of coercive takeover practices and inadequate takeover bids. These provisions may also encourage persons seeking to acquire control of us to first negotiate with our board of directors.

Classified Board. The Amended and Restated Bylaws of Ocugen 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, as amended. 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.

Requirements for Advance Notification of Stockholder Nominations and Proposals. Our Amended and Restated Bylaws, as amended, establish advance notice procedures with respect to stockholder proposals and the nomination of candidates for election as directors, other than nominations made by or at the direction of the board of directors.

Special Meetings of the Stockholders. The Sixth Amended and Restated Certificate of Incorporation and the Amended and Restated Bylaws of Ocugen provide that special meetings of stockholders may be called only by the chairman of the board, the chief executive officer or the president or by the board of directors acting pursuant to a resolution adopted by a majority of the whole board.

No Cumulative Voting. The Amended and Restated Bylaws of Ocugen does not have a provision granting cumulative voting rights in the election of its directors.

Undesignated Preferred Stock. The authorization of undesignated preferred stock in our Amended and Restated Articles of Incorporation, as amended, makes it possible for our board of directors to issue preferred stock with voting or other rights or preferences that could impede the success of any attempt to change control of the Company. These and other provisions may have the effect of deferring hostile takeovers or delaying changes in control or management of the Company.

Delaware Law

Ocugen 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. Ocugen has not opted out of these provisions. As a result, mergers or other

takeover or change in control attempts of Ocugen 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

Ocugen's sixth amended and restated certificate of incorporation provides that, unless Ocugen 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 Ocugen's behalf, (ii) any action asserting a claim of breach of a fiduciary duty owed by any of Ocugen's directors, officers or other employees to Ocugen 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

Ocugen's sixth amended and restated certificate of incorporation includes provisions that limit the liability of Ocugen's directors for monetary damages for breach of their fiduciary duty as directors, except for liability that cannot be eliminated under the DGCL. Accordingly, Ocugen's 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 Ocugen 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. Ocugen's sixth amended and certificate of incorporation and bylaws also provides that Ocugen will indemnify its directors and officers to the fullest extent permitted by Delaware law. Ocugen's sixth amended and certificate of incorporation and bylaws also permit Ocugen 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, Ocugen has entered into separate indemnification agreements with its directors and executive officers that require Ocugen, 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. Ocugen 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 Ocugen's 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 Ocugen and its stockholders. A stockholder's investment may be harmed to the extent Ocugen pays the costs of settlement and damage awards against directors and officers pursuant to these indemnification provisions.

LEGAL MATTERS

Morgan, Lewis & Bockius LLP will pass on the validity of Ocugen common stock offered by this registration statement.

EXPERTS

The audited financial statements of Histogenics Corporation (now known as Ocugen, Inc.) incorporated by reference in this prospectus and elsewhere in the registration statement have been so incorporated by reference 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. (Old Ocugen) for the years ended December 31, 2018 and 2017, appearing in Ocugen, Inc.'s (formerly known as Histogenics Corporation) Registration Statement on Form S-4 (No. 333-232147) 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 Old Ocugen's ability to continue as a going concern as described in Note 1 to Old Ocugen's consolidated financial statements) thereon, included therein, and incorporated herein by reference. Such consolidated financial statements are incorporated herein by reference in reliance upon such report given on the authority of such firm as experts in accounting and auditing.

WHERE YOU CAN FIND MORE INFORMATION

Ocugen files annual, quarterly and special reports, proxy statements and other information with the SEC. Ocugen's SEC filings are available on the website maintained by the SEC at http://www.sec.gov. Reports, proxy statements and other information concerning Ocugen also may be inspected at the offices of the National Association of Securities Dealers, Inc., Listing Section, 1735 K Street, Washington, D.C. 20006.

If you would like to request documents from Ocugen, please send a request in writing or by telephone to Ocugen at the following address:

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

DISCLOSURE OF COMMISSION POSITION ON INDEMNIFICATION FOR SECURITIES ACT LIABILITIES

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to our directors, officers, and persons controlling us pursuant to the provisions described in Item 15 of the registration statement of which this prospectus forms a part or otherwise, we have 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 our payment of expenses incurred or paid by our directors, officers, or controlling persons in the successful defense of any action, suit, or proceeding) is asserted by our directors, officers, or controlling persons in connection with the common stock being registered, we will, unless in the opinion of our counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by us is against public policy as expressed in the Securities Act and will be governed by the final adjudication of the issue.

IMPORTANT INFORMATION INCORPORATED BY REFERENCE

The SEC allows us to "incorporate by reference" information into this prospectus, which means that we can disclose important information to you by referring you to another document filed separately with the SEC. The documents incorporated by reference into this prospectus contain important information that you should read about us.

The following documents are incorporated by reference into this prospectus:

(a) Ocugen's Annual Report on Form 10-K for the fiscal year ended December 31, 2018, filed with the SEC on March 22, 2019;

(b) The Registrant's Quarterly Reports on Form 10-Q for the quarters ended March 31, 2019, filed with the SEC May 15, 2019; and June 30, 2019, filed with the SEC on August 9, 2019; and

(c) Ocugen's Current Reports on Form 8-K filed with the SEC on January 24, 2019, February 8, 2019, February 25, 2019, March 5, 2019, March 15, 2019, April 8, 2019, April 18, 2019, May 6, 2019, May 13, 2019 (two filings), June 3, 2019, June 14, 2019, June 21, 2019, July 3, 2019, July 19, 2019, September 11, 2019, September 12, 2019, September 26, 2019, October 1, 2019 (as amended by Form 8-K/A filed on October 7, 2019) and October 7, 2019; and

(d) the description of the Common Shares contained in Ocugen's Registration Statement on Form 8-A (File No. 001-36751) filed under the Exchange Act on November 18, 2014, including any amendment or reports filed for the purpose of updating such descriptions).

We also incorporate by reference any future filings (other than current reports furnished under Item 2.02 or Item 7.01 of Form 8-K and exhibits filed on such form that are related to such items unless such Form 8-K expressly provides to the contrary) made with the SEC pursuant to Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act, including those made after the date of the initial filing of the registration statement of which this prospectus forms a part and prior to effectiveness of such registration statement, until we file a post-effective amendment that indicates the termination of the offering of the Common Shares made by this prospectus and such future filings will become a part of this prospectus from the respective dates that such documents are filed with the SEC. Any statement contained herein or in a document incorporated or deemed to be incorporated by reference herein shall be deemed to be modified or superseded for purposes hereof or of the related prospectus supplement to the extent that a statement contained herein or in any other subsequently filed document which is also incorporated or deemed to be incorporated herein modifies or supersedes such statement. Any such statement so modified or superseded shall not be deemed, except as so modified or superseded, to constitute a part of this prospectus.

Documents incorporated by reference are available from us, without charge. You may obtain documents incorporated by reference in this prospectus by requesting them in writing or by telephone at the following address:

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

PART II

INFORMATION NOT REQUIRED IN PROSPECTUS

Item 14. Other Expenses of Issuance and Distribution

The following table sets forth all expenses payable by the Registrant in connection with the sale of the common stock being registered. The security holders will not bear any portion of such expenses. All the amounts shown are estimates except for the registration fee.

SEC registration fee	$ 27,942.54
Legal fees and expenses	75,000
Accounting fees and expenses	25,000
Printing, transfer agent fees and miscellaneous expenses	10,000
Total	$ 137,942.54

Item 15. Indemnification of Directors and Officers

Ocugen's sixth amended and restated certificate of incorporation includes provisions that limit the liability of Ocugen's directors for monetary damages for breach of their fiduciary duty as directors, except for liability that cannot be eliminated under the DGCL. Accordingly, Ocugen's 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 Ocugen 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.

Ocugen's sixth amended and certificate of incorporation and bylaws also provides that Ocugen will indemnify its directors and officers to the fullest extent permitted by Delaware law. Ocugen's sixth amended and certificate of incorporation and bylaws also permit Ocugen 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, Ocugen has entered into separate indemnification agreements with its directors and executive officers that require Ocugen, 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. Ocugen 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 Ocugen's 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 Ocugen and its stockholders. A stockholder's investment may be harmed to the extent Ocugen pays the costs of settlement and damage awards against directors and officers pursuant to these indemnification provisions.

Item 16. Exhibits

Exhibit Number	Description of Document
3.1	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)
3.2	Certificate of Designation of Preferences, Rights and Limitations of Series A Convertible Preferred Stock (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)
3.3	Amendment to Sixth Amended and Restated Certificate of Incorporation related to the Reverse Stock Split and the Authorized Share Increase (filed as Exhibit 3.1 to the Registrant's Current Report on Form 8-K as filed on October 1, 2019, and incorporated herein by reference)
3.4	Amendment to Sixth Amended and Restated Certificate of Incorporation related to the Name Change (filed as Exhibit 3.2 to the Registrant's Current Report on Form 8-K as filed on October 1, 2019, and incorporated herein by reference)
3.5	Amended and Restated Bylaws (filed as Exhibit 3.3 to the Registrant's Current Report on Form 8-K as filed on October 1, 2019, and incorporated herein by reference)
4.1	Form of Series A Investor Warrant (filed as Exhibit 4.1 to the Registrant's Current Report on Form 8-K as filed on October 7, 2019, and incorporated herein by reference)
4.2	Form of Series B Investor Warrant (filed as Exhibit 4.2 to the Registrant's Current Report on Form 8-K as filed on October 7, 2019, and incorporated herein by reference)
4.3	Form of Series C Investor Warrant (filed as Exhibit 4.3 to the Registrant's Current Report on Form 8-K as filed on October 7, 2019, and incorporated herein by reference)
4.4	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)
5.1*	Opinion of Morgan, Lewis & Bockius LLP
23.1*	Consent of Ernst & Young LLP, Independent Registered Public Accounting Firm to Ocugen, Inc.
23.2*	Consent of Grant Thornton LLP, Independent Registered public Accounting Firm to Histogenics Corporation
23.3*	Consent of Morgan, Lewis & Bockius LLP (included in Exhibit 5.1)
24.1*	Power of Attorney (included on signature page)

* Filed herewith.

Item 17. Undertakings

The undersigned Registrant hereby undertakes:

(1) To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:

(i) To include any prospectus required by section 10(a)(3) of the Securities Act of 1933;

(ii) To reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Commission pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than a 20 percent change in the maximum aggregate offering price set forth in the "Calculation of Registration Fee" table in the effective registration statement.

(iii) To include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement;

Provided, *however*, that:

Paragraphs (1)(i), (1)(ii) and (1)(iii) of this section do not apply if the information required to be included in a post-effective amendment by those paragraphs is contained in reports filed with or furnished to the Commission by the registrant pursuant to section 13 or section 15(d) of the Securities Exchange Act of 1934 that are incorporated by reference in the registration statement, or is contained in a form of prospectus filed pursuant to Rule 424(b) that is part of the registration statement.

(2) That, for the purpose of determining any liability under the Securities Act of 1933, 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.

(3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.

(4) That, for the purpose of determining liability under the Securities Act of 1933 to any purchaser:

(i) Each prospectus filed by the registrant pursuant to Rule 424(b)(3) shall be deemed to be part of the registration statement as of the date the filed prospectus was deemed part of and included in the registration statement; and

(ii) Each prospectus required to be filed pursuant to Rule 424(b)(2), (b)(5), or (b)(7) as part of a registration statement in reliance on Rule 430B relating to an offering made pursuant to Rule 415(a)(1)(i), (vii), or (x) for the purpose of providing the information required by section 10(a) of the Securities Act of 1933 shall be deemed to be part of and included in the registration statement as of the earlier of the date such form of prospectus is first used after effectiveness or the date of the first contract of sale of securities in the offering described in the prospectus. As provided in Rule 430B, for liability purposes of the issuer and any person that is at that date an underwriter, such date shall be deemed to be a new effective date of the registration statement relating to the securities in the registration

statement to which that prospectus relates, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof. *Provided, however*, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such effective date, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such effective date.

(5) If the registrant is subject to Rule 430C, each prospectus filed pursuant to Rule 424(b) as part of a registration statement relating to an offering, other than registration statements relying on Rule 430B or other than prospectuses filed in reliance on Rule 430A, shall be deemed to be part of and included in the registration statement as of the date it is first used after effectiveness. Provided, however, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such first use, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such date of first use.

(6) That, for purposes of determining any liability under the Securities Act of 1933, each filing of the registrant's annual report pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934 (and, where applicable, each filing of an employee benefit plan's annual report pursuant to Section 15(d) of the Securities Exchange Act of 1934) that is incorporated by reference in the registration statement 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.

(7) Insofar as indemnification for liabilities arising under the Securities Act of 1933 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 Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act of 1933 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 of 1933 and will be governed by the final adjudication of such issue.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, as amended, the Registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form S-3 and has duly caused this Registration Statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Malvern, Commonwealth of Pennsylvania on October 7, 2019.

OCUGEN, INC.

By: /s/ SHANKAR MUSUNURI, PH.D., MBA

Shankar Musunuri, Ph.D., MBA
Chief Executive Officer

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POWER OF ATTORNEY

Know All Persons By These Presents, that each person whose signature appears below constitutes and appoints Shankar Musunuri, Ph.D. and Sanjay Subramanian his or her true and lawful attorney-in-fact and agent, with full power of substitution and resubstitution, for him or her and in his or her name, place and stead, in any and all capacities, to sign any and all amendments (including post-effective amendments) to this Registration Statement, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorney-in-fact and agent full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully to all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that said attorney-in-fact and agent or his substitutes or substitute, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act of 1933, this Registration Statement has been signed by the following persons in the capacities and on the dates indicated.

Signature	Title	Date
/s/ SHANKAR MUSUNURI, PH.D., MBA Shankar Musunuri, Ph.D., MBA	Chief Executive Officer and Chairman (Principal Executive Officer)	October 7, 2019
/s/ SANJAY SUBRAMANIAN Sanjay Subramanian	(Principal Financial and Accounting Officer) Chief Financial Officer	October 7, 2019
/s/ UDAY KOMPELLA, PH.D Uday Kompella, Ph.D	Director	October 7, 2019
/s/ RAMESH KUMAR, PH.D Ramesh Kumar, Ph.D	Director	October 7, 2019
/s/ FRANK LEO Frank Leo	Director	October 7, 2019
/s/ MANISH POTTI Manish Potti	Director	October 7, 2019
/s/ SUHA TASPOLATOGLU, M.D. Suha Taspolatoglu, M.D.	Director	October 7, 2019
/s/ JUNGE ZHANG Junge Zhang	Director	October 7, 2019

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Exhibit 5.1

Morgan Lewis

October 7, 2019

Ocugen, Inc.
5 Great Valley Parkway, Suite 160
Malvern, PA 19355

RE: *Ocugen, Inc., Registration Statement on Form S-3*

Ladies and Gentlemen:

We have acted as counsel to Ocugen, Inc., a Delaware corporation (formerly known as Histogenics Corporation) (the "Company"), in connection with the transactions contemplated by that certain Securities Purchase Agreement, dated as of June 13, 2019, as amended by the Amendment Agreements, dated as of June 28, 2019 (as so amended, the "Securities Purchase Agreement"), relating to, among other things, the issuance and sale by the Company of three series of common stock purchase warrants (collectively, the "Warrants") to purchase shares of the Company's common stock, par value $0.01 per share (the "Common Stock"), as described in the Registration Statement on Form S-3 (the "Registration Statement"), including the prospectus set forth therein (the "Prospectus"), as filed on the date hereof by the Company with the Securities and Exchange Commission (the "Commission") under the Securities Act of 1933, as amended (the "Securities Act"). Pursuant to the Registration Statement, the Company is offering up to 111,540,825 shares (the "Warrant Shares") of Common Stock that may be issued upon the exercise of the Warrants.This opinion is being furnished in accordance with the requirements of Item 601(b)(5) of Regulation S-K.

In connection with this opinion, we have examined originals, or copies certified or otherwise identified to our satisfaction, of (i) the certificate of incorporation of the Company, (ii) the by-laws of the Company, (iii) the Securities Purchase Agreement, (iv) the Form of Warrant for each of the Company's Series A, Series B and Series C Warrants, (v) the Registration Statement, (vi) the Prospectus, and (vii) such other documents and records as we deemed appropriate for purposes of the opinions set forth herein.

We have assumed the genuineness of all signatures, the legal capacity of natural persons, the authenticity of the documents submitted to us as originals, the conformity to the original documents of all documents submitted to us as certified, facsimile or photostatic copies, and the authenticity of the originals of all documents submitted to us as copies.

As to any facts that are material to the opinions hereinafter expressed, we have relied without investigation upon certificates of officers of the Company.

Based on the foregoing, we are of the opinion that the Warrant Shares, when issued upon the exercise of Warrants in accordance with the terms thereof, will be validly issued, fully paid and non-assessable.

Our opinions expressed above are subject to the following limitations, exceptions, qualifications and assumptions.

The opinions expressed herein are limited to Delaware law and we express no opinion as to laws of any other jurisdiction.

Morgan, Lewis & Bockius LLP

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This opinion is effective only as of the date hereof. We do not assume responsibility for updating this opinion as of any date subsequent to its date, and we assume no responsibility for advising you of any changes with respect to any matters described in this opinion that may occur, or facts that may come to our attention, subsequent to the date hereof.

We hereby consent to the incorporation by reference of this opinion as an exhibit to the Registration Statement and to the reference to us under the caption "Legal Matters" in the prospectus included in the Registration Statement. In giving such consent, we do not hereby admit that we are acting within the category of persons whose consent is required under Section 7 of the Securities Act or the rules or regulations of the Commission thereunder.

Very truly yours,

/s/ Morgan, Lewis & Bockius LLP

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Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the reference to our firm under the caption "Experts" in the Registration Statement (Form S-3) and related Prospectus of Ocugen, Inc. (formerly known as Histogenics Corporation) for the registration of 111,540,825 shares of its common stock and to the incorporation by reference therein of our report dated June 14, 2019, with respect to the consolidated financial statements of Ocugen, Inc. ("Old Ocugen") included in the Registration Statement (Form S-4 No. 333-232147) filed with the Securities and Exchange Commission.

/s/ Ernst & Young LLP

Philadelphia, Pennsylvania

October 7,2019

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Exhibit 23.2

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 (now known as Ocugen, Inc.) included in the Annual Report on Form 10-K for the year ended December 31, 2018, which is incorporated by reference in this Registration Statement. We consent to the incorporation by reference of the aforementioned report in this Registration Statement, and to the use of our name as it appears under the caption "Experts".

/s/ GRANT THORNTON LLP

Hartford, Connecticut

October 7, 2019

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