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

FORM 10-Q

(Mark One)

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended June 30, 2019

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

Commission File Number 001-36751

Histogenics Corporation
(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.)**
830 Winter Street, 3rd Floor Waltham, Massachusetts	**02451**
(Address of principal executive offices)	**(Zip Code)**

(781) 547-7900
(Registrant's telephone number, including area code)

Not Applicable
(Former name, former address and former fiscal year, if changed since last report)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading symbol(s)	Name of each exchange on which registered
Common Stock	**HSGX**	**The Nasdaq Stock Market LLC (The Nasdaq Capital Market)**

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

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

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☐	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. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

As of August 6, 2019, there were 94,599,601 outstanding shares of the registrant's common stock, $0.01 par value per share.

HISTOGENICS CORPORATION
QUARTERLY REPORT ON FORM 10-Q
FOR THE QUARTERLY PERIOD ENDED JUNE 30, 2019

INFORMATION REGARDING FORWARD-LOOKING STATEMENTS

As used in this Quarterly Report on Form 10-Q, the terms “Histogenics,” “Company,” “registrant,” “we,” “us,” and “our” mean Histogenics Corporation and its subsidiaries unless the context indicates otherwise. This Quarterly Report on Form 10-Q contains “forward-looking statements” that involve substantial risks and uncertainties. All statements other than statements of historical facts contained in this Quarterly Report on Form 10-Q, including statements regarding our future results of operations and financial position, strategy and plans, and our expectations for future operations, are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. The words “anticipate,” “believe,” “contemplates,” “continue,” “could,” “design,” “estimate,” “expect,” “intend,” “likely,” “may,” “ongoing,” “plan,” “potential,” “predict,” “project,” “will,” “would,” “seek,” “should,” “target,” or the negative version of these words and similar expressions are intended to identify forward-looking statements. These forward-looking statements include, but are not limited to, statements about:

- our ability to satisfy the required conditions and otherwise complete our planned merger (the “Merger”), with Ocugen, Inc. (“Ocugen”), pursuant to the Agreement and Plan of Merger and Reorganization, dated April 5, 2019, as amended from time to time (the “Merger Agreement”), by and among the Company, Restore Merger Sub, Inc., a wholly-owned subsidiary of the Company, and Ocugen, on a timely basis or at all;
- the expected benefits and potential value created by the proposed Merger for our stockholders, including the ownership percentage of our stockholders in the combined organization immediately following the consummation of the proposed Merger if it is completed;
- our ability to maintain our operations and obtain additional funding for our operations, if necessary, until the consummation of the proposed Merger;
- our ability to establish and maintain development and commercialization partnerships;
- our ability to protect our intellectual property and operate our business without infringing upon the intellectual property rights of others;
- the accuracy of our estimates regarding expenses, capital requirements and need for additional financing;
- our ability to retain key consultants;
- regulatory developments in the United States and foreign countries; and
- our estimates regarding the sufficiency of our cash resources, expenses, including those related to the consummation of the proposed Merger, capital requirements and needs for additional financing, and our ability to obtain additional financing and to continue as a going concern if the Merger is not completed.

Any forward-looking statements in this Quarterly Report on Form 10-Q reflect our current views with respect to future events or to our future financial performance and involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by these forward-looking statements. Factors that may cause actual results to differ materially from current expectations include, among other things, those described in the sections titled “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” in this Quarterly Report on Form 10-Q and those described in the sections titled “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” in our Annual Report on Form 10-K, filed with the Securities and Exchange Commission on March 22, 2019. Given these uncertainties, you should not place undue reliance on these forward-looking statements. We specifically disclaim any obligation to update these forward-looking statements in the future, except as required by law.

HISTOGENICS CORPORATION
CONSOLIDATED BALANCE SHEETS
(in thousands, except share and per share data)

	June 30, 2019 (Unaudited)	December 31, 2018
ASSETS		
Current assets:		
Cash and cash equivalents	$ 2,786	$ 15,542
Prepaid expenses and other current assets	414	858
Total current assets	3,200	16,400
Property and equipment, net	—	141
Other assets, long-term	—	750
Restricted cash	—	137
Total assets	$ 3,200	$ 17,428
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable	$ 538	$ 1,590
Accrued expenses	253	1,000
Current portion of deferred rent	—	45
Current portion of deferred lease incentive	—	238
Total current liabilities:	791	2,873
Accrued expenses due to Intrexon Corporation	1,125	1,125
Deferred revenue	10,000	10,000
Deferred rent, net of current portion	—	351
Deferred lease incentive, net of current portion	—	1,025
Warrant liability	15	2,512
Total liabilities	11,931	17,886
Commitments and contingencies (Note 5)		
Convertible preferred stock and stockholders' deficit:		
Convertible preferred stock, $0.01 par value; 30,000 shares authorized, 400.4910 shares issued and outstanding at June 30, 2019 and December 31, 2018	—	—
Common stock, $0.01 par value; 100,000,000 shares authorized, 94,599,601 and 62,025,398 shares issued and outstanding at June 30, 2019 and December 31, 2018, respectively	839	513
Additional paid-in capital	219,911	215,859
Accumulated deficit	(229,481)	(216,830)
Total stockholders' deficit	(8,731)	(458)
Total liabilities and stockholders' deficit	$ 3,200	$ 17,428

See accompanying notes to unaudited consolidated financial statements.

HISTOGENICS CORPORATION
CONSOLIDATED STATEMENTS OF OPERATIONS
(unaudited)
(in thousands, except share and per share data)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Revenue	$ —	$ —	$ —	$ —
Operating expenses:				
Research and development	446	4,458	2,029	7,744
General and administrative	2,614	2,826	5,543	5,633
Restructuring charge	—	—	2,789	—
Loss due to asset impairment	—	—	750	—
Total operating expenses	3,060	7,284	11,111	13,377
Loss from operations	(3,060)	(7,284)	(11,111)	(13,377)
Other income (expense):				
Interest income (expense), net	7	32	55	69
Loss on extinguishment of lease obligations	(270)	—	(270)	—
Other income (expense), net	92	(26)	87	(50)
Change in fair value of warrant liability	(5)	3,501	(1,412)	(5,252)
Total other income (expense), net	(176)	3,507	(1,540)	(5,233)
Net loss	$ (3,236)	$ (3,777)	$ (12,651)	$ (18,610)
Comprehensive loss	$ (3,236)	$ (3,777)	$ (12,651)	$ (18,610)
Net loss attributable to common stockholders—basic and diluted	$ (3,230)	$ (3,697)	$ (12,625)	$ (18,124)
Net loss per common share—basic and diluted	$ (0.03)	$ (0.13)	$ (0.14)	$ (0.64)
Weighted-average shares used to compute loss per common share—basic and diluted	94,599,601	28,740,030	87,580,850	28,208,030

See accompanying notes to unaudited consolidated financial statements.

HISTOGENICS CORPORATION
CONSOLIDATED STATEMENTS OF CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' DEFICIT
(unaudited)
(in thousands, except share and per share amounts)

	Series A Convertible Preferred Stock $0.01 Par Value		Common Stock $0.01 Par Value		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount			
Balance at December 31, 2018	400	$ —	62,025,398	$ 513	$215,859	$ (216,830)	$ (458)
Stock-based compensation expense	—	—	—	—	107	—	107
Exercise of warrants	—	—	32,574,203	326	3,908	—	4,234
Net loss	—	—	—	—	—	(9,415)	(9,415)
Balance at March 31, 2019	400	$ —	94,599,601	$ 839	$219,874	$ (226,245)	$ (5,532)
Stock-based compensation expense	—	—	—	—	37	—	37
Net loss	—	—	—	—	—	(3,236)	(3,236)
Balance at June 30, 2019	400	$ —	94,599,601	$ 839	$219,911	$ (229,481)	$ (8,731)
Balance at December 31, 2017	4,605	$ —	24,571,029	$ 159	$196,760	$ (208,187)	$ (11,268)
Stock-based compensation expense	—	—	—	—	403	—	403
Exercise of common stock options	—	—	919	—	2	—	2
Issuance of common stock—net	—	—	2,691,494	27	5,842	—	5,869
Fees related to issuance of common stock	—	—	—	—	(243)	—	(243)
Conversion of convertible preferred stock	(3,204)	—	1,423,970	—	—	—	—
Net loss	—	—	—	—	—	(14,833)	(14,833)
Balance at March 31, 2018	1,401	$ —	28,687,412	$ 186	$202,764	$ (223,020)	$ (20,070)
Stock-based compensation expense	—	—	—	—	407	—	407
Exercise of common stock warrants	—	—	104,092	—	2	—	2
Net loss	—	—	—	—	—	(3,777)	(3,777)
Balance at June 30, 2018	1,401	$ —	28,791,504	$ 186	$203,173	$ (226,797)	$ (23,438)

See accompanying notes to unaudited consolidated financial statements

HISTOGENICS CORPORATION
CONSOLIDATED STATEMENTS OF CASH FLOWS
(unaudited)
(in thousands)

	Six Months Ended June 30,	
	2019	2018
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (12,651)	$ (18,610)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	115	322
Loss on asset impairment	750	—
Loss on extinguishment of lease obligations	270	—
Loss on sale of fixed assets	25	—
Deferred rent and lease incentive	—	814
Stock-based compensation	144	810
Change in fair value of warrant liability	1,412	5,252
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	386	(687)
Other assets and accrued lease obligations, net	(202)	(188)
Accounts payable	(1,051)	1,431
Accrued expenses	(747)	(1,071)
Deferred revenue	—	10,000
Net cash used in operating activities	(11,549)	(1,927)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchases of property and equipment	—	(2,734)
Proceeds from sale of fixed assets	110	—
Proceeds from maturities of marketable securities	—	900
Net cash provided by (used in) investing activities	110	(1,834)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Payment to extinguish lease obligations	(1,780)	—
Repayments on equipment term loan	—	(178)
Net proceeds from issuance of common stock	—	5,732
Expenses incurred for at-the-market sales agreement of common stock	—	(106)
Proceeds from exercise of warrants	326	2
Proceeds from exercise of stock options	—	2
Net cash provided by (used in) financing activities	(1,454)	5,452
Net increase (decrease) in cash and cash equivalents and restricted cash	(12,893)	1,691
Cash and cash equivalents and restricted cash—Beginning of period	15,679	7,218
Cash and cash equivalents and restricted cash—End of period	$ 2,786	$ 8,909
Reconciliation of cash, cash equivalents and restricted cash reported within the consolidated balance sheets:		
Cash and cash equivalents	$ 2,786	$ 8,772
Restricted cash	—	137
Total cash, cash equivalents, and restricted cash at the end of period	$ 2,786	$ 8,909
Supplemental cash flow disclosures from investing and financing activities:		
Purchases of property and equipment in accounts payable and accrued expenses	$ —	$ 854

See accompanying notes to unaudited consolidated financial statements

HISTOGENICS CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(unaudited)

1. NATURE OF BUSINESS

Organization

Histogenics Corporation (the "Company") was incorporated under the laws of the Commonwealth of Massachusetts on June 28, 2000 and has its principal operations in Waltham, Massachusetts. In 2006, the Company's board of directors approved a corporate reorganization pursuant to which the Company incorporated as a Delaware corporation. The Company historically focused on the development of restorative cell therapies ("RCTs"). RCTs refer to a new class of products that are designed to offer patients rapid-onset pain relief and restored function through the repair of damaged or worn tissue. The Company's lead product, NeoCart®, is an innovative cell therapy designed to treat tissue injury in the field of orthopedics, specifically cartilage damage in the knee. In the third quarter of 2018, the Company announced that its Phase 3 clinical trial of NeoCart did not meet the primary endpoint in the Phase 3 clinical trial. Histogenics subsequently initiated a dialogue with the United States Food and Drug Administration ("FDA") to discuss the regulatory path forward for NeoCart with a goal of determining whether the FDA would accept a submission of a Biologics License Application ("BLA") for NeoCart without data from an additional Phase 3 clinical trial. In December 2018, the Company received final feedback from the FDA indicating the need for an additional Phase 3 clinical trial prior to the FDA's acceptance of a NeoCart BLA submission. However, considering the time and funding required to conduct such a trial, the Company discontinued the development of NeoCart and is not planning to submit a BLA.

In connection with the decision to discontinue the development of NeoCart, the Company's board of directors engaged a financial advisory firm to help explore its available strategic alternatives, including possible mergers and business combinations, a sale of part or all of its assets, and collaboration and licensing arrangements. On April 5, 2019, the Company and Ocugen, Inc. ("Ocugen") announced that they entered into the Merger Agreement, which was subsequently amended on June 14, 2019. Upon the terms and subject to the satisfaction of the conditions described in the Merger Agreement, including approval of the transaction by the Company's stockholders and Ocugen's stockholders, a wholly-owned subsidiary of the Company will be merged with and into Ocugen, with Ocugen surviving the Merger as a wholly-owned subsidiary of the Company.

The proposed Merger is structured as a stock-for-stock transaction whereby all of Ocugen's outstanding shares of common stock and securities convertible into or exercisable for Ocugen's common stock will be converted into the right to receive the Company's common stock and securities convertible into or exercisable for the Company's common stock. Under the exchange ratio formula in the Merger Agreement, the former Ocugen equity holders immediately before the Merger are expected to own approximately 83% of the outstanding capital stock of Histogenics, and the stockholders of Histogenics immediately before the Merger are expected to own approximately 17% of the outstanding capital stock of Histogenics, each as calculated immediately prior to an approximately $25 million financing of the combined company contemplated in connection with the closing of the proposed Merger (the "Closing"). The exchange ratio formula includes Ocugen's outstanding stock options and warrants and Histogenics' outstanding stock options, warrants and Series A Convertible Preferred Stock.

At the effective time of the Merger (the "Effective Time"), the Company's board of directors is expected to consist solely of members designated by Ocugen. Following the Closing, Shankar Musunuri is expected to serve as Histogenics' Chairman of the Board and Chief Executive Officer. Also at the Effective Time, the Company will effect a name change to "Ocugen, Inc." and it is anticipated that trading for Ocugen's securities will be listed on The Nasdaq Capital Market under the symbol "OCGN."

The Merger Agreement contains customary representations, warranties and covenants made by the Company and Ocugen, including covenants relating to obtaining the requisite approvals of the stockholders of the Company and Ocugen, indemnification of directors and officers, and the Company's and Ocugen's conduct of their respective businesses between the date of signing of the Merger Agreement and the Closing.

In connection with the Merger, the Company has prepared and filed with the U.S. Securities and Exchange Commission ("SEC") a registration statement on Form S-4 that contains a prospectus/proxy statement/information statement, and is in the process of seeking the approval of the Company's stockholders with respect to certain actions, including the following (collectively, the "Histogenics Stockholder Matters"):

- the Merger Agreement, including the issuance of shares of Histogenics common stock to Ocugen's stockholders in connection with the transactions contemplated by the Merger Agreement;
- the amendment of Histogenics' restated certificate of incorporation to effect a reverse split of all outstanding shares of the Company's common stock at a reverse stock split ratio as mutually agreed to by Histogenics and Ocugen;
- the amendment of Histogenics' restated certificate of incorporation to effect an increase in the number of authorized shares of the Company's common stock from 100,000,000 to 200,000,000;
- the amendment of Histogenics' restated certificate of incorporation to change the Company's name to "Ocugen, Inc." following the Effective Time; and
- the change of control of the Company resulting from the Merger pursuant to pertinent Nasdaq rules.

The Closing is subject to satisfaction or waiver of certain conditions including, among other things, (i) the required approvals by the parties' stockholders, (ii) the accuracy of the representations and warranties, subject to certain materiality qualifications, (iii) compliance by the parties with their respective covenants, (iv) no law or order preventing the Merger and related transactions, and (v) the listing of the Shares on The Nasdaq Capital Market.

The Merger Agreement contains certain termination rights for both Histogenics and Ocugen, and further provides that, upon termination of the Merger Agreement under specified circumstances, Histogenics may be required to pay to Ocugen a termination fee of $0.6 million or Ocugen may be required to pay to Histogenics a termination fee of $0.7 million, and in other circumstances each party may be required to reimburse the other party's expenses incurred, up to a maximum of $0.3 million. In the six months ended June 30, 2019, Ocugen paid the Company $0.1 million per the terms of the Merger Agreement as reimbursement of certain expenses related to the Merger.

In connection with the execution of the Merger Agreement, the executive officers and directors of the Company entered into voting agreements with Ocugen and Histogenics relating to the Merger covering less than one percent of the outstanding capital stock of Histogenics, as of date of the Merger Agreement (the "Histogenics Voting Agreements"). The Histogenics Voting Agreements provide, among other things, that the stockholders who are parties to the Histogenics Voting Agreements will vote all of the shares held by them in favor of Histogenics Stockholder Matters and against any competing acquisition proposals. The Histogenics Voting Agreements also place certain restrictions on the transfer of the shares of Histogenics held by the respective signatories thereto.

In connection with the execution of the Merger Agreement, certain officers, directors, stockholders and noteholders of Ocugen entered into voting agreements with Histogenics and Ocugen covering approximately 68% of the outstanding capital stock of Ocugen as of date of the Merger Agreement (the "Ocugen Voting Agreements"). The Ocugen Voting Agreements provide, among other things, that the officers, stockholders and investors party to the Ocugen Voting Agreements will vote all of the shares of Ocugen held by them in favor of the adoption of the Merger Agreement, the approval of the Merger and the other transactions contemplated by the Merger Agreement and against any competing acquisition proposals. The Ocugen Voting Agreements also place certain restrictions on the transfer of the shares of Ocugen held by the respective signatories thereto.

Concurrently with the execution of the Merger Agreement, the officers and directors of Histogenics and the officers, directors and certain stockholders of Ocugen entered into lock-up agreements, pursuant to which they accepted certain restrictions on transfers of any shares of Histogenics' common stock for the 180-day period following the Effective Time.

Although the Company has entered into the Merger Agreement and intends to consummate the proposed Merger, there is no assurance that it will be able to successfully consummate the proposed Merger on a timely basis, or at all. If, for any reason, the proposed Merger is not completed, Histogenics will reconsider its strategic alternatives and could pursue one or more of the following courses of action:

- ***Pursue potential collaborative, partnering or other strategic arrangements for our NeoCart assets, including a sale or other divestiture.*** Although Histogenics has discontinued further development of the NeoCart program and does not currently have any plans to resume the development of NeoCart, the Company initiated and evaluated several collaborative, partnering or other strategic arrangements for the NeoCart assets, including a sale or other divestiture of such assets. On May 8, 2019, the Company entered into an asset purchase agreement

with Medavate Corp., a Colorado corporation (the "Asset Purchase Agreement"), pursuant to which the Company has agreed to sell substantially all of its assets relating to its NeoCart program, including, without limitation, intellectual property, business and license agreements and clinical trial data (the "Assets") in return for a cash payment of $6.5 million. The closing of the sale of the Assets is subject to and conditioned upon the consummation of the planned Merger with Ocugen following the vote of the Company's stockholders approving such transaction as contemplated by the Merger Agreement.

- ***Pursue another strategic transaction like the proposed Merger.*** The Company's board of directors may elect to pursue an alternative strategy, one of which may be a strategic transaction similar to the proposed Merger.
- ***Dissolve and liquidate the Company's assets.*** If, for any reason, the proposed Merger is not consummated and the Company is unable to identify and complete an alternative strategic transaction like the Merger or potential collaborative, partnering or other strategic arrangements for the NeoCart assets, the Company may be required to dissolve and liquidate its assets. In such case, Histogenics would be required to pay all of its debts and contractual obligations, and to set aside certain reserves for potential future claims, and there can be no assurances as to the amount or timing of available cash left to distribute to stockholders after paying debts and other obligations and setting aside funds for reserves.

Since its inception, the Company has devoted substantially all of its efforts to product development, recruiting management and technical staff, raising capital, starting up production and building infrastructure and has not yet generated product revenues. Expenses have primarily been for research and development and related administrative costs.

The Company is subject to a number of risks including the successful development of therapeutics, the ability to obtain adequate financing, the ability to obtain FDA approval and reimbursement for any products we may develop, protection of intellectual property, fluctuations in operating results, dependence on key personnel and collaborative partners, rapid technological changes inherent in the target markets of any products the Company may develop, the introduction of substitute products and competition from larger companies.

Liquidity

The consolidated financial statements have been prepared on a going-concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. As shown in the accompanying consolidated financial statements, the Company has incurred losses and cash flow deficits from operations since inception, resulting in an accumulated deficit at June 30, 2019 of $229.5 million. The Company has financed operations to date primarily through public and private placements of equity securities, and borrowings under debt agreements. The Company anticipates that it will continue to incur net losses for the foreseeable future. The Company believes that its existing cash and cash equivalents will only be sufficient to fund its projected cash needs through the closing of the Merger which is expected in the third quarter of 2019. Accordingly, these factors, among others, raise substantial doubt about the Company's ability to continue as a going concern and its ability to complete the proposed Merger with Ocugen should there be a delay in the Closing. If Histogenics needs to raise additional capital to complete the Merger, the Company would need to pursue a debt or equity financing or other strategic transactions. However, any such financing may not be on favorable terms or available to the Company, if at all. The failure of the Company to obtain sufficient funds on commercially acceptable terms when needed will have a material adverse effect on the Company's business, results of operations and financial condition and could result in the need to pursue an immediate dissolution of the Company. The forecast of cash resources is forward-looking information that involves risks and uncertainties, and the actual amount of our expenses could vary materially and adversely as a result of a number of factors. The Company has based its estimates on assumptions that may prove to be wrong, and the Company's expenses could prove to be significantly higher than it currently anticipates.

Basis of Accounting

The consolidated financial statements are unaudited and have been prepared in conformity with accounting principles generally accepted in the United States of America ("GAAP"). However, they do not include all of the information and footnotes required by GAAP for complete financial statements. These interim consolidated financial statements, in the opinion of the Company's management, reflect all normal recurring adjustments necessary for a fair presentation of the Company's financial position and results of operations for the interim periods ended June 30, 2019 and 2018. The results of operations for the interim periods are not necessarily indicative of the results of operations to be expected for the full year. These interim financial statements should be read in conjunction with the audited financial statements as of and for the year ended December 31, 2018, and the notes thereto, which are included in the Company's Annual Report on Form 10-K, filed with the Securities and Exchange Commission (the "SEC") on March 22, 2019.

The consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries, ProChon and Histogenics Securities Corporation. All significant intercompany accounts and transactions are eliminated in consolidation.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

During the six months ended June 30, 2019, there have been no material changes to the significant accounting policies described in the Company's audited financial statements as of and for the year ended December 31, 2018, and the notes thereto, which are included in the Annual Report on Form 10-K, except as noted below.

Recently Adopted Accounting Standards – Leases

The Company adopted Financial Accounting Standards Board Accounting Standards Update No. 2016-02, Leases (Topic 842) on January 1, 2019, using the alternative modified transition method, which requires a cumulative-effect adjustment, if any, to the opening balance of retained earnings to be recognized on the date of adoption with no restatement of prior periods not restated. There was no cumulative-effect adjustment recorded on January 1, 2019. However, the adoption of ASU 2016-02 did result in the recording of right of use assets and lease liabilities of approximately $6.6 million and $8.3 million, respectively, as of January 1, 2019. Please see Note 5 – Commitments and Contingencies for a description of the Company's Leases and related impact on the financial statements.

The Company elected the following practical expedients when assessing the transition impact of the new standard from both the lessee and lessor perspective and did not: (i) reassess whether any expired or existing contracts as of January 1, 2019, are or contain leases; (ii) reassess the lease classification for any expired or existing leases as of January 1, 2019; (iii) reassess initial direct costs for any existing leases as of January 1, 2019; and (iv) reassess whether land easements meet the definition of a lease. The primary impact was the balance sheet recognition of right-of-use ("ROU") assets which is included in Other assets and lease liabilities for operating leases as a lessee.

Fair Value Measurements

The carrying amounts reported in the Company's consolidated financial statements for cash and cash equivalents, accounts payable, and accrued liabilities approximate their respective fair values because of the short-term nature of these accounts.

Fair value is defined as the price that would be received if selling an asset or paid to transfer a liability in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date.

Additionally, from time to time, the Company may be required to record at fair value other assets on a nonrecurring basis, such as assets held for sale and certain other assets. These nonrecurring fair value adjustments typically involve the application of lower-of-cost-or-market accounting or write-downs of individual assets.

The fair value hierarchy gives the highest priority to unadjusted quoted prices in active markets for identical assets (Level 1), and the lowest priority to unobservable inputs (Level 3). The Company's financial assets are classified within the fair value hierarchy based on the lowest level of inputs that is significant to the fair value measurement. The three levels of the fair value hierarchy, and their applicability to the Company's financial assets, are described below.

Level 1: Unadjusted quoted prices in active markets that are accessible at the measurement date of identical, unrestricted assets.

Level 2: Quoted prices for similar assets, or inputs that are observable, either directly or indirectly, for substantially the full term through corroboration with observable market data. Level 2 includes investments valued at quoted prices adjusted for legal or contractual restrictions specific to the security.

Level 3: Pricing inputs are unobservable for the assets. Level 3 assets include private investments that are supported by little or no market activity. Level 3 valuations are for instruments that are not traded in active markets or are subject to transfer restrictions and may be adjusted to reflect illiquidity and/or non-transferability, with such adjustment generally based on available market evidence. In the absence of such evidence, management's best estimate is used.

An adjustment to the pricing method used within either Level 1 or Level 2 inputs could generate a fair value measurement that effectively falls in a lower level in the hierarchy. The Company had no material re-measurements of fair value with respect to financial assets and liabilities, during the periods presented, other than those assets and liabilities that are measured

at fair value on a recurring basis. At June 30, 2019, the only assets or liabilities classified as Level 3 were the outstanding warrants issued in connection with the private placement transaction which closed on September 29, 2016. At December 31, 2018 the Company's only assets or liabilities classified as level 3 were the warrants issued in connection with the September 2016 private placement and the October 2018 underwritten public offering. Transfers are calculated using values as of the transfer date. There were no transfers between Levels 1, 2 and 3 during the six months ended June 30, 2019 and the twelve months ended December 31, 2018.

The fair value of the warrants issued in connection with the September 2016 private placement was determined using a Monte Carlo simulation model. This model incorporated several assumptions at each valuation date including: the price of the Company's common stock on the date of valuation, the historical volatility of the price of the Company's common stock, the remaining contractual term of the warrant and estimates of the probability of a fundamental transaction occurring. The fair value of the warrants issued in connection with the October 2018 underwritten public offering was determined using the Black Scholes model. See Note 6, Capital Stock, for further discussion of the private placement and underwritten public offering.

The Company's financial instruments as of June 30, 2019 and December 31, 2018 consisted primarily of cash and cash equivalents and warrant liability. As of June 30, 2019, and December 31, 2018, the Company's financial assets recognized at fair value consisted of the following:

Description	Total	Quoted prices in active markets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
		(in thousands)		
June 30, 2019				
Assets:				
Cash Equivalents				
Money market funds	$ 11	$ 11	$ —	$ —
Liabilities:				
Warrant liability	$ 15	$ —	$ —	$ 15
December 31, 2018				
Assets:				
Cash Equivalents				
Money market funds	$9,711	$ 9,711	$ —	$ —
Liabilities:				
Warrant liability	$2,512	$ —	$ —	$ 2,512

The following table provides a reconciliation of all liabilities measured at fair value using Level 3 significant unobservable inputs:

	June 30, 2019 (in thousands)
Beginning balance, December 31, 2018	$ 2,512
Exercise of warrants	(3,909)
Change in fair value of warrant liability	1,412
Ending balance	$ 15

Cash and Cash Equivalents

The Company considers all highly liquid securities with original maturities of three months or less from the date of purchase to be cash equivalents. Cash and cash equivalents are comprised of funds in money market accounts. In addition, the Company has recorded restricted cash of $0.1 million as of December 31, 2018. Restricted cash consists of a security deposit related to a lease obligation. The restricted cash balance was paid to the lessor in the second quarter of 2019 as part of the settlement of the Company's lease obligations (see Note 5).

Revenue Recognition

In May 2014, the Financial Accounting Standards Board (the "FASB") issued a new standard related to revenue recognition, Accounting Standard Update ("ASU") No. 2014-09, Revenue from Contracts with Customers. This new accounting standard will replace most current U.S. GAAP guidance on this topic and eliminate most industry-specific guidance. It provides a unified model to determine when and how revenue is recognized. The core principle is that an entity should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration for which the entity expects to be entitled in exchange for those goods or services. Entities may adopt the new standard either retrospectively to all periods presented in the financial statements (the full retrospective method) or as a cumulative-effect adjustment as of the date of adoption (modified retrospective method) in the year of adoption without applying to comparative years' financial statements. Further, in August 2015, the FASB issued ASU No. 2015-14, Revenue from Contracts with Customers: Deferral of the Effective Date, to defer the effective adoption date by one year to December 15, 2017 for annual reporting periods beginning after that date and permitted early adoption of the standard, but not before fiscal years beginning after the original effective date of December 15, 2016. The Company elected to early adopt the guidance in 2017 using the modified retrospective method. There was no cumulative impact due to the adoption of this standard.

Revenue is recognized when, or as, performance obligations are satisfied, which occurs when control of the promised products or services is transferred to customers. Revenue is measured as the amount of consideration the Company expects to receive in exchange for transferring products or services to a customer ("transaction price"). To the extent that the transaction price includes variable consideration, the Company estimates the amount of variable consideration that should be included in the transaction price utilizing the most likely amount method. Variable consideration is included in the transaction price if, in the Company's judgment, it is probable that a significant future reversal of cumulative revenue under the contract will not occur. Estimates of variable consideration and determination of whether to include estimated amounts in the transaction price are based largely on an assessment of the Company's anticipated performance and all information (historical, current and forecasted) that is reasonably available.

If the contract contains a single performance obligation, the entire transaction price is allocated to the single performance obligation. Contracts that contain multiple performance obligations require an allocation of the transaction price to each performance obligation based on a relative standalone selling price basis unless the transaction price is variable and meets the criteria to be allocated entirely to a performance obligation or to a distinct service that forms part of a single performance obligation. The Company currently generates revenue primarily through collaborative research, development and commercialization agreements. The terms of these agreements may contain multiple promises which may include: (i) licenses to the Company's technology; (ii) services related to the transfer and update of know-how; and (iii) manufacturing supply services. Payments to the Company under these arrangements typically include one or more of the following: non-refundable upfront license fees; milestone payments; royalties on future product sales; and fees for manufacturing supply services. None of the Company's contracts as of June 30, 2019 contained a significant financing component.

The Company assesses the promises to determine if they are distinct performance obligations. Once the performance obligations are determined, the transaction price is allocated based on a relative standalone selling price basis. Milestone payments and royalties are typically considered variable consideration at the outset of the contract and are recognized in the transaction price either upon occurrence or when the constraint of a probable reversal is no longer applicable.

Collaboration Revenue

While no revenue has been recognized as of June 30, 2019, the Company has collaboration and license agreements with strategic partners for the development and commercialization of product candidates. The collaboration and license agreements are within the scope of Accounting Standards Codification (ASC 606) Revenue from Contracts with Customers.

In determining the appropriate amount of revenue to be recognized as it fulfills its obligations under the agreements, the Company performs the following steps: (i) identification of the promised goods or services in the contract; (ii) determination of whether the promised goods or services are performance obligations including whether they are distinct in the context of the contract; (iii) measurement of the transaction price, including the constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations; and (v) recognition of revenue when (or as) the Company satisfies each

performance obligation. As part of the accounting for the arrangement, the Company must develop assumptions that require judgment to determine the stand-alone selling price for each performance obligation identified in the contract. The Company uses key assumptions to determine the stand-alone selling price, which may include market conditions, reimbursement rates for personnel costs, development timelines and probabilities of regulatory success.

Licenses of intellectual property: If the license to the Company's intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, the Company recognizes revenues from non-refundable, up-front fees allocated to the license when the license is transferred to the customer and the customer is able to use and benefit from the license. For licenses that are bundled with other promises, the Company utilizes judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue from non-refundable, up-front fees. The Company evaluates the measure of progress each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition.

Manufacturing Supply Services: If the promise to supply products for clinical and/or commercial development are determined to be distinct from the other performance obligations identified in the arrangement, the Company recognizes revenues from the fees allocated to the supply when or as the supply is transferred to the customer, generally upon delivery to the customer. If the promise to supply products for clinical and/or commercial development are not determined to be distinct from the other performance obligations identified in the arrangement, the Company utilizes judgement to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue , including amounts from non-refundable, up-front fees. The Company evaluates the measure of progress each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition.

Milestone Payments: At the inception of each arrangement that includes developmental and regulatory milestone payments, the Company evaluates whether the achievement of each milestone specifically relates to the Company's efforts to satisfy a performance obligation or transfer a distinct good or service within a performance obligation. If the achievement of a milestone is considered a direct result of the Company's efforts to satisfy a performance obligation or transfer a distinct good or service and the receipt of the payment is based upon the achievement of the milestone, the associated milestone value is allocated to that distinct good or service and revenue is recognized in the period in which the milestone is achieved. If the milestone payment is not specifically related to the Company's effort to satisfy a performance obligation or transfer a distinct good or service, the Company evaluates the milestone to determine whether the milestone is considered probable of being reached and estimates the amount to be included in the transaction price using either the most likely amount or the expected value method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price to be allocated. At the end of each subsequent reporting period, the Company re-evaluates the probability of achievement of such development milestones and any related constraint, and if necessary, adjusts its estimate of the overall allocation. Any such adjustments are recorded on a cumulative catch-up basis, which would affect license, collaboration and other revenues and earnings in the period of adjustment.

Royalties: For arrangements that include sales-based or usage-based royalties, including milestone payments based on the level of sales, and the license is deemed to be the predominant item to which the royalties relate, the Company will recognize revenue at the later of: (i) when the related sales occur; or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied).

License and Collaboration Arrangements

MEDINET Co., Ltd.

In December 2017, the Company entered into a License and Commercialization Agreement (the "License Agreement") with MEDINET Co., Ltd. ("MEDINET") to grant MEDINET a license under certain patents, patent applications, know-how, and technology to develop and commercialize certain therapeutic products to replace or repair damaged, worn, or defective cartilage in humans and non-human animals.

In exchange for the license, MEDINET agreed to pay the Company an upfront cash payment of $10.0 million which the Company received in January 2018. As of June 30, 2019, the contract with MEDINET was wholly unperformed and all revenue under the License Agreement has been deferred and has not been recognized. As of June 30, 2019, the aggregate amount of the transaction price allocated to remaining performance obligations was $10.0 million. Because the License Agreement was not terminated as of June 30, 2019, the authoritative accounting literature requires that the $10.0 million of deferred revenue remain a liability on the Company's balance sheet.

Pursuant to the Asset Purchase Agreement with Medavate, the Company has agreed to sell the NeoCart Assets in return for a cash payment of $6.5 million. The Company anticipates that the License Agreement with MEDINET and the related rights and obligations will be included in the Assets that the Company expects to sell to Medavate Corp. upon the closing of the Merger with Ocugen and that the $10 million in deferred revenue will be eliminated as part of the purchase accounting adjustments related to the Merger.

At contract inception, the Company determined that the $10.0 million non-refundable upfront amount constituted the entirety of the consideration to be included in the transaction price as the development, regulatory, and commercial milestones represent variable consideration and were fully constrained. As part of its evaluation of the constraint, the Company considered numerous factors, including that receipt of the milestones is outside the control of the Company and contingent upon success in future clinical trials and the licensees' efforts. Any consideration related to sales-based milestones (including royalties) will be recognized when the related sales occur. The Company re-evaluates the transaction price in each reporting period and as uncertain events are resolved or other changes in circumstances occur. The Company also determined that consideration associated with the clinical trials, which are payable by MEDINET on per-patient basis represent variable consideration, will be included in the transaction price upon occurrence, or once the associated clinical manufacturing service(s) for the patient are concluded.

The Company incurred costs of $0.9 million related to the License Agreement with MEDINET. $0.8 million was recorded as an asset that was to be expensed proportionally over the performance service period. However, given the Company's decision to discontinue the development of NeoCart and terminate its manufacturing operations, the Company concluded that the asset was impaired and a decision was made to fully write down the value of this asset in the first quarter of 2019. This impairment resulted in a charge to the income statement of $0.8 million.

Stock-Based Compensation

The Company accounts for stock options and restricted stock based on their grant date fair value and recognizes compensation expense on a straight-line basis over their vesting period. The Company estimates the fair value of stock options as of the date of grant using the Black-Scholes option pricing model, with the exception of stock options that include a market condition, and restricted stock based on the fair value of the underlying common stock as of the date of grant or the value of the services provided, whichever is more readily determinable. The Company, in conjunction with adoption of ASU 2016-09- Stock Compensation: Improvements to Employee Share-Based Payment Accounting has elected to estimate forfeitures at the time of grant, and revise those estimates in subsequent periods if actual forfeitures differ from its estimates. The Company uses historical data to estimate pre-vesting option forfeitures and records stock-based compensation expense only for those awards that are expected to vest. To the extent that actual forfeitures differ from the Company's estimates, the differences are recorded as a cumulative adjustment in the period the estimates were revised. Stock-based compensation expense is classified as research and development or general and administrative based on the grantee's respective compensation classification.

For stock option grants with vesting triggered by the achievement of performance-based milestones, the expense is recorded over the remaining service period after the point when the achievement of the milestone is probable or the performance condition has been achieved. For stock option grants with both performance-based milestones and market conditions, expense is recorded over the derived service period after the point when the achievement of the performance-based milestone is probable or the performance condition has been achieved. For stock option grants with market conditions, the expense is calculated using the Monte Carlo model based on the grant date fair value of the option and is recorded on a straight line basis over the requisite service period, which represents the derived service period and accelerated when the market condition is satisfied. The Company did not issue awards with market conditions during the six months ended June 30, 2019. The Company accounts for stock options and restricted stock awards to non-employees using the fair value approach. Stock options and restricted stock awards to non-employees are subject to periodic revaluation over their vesting terms.

Warrant Accounting

As noted in Note 6, Capital Stock, the Company classifies a warrant to purchase shares of its common stock as a liability on its consolidated balance sheet if the warrant is a free-standing financial instrument that may require the Company to transfer consideration upon exercise. Each warrant of this type is initially recorded at fair value on date of grant using the Monte Carlo simulation model net of issuance costs, and is subsequently re-measured to fair value at each subsequent balance sheet

date. Changes in fair value of the warrant are recognized as a component of other income (expense), net in the consolidated statement of operations and comprehensive loss. The Company will continue to adjust the liability for changes in fair value until the earlier of the exercise or expiration of the warrant.

Recent Accounting Pronouncements

In November 2018, the FASB issued ASU No. 2018-18, Collaborative Arrangements (Topic 808): Clarifying the Interaction between Topic 808 and Topic 606. The amendments in this update provide guidance on whether certain transactions between collaborative arrangement participants should be accounted for with revenue under Topic 606. The guidance also provides more comparability in the presentation of revenue for certain transactions between collaborative arrangement participants. For public business entities, the amendments in this update are effective for fiscal years and interim periods within those fiscal years, beginning after December 15, 2019. Early adoption is permitted, including adoption in any interim period, for public business entities for periods for which financial statements have not yet been issued. The Company is currently evaluating the impact that the adoption of this guidance will have on the Company's consolidated financial statements and related disclosures.

In August 2018, the FASB issued ASU No. 2018-13, Fair Value Measurement (Topic 820): Changes to the Disclosure Requirements for Fair Value Measurement. The amendments in this update modify the disclosure requirements on fair value measurements based on the concepts in the Concepts Statement, including the consideration of costs and benefits. The amendments in this update are effective for all entities for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2019 with early adoption permitted upon issuance of this Update. The Company is currently evaluating the impact that the adoption of this guidance will have on the Company's consolidated financial statements and related disclosures.

In August 2018, the SEC adopted the final rule under SEC Release No. 33-10532, Disclosure Update and Simplification. This final rule amends certain disclosure requirements that are redundant, duplicative, overlapping, outdated or superseded. In addition, the amendments expand the disclosure requirements on the analysis of stockholders' equity for interim financial statements. Under the amendments, an analysis of changes in each caption of stockholders' equity presented in the balance sheet must be provided in a note or separate statement. The analysis should present a reconciliation of the beginning balance to the ending balance of each period for which a statement of comprehensive income is required to be filed. This final rule is effective for the Company for all filings made on or after November 5, 2018. The SEC staff clarified that the first presentation of the changes in shareholders' equity may be included in the first Form 10-Q for the quarter that begins after the effective date of the amendments. The adoption of the final rule did not have a material impact on the Company's consolidated financial statements.

In June 2018, the FASB issued ASU No. 2018-07, Compensation-Stock Compensation (Topic 718): Improvements to Nonemployee Share- Based Payment Accounting. This update is to simplify the aspects of accounting for nonemployee share-based payment transactions for acquiring goods or services from nonemployees. The amendments in this update are effective for fiscal years beginning after December 15, 2018, including interim periods within that year. The Company has concluded that this guidance has no material impact on the Company's consolidated financial statements and related disclosures.

No other accounting standards known by the Company to be applicable to it that have been issued by the FASB or other standard-setting bodies and that do not require adoption until a future date are expected to have a material impact on the Company's consolidated financial statements.

3. LOSS PER COMMON SHARE

The Company computes basic and diluted loss per share using a methodology that gives effect to the impact of outstanding participating securities (the "two-class method"). For the six months ended June 30, 2019 and 2018.

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
	(In thousands, except share and per share data)			
Numerator				
Net loss	$ (3,236)	$ (3,777)	$ (12,651)	$ (18,610)
Net loss attributable to Series A Preferred Stock (a)	(6)	(80)	(26)	(486)
Income attributable to common stockholders—basic and diluted	$ (3,230)	$ (3,697)	$ (12,625)	$ (18,124)
Denominator:				
Weighted-average number of common shares used in loss per share—basic and diluted	94,599,601	28,740,030	87,580,850	28,208,030
Loss per share—basic and diluted	$ (0.03)	$ (0.13)	$ (0.14)	$ (0.64)

(a) The Series A Preferred Stock participates in income and losses.

The following potentially dilutive securities have been excluded from the computation of diluted weighted-average shares outstanding, as they would be anti-dilutive (in common stock equivalent shares):

	Six Months Ended June 30,	
	2019	2018
Unvested restricted stock and options to purchase common stock	394,317	3,305,743
Series A preferred stock unconverted	177,996	622,987
Warrants exercisable into common stock	571,025	13,528,978

4. PROPERTY AND EQUIPMENT

Property and equipment consisted of the following:

	June 30, 2019	December 31, 2018
	(in thousands)	
Office equipment	$ —	$ 266
Laboratory equipment	—	4,561
Leasehold improvements	—	5,504
Software	—	96
Total property and equipment	—	10,427
Less: accumulated depreciation	—	(10,286)
Property and equipment, net	$ —	$ 141

Depreciation expense related to property and equipment amounted to less than $0.1 million and $0.3 million for the six months ended June 30, 2019 and 2018, respectively.

In the second quarter of 2019, the Company disposed of its remaining property and equipment (other than the Assets to be sold to Medavate pursuant to the Asset Purchase Agreement in connection with the closing of the proposed Merger). The Company realized cash proceeds of $0.1 million from the sale of the remaining assets and recorded a loss on disposal of $25 thousand.

5. COMMITMENTS AND CONTINGENCIES

Leases

The Company leased its office and research facilities in Waltham and Lexington, Massachusetts under non-cancellable operating leases. The Lexington, Massachusetts facility lease would have expired in June 2023. The Waltham, Massachusetts facility lease was extended in April 2017. The effective date of the extension was January 2018. Under the terms of the extension, the lease would have expired in December 2024 with one extension term of five years. Terms of the agreements generally provided for an initial rent-free period and future rent escalation and provide that in addition to minimum lease rental payments, the Company was responsible for a pro-rata share of common area operating expenses. Rent expense under operating lease agreements amounted to approximately $0.2 million and $0.4 million for the three months ended June 30, 2019 and 2018, respectively, and $0.6 million and $0.8 million for the six months ended June 30, 2019 and 2018, respectively. The Company adopted ASU 2016-02 in January 2019. In connection with the adoption, the Company recorded right of use assets and lease liabilities of approximately $6.6 million and $8.3 million, respectively, as of January 1, 2019.

In the second quarter of 2019, in connection with its decision to restructure operations, the Company vacated its Waltham and Lexington facilities and negotiated settlements with the lessors to extinguish the remaining lease obligations. In connection with these settlements, the Company paid the lessors a combined total of $1.8 million (including $0.1 million of restricted cash that was held as a security deposit) in full settlement of its remaining lease obligations, and recorded a loss of $0.3 million on the extinguishment of the lease obligations.

In connection with the termination of the lease of the Waltham facility, the Company agreed to make a payment to the Waltham landlord in the amount of $315,795 no later than 45 days following the Effective Time (as defined in the Merger Agreement).

License Agreements

From time to time, the Company enters into various licensing agreements whereby the Company may use certain technologies in conjunction with its product research and development. Licensing agreements and the Company’s commitments under the agreements are as follows:

Hydrogel License

In May 2005, the Company entered into an exclusive license agreement with Angiotech Pharmaceuticals (US), Inc. for the use of certain patents, patent applications, and knowledge related to the manufacture and use of a hydrogel material in conjunction with NeoCart and certain other products (“Hydrogel License Agreement”). As of June 30, 2019, the Company has paid an aggregate $3.2 million in commercialization milestones under the terms of the Hydrogel License Agreement, which have been expensed to research and development.

Under the terms of the Hydrogel License Agreement, the Company's future commitments include:

- A one-time $3.0 million payment upon approval of an eligible product by the FDA; and
- Single digit royalties on the net sales of NeoCart and certain other future products.

Tissue Regeneration License

In April 2001, the Company entered into an exclusive license agreement with The Board of Trustees of the Leland Stanford Junior University ("Stanford University") for the use of certain technology to develop, manufacture and sell licensed products in the field of growth and regeneration of cartilage ("Tissue Regeneration License Agreement"). The term of the Tissue Regeneration License Agreement extends to the expiration date of Stanford University's last to expire domestic or foreign patents. As of June 30, 2019, the Company has paid an aggregate $0.8 million in patent reimbursement costs, royalty fees, and commercialization milestone payments under the terms of the Tissue Regeneration License Agreement, which have been recorded to research and development expense.

Under the terms of the Tissue Regeneration License Agreement, the Company's future commitments include:

- A one-time $0.3 million payment upon approval of an eligible product by the FDA;
- An annual minimum non-refundable royalty fee of $10 thousand for the life of the license that may be used to offset up to 50% of the earned royalty below; and
- Low single digit royalties on net sales.

Tissue Processor Sub-License

In December 2005, the Company entered into an exclusive agreement to sub-license certain technology from Purpose, Co. ("Purpose"), which is owned by a stockholder of the Company ("Sub-License Agreement"). Purpose entered into the original license agreement ("Original Agreement") with Brigham and Women's Hospital, Inc. ("Brigham and Women's") in August 2001. The Original Agreement shall remain in effect for the term of the licensed patents owned by Brigham and Women's unless extended or terminated as provided for in the agreement. The technology is to be used to develop, manufacture, use and sell licensed products that cultivate cell or tissue development. The Sub-License Agreement extends to the expiration date of the last to expire domestic or foreign patents covered by the agreement. As of June 30, 2019, the Company has paid an aggregate $0.7 million in royalty and sub-license payments under the terms of the Sub-License Agreement.

The Sub-License Agreement was amended and restated in June 2012. Under the amended and restated agreement, the Company made Purpose the sole supplier of equipment the Company uses in its manufacturing processes and granted Purpose distribution rights of the Company's products for certain territories. In exchange, Purpose allowed for the use of its technology (owned or licensed) and manufactured and serviced exogenous tissue processors used by the Company. Under the terms of the agreement, as amended, Purpose granted the Company: (a) exclusive rights to all of Purpose's technology (owned or licensed) related to the exogenous tissue processors, (b) continued supply of exogenous tissue processors during the Company's clinical trials, and (c) rights to manufacture the exogenous tissue processors at any location the Company chooses. In exchange for such consideration, the Company granted Purpose an exclusive license in Japan for the use of all of the Company's technology and made a payment of $0.3 million to reimburse Purpose for development costs on a next generation tissue processor.

In May 2016, the Original Agreement was amended whereby the Company acquired the development and commercialization rights to NeoCart for the Japanese market from Purpose. Under the terms of the amended agreement, the Company assumes sole responsibility for and rights to the development and commercialization of NeoCart in Japan. In exchange for the transfer of development and commercialization rights, the Company will pay a success-based milestone to Purpose upon conditional approval of NeoCart in Japan, as well as commercial milestones and a low single digit royalty on Japanese sales of NeoCart, upon full approval, if any, in Japan.

In addition to the above, the Company's future commitments under the terms of the Original Agreement and Sub-License Agreement include:

- A minimum non-refundable annual royalty fee of $20 thousand, for the life of the license;
- An additional, non-refundable annual royalty fee of $30 thousand from 2016 through 2019;

- $10.2 million in potential milestone payments; and
- Low single digit royalties on net sales of a licensed product.

6. CAPITAL STOCK

In October 2018, the Company closed an underwritten public offering of 26,155,000 shares of its common stock and warrants to purchase up to 19,616,250 shares of common stock, at a combined purchase price of $0.65 per share of common stock and accompanying warrant. The gross proceeds to the Company from this offering were $17.0 million, before deducting underwriting discounts and commissions, and offering expenses payable by the Company. The warrants were exercisable immediately upon issuance at a price of $0.70 per share of common stock and had a term of five years commencing on the date of issuance. The exercise price of the warrants was subject to adjustment upon the occurrence of specific events, including stock dividends, stock splits, combinations and reclassifications of the Company's Common Stock. In the event of certain fundamental transactions of the Company, a warrant holder may have demanded redemption of its warrant for cash in accordance with a Black-Scholes option pricing model. A fundamental transaction was defined as a merger, sale of assets, sale of the Company, recapitalization of stock and a sale of stock whereby any owner after the transaction would own greater than 50% of the outstanding common stock in the Company. The Company determined the warrants were classified as a liability on the consolidated balance sheet because of the provision whereby in a fundamental transaction (as described above), the holder could have elected to receive either the amount they were entitled to on an as-if-exercised basis or an amount based on the Black-Scholes value of the warrants at the time of the fundamental transaction. At the issuance date, the warrants were recorded at the fair value of $8.4 million.

In the first quarter of 2019, the Company reduced the exercise price of the warrants issued in 2018 from $0.70 to $0.01 per share (the "2018 Reduced Exercise Price") and all of the holders of these warrants (the "Participating 2018 Holders") entered into a Warrant Exercise Agreement (the "2018 Exercise Agreement") pursuant to which, in consideration for the 2018 Reduced Exercise Price, the Participating 2018 Holders agreed to exercise the warrants held by such Participating 2018 Holders in full at the 2018 Reduced Exercise Price for cash. In connection with the exercise of the warrants by the Participating 2018 Holders, the Company received aggregate gross proceeds of approximately $0.2 million.

In March 2018, the Company entered into an equity distribution agreement ("ATM Agreement") with Canaccord Genuity Inc. ("Canaccord"), pursuant to which the Company may, from time to time, sell shares of its common stock having an aggregate offering price of up to up to $10.0 million (the "Shares") through Canaccord, as sales agent. The Shares will be offered and sold by the Company pursuant to its previously filed and currently effective Registration Statement on Form S-3 (Reg. No. 333-216741) (the "Registration Statement"). The Shares may only be offered and sold by means of a prospectus, including a prospectus supplement, forming part of the effective Registration Statement. Sales of the common stock, if any, will be made at market prices by methods deemed to be an "at the market offering" as defined in Rule 415 promulgated under the Securities Act of 1933, as amended (the "Securities Act"), including sales made directly on The Nasdaq Capital Market, on any other existing trading market for the common stock, or to or through a market maker other than on an exchange. There were no sales of common stock under the ATM Agreement during the six months ended June 30, 2019 and June 30, 2018.

In January 2018, the Company completed an underwritten registered direct offering of 2,691,494 shares of common stock at a price of $2.35 per share. The total net proceeds of the offering were $5.7 million after deducting underwriter's discounts and commissions, and expenses related to the offering.

In September 2016, the Company closed the private placement contemplated by the securities purchase agreement (the "Purchase Agreement"), dated September 15, 2016, between the Company and certain institutional and accredited investors in which the Company received gross proceeds of $30.0 million (the "Private Placement"). The net proceeds after deducting placement agent fees and other transaction-related expenses was $27.6 million. At the closing, the Company issued 2,596,059 shares of the Company's common stock at a per share price of $2.25 and 24,158.8693 shares of the Company's newly-created Series A Convertible Preferred Stock ("Series A Preferred Stock"), which are convertible into approximately 10,737,275 shares of common stock. As of June 30, 2019, there were 400.4910 shares of Series A Preferred Stock outstanding, which remain convertible into 177,996 shares of the Company's common stock. As part of the Private Placement, the investors received warrants to purchase up to 13,333,334 shares of the Company's common stock at an exercise price of $2.25 per share. The placement agent for the Private Placement, H.C. Wainwright & Co. LLC ("HCW"), and certain of its affiliates were also granted warrants to purchase 133,333 shares of the Company's common stock at an exercise price of $2.25 per share in exchange for the services provided by HCW. The placement agent warrants were considered a financing cost of the Company and included in warrant expense within the consolidated statements of operations.

The warrants include a cashless-exercise feature that may be exercised solely in the event there is no effective registration statement, or no current prospectus available for, the resale of the shares of common stock underlying the warrants as of the six-month anniversary of the closing of the Private Placement. Upon a fundamental transaction, the holders of the warrant may require the Company to purchase any unexercised warrants in an amount equal to the Black-Scholes value of the option. A fundamental transaction is defined as a merger, sale of assets, sale of the Company, recapitalization of stock and a sale of stock whereby any owner after the transaction would own greater than 50% of the outstanding common stock in the Company. The warrants became exercisable following approval of the Private Placement by our stockholders in the fourth quarter of 2016 and expire five years after the date of such stockholder approval. The Company determined the warrants are classified as a liability on the consolidated balance sheet because they contain a provision whereby in a fundamental transaction (as described above), the holder can elect to receive either the amount they are entitled to on an as-if-exercised basis or an amount based on the Black-Scholes value of the warrants at the time of the fundamental transaction. At the issuance date, the warrants were recorded at the fair value of $30.7 million.

Concurrent with the closing of the Private Placement, the Company's Certificate of Incorporation was amended by the filing of a Certificate of Designation to create the Series A Preferred Stock. The Series A Preferred Stock has a par value of $0.01 and each share is convertible into 444.44 shares of common stock, at a conversion price of $2.25 per share, at the option of the holder. The Series A Preferred Stock has no voting rights and is only entitled to dividends as declared on an as-converted basis. The Series A Preferred Stock contains no liquidation preferences or redemption rights and shares in distributions of the Company on an as-converted basis with the common stock.

As part of the Private Placement, affiliates of certain members of the Company's Board of Directors purchased an aggregate of 283,046 shares of common stock, an aggregate of 2,563.1439 shares of Series A Preferred Stock and received warrants to purchase up to 1,422,221 shares of common stock at an exercise price of $2.25 per share in the Private Placement. These amounts are included in the amounts noted above.

In the first quarter of 2019, the Company and certain holders of the warrants issued in 2016 (the "Participating 2016 Holders") entered into a Warrant Amendment and Exercise Agreement (the "2016 Exercise Agreement") pursuant to which the Company agreed to reduce the exercise price of the warrants held by such Participating 2016 Holders from $2.25 to $0.01 per share (the "2016 Reduced Exercise Price") in consideration for the exercise of the warrants held by such Participating 2016 Holders in full at the 2016 Reduced Exercise Price for cash. In connection with the exercise of the warrants by the Participating 2016 Holders, the Company received aggregate gross proceeds of approximately $0.1 million. After the full exercise of the warrants held by the Participating 2016 Holders, warrants issued in 2016 to purchase approximately 508,714 shares of the Company's Common Stock are outstanding.

7. WARRANTS

The Company has warrants to purchase its common stock outstanding as of June 30, 2019, as follows:

Issue Date	Classification	Warrants Outstanding	Exercise Price	Expiration
September 2016	Liability	508,714	$ 2.25	November 2021
March 2015	Equity	3,699	9.75	March 2025
July 2014	Equity	6,566	7.99	July 2024
July 2012	Equity	52,046	0.01	July 2022

8. STOCK-BASED COMPENSATION

Stock option activity under the Company's 2012 Equity Incentive Plan (the "2012 Plan") and 2013 Equity Incentive Plan (the "2013 Plan") for the six months ended June 30, 2019 is summarized as follows:

	Number of Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2018	3,339,471	$ 1.03	8.1	$ —
Cancelled	(2,945,154)	0.74	—	—
Outstanding at June 30, 2019	394,317	$ 3.20	7.7	$ —
Vested and expected to vest at June 30, 2019	375,592	$ 3.23	7.7	$ —
Exercisable at June 30, 2019	368,484	$ 3.24	7.6	$ —

As of June 30, 2019, the weighted average grant date fair value of vested options and options outstanding was $2.09.

Stock-Based Compensation Expense

The Company did not grant any stock options to employees during the six months ended June 30, 2019 but did grant stock options to employees during the six months ended June 30, 2018. The Company estimates the fair value of stock options as of the date of grant using the Black-Scholes option pricing model and restricted stock based on the stock price, with the exception of those stock options that included a market condition. The Company estimates the fair value of stock options that include a market condition using a Monte-Carlo model. Stock options and restricted stock issued to non-board member, non-employees are accounted for using the fair value approach and are subject to periodic revaluation over their vesting terms.

Stock-based compensation expense amounted to $0.1 million and $0.8 million for the six months ended June 30, 2019 and 2018, respectively.

The allocation of stock-based compensation expense for all options granted and restricted stock awards is as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
	(in thousands)			
Research and development	$ —	$ 120	$ (38)	$ 594
General and administrative	36	288	182	216
Total stock-based compensation expense	$ 36	$ 408	$ 144	$ 810

The weighted-average assumptions used in the Black-Scholes option pricing model to determine the fair value of the employee stock option grants and non-employee stock option grants for the three and six month periods ended June 30, 2018 were as follows:

	Three Months Ended June 30, 2018		Six Months Ended June 30, 2018	
	Employees	Non-Employees	Employees	Non-Employees
Risk-free interest rate	2.81%	1.97%	2.72%	1.97%
Expected volatility	59.8%	74.0%	83.1%	74%
Expected term (in years)	6.08	6.08	6.08	6.08
Expected dividend yield	0.0%	0.0%	0.0%	0.0%

9. INCOME TAXES

Deferred tax assets and deferred tax liabilities are recognized based on temporary differences between the financial reporting and tax basis of assets and liabilities using statutory rates. A valuation allowance is recorded against deferred tax assets if it is more likely than not that some or all of the deferred tax assets will not be realized. Due to the uncertainty surrounding the realization of the favorable tax attributes in future tax returns, the Company has recorded a full valuation allowance against the Company's otherwise recognizable net deferred tax assets. The Company recorded no income tax expense or benefit during the six months ended June 30, 2019 and 2018, due to a full valuation allowance recognized against its deferred tax assets.

TAX REFORM

On December 22, 2017, the Tax Cuts and Jobs Act (the "TCJA") was signed into United States law. The TCJA includes a number of changes to existing tax law, including, among other things, a permanent reduction in the federal corporate income tax rate from 34% to 21%, effective as of January 1, 2018, as well as limitation of the deduction for net operating losses to 80% of annual taxable income and elimination of net operating loss carrybacks, in each case, for losses arising in taxable years beginning after December 31, 2017 (though any such net operating losses may be carried forward indefinitely). The tax rate change resulted in (i) a reduction in the gross amount of the Company's deferred tax assets recorded as of December 31, 2017, without an impact on the net amount of its deferred tax assets, which are recorded with a full valuation allowance, and (ii) no income tax expense or benefit being recognized as of the enactment date of the TCJA.

The staff of the Securities and Exchange Commission issued Staff Accounting Bulletin No. 118 to address the application of U.S. GAAP in situations when a registrant does not have the necessary information available, prepared or analyzed (including computations) in reasonable detail to complete the accounting for certain income tax effects of the TCJA. In connection with the initial analysis of the impact of the TCJA, the Company remeasured its deferred tax assets and liabilities based on the rates at which they are expected to reverse in the future, which is generally 21%.

10. RELATED PARTIES

Purpose, Co.

In June 2012, the Company entered into an agreement with Purpose to amend its previous agreements. In the previous agreements, Purpose granted the Company a perpetual license to its patents related to its exogenous tissue processor which is used in the development of the Company's products. In exchange, the Company granted Purpose a perpetual license to all of the Company's biotechnology and biomaterial for use in Japan. The agreement provided for Purpose to manufacture and sell machinery to the Company for cost until the Company's products become commercially viable. The Company also agreed to pay royalties on any third-party revenue generated using Purpose's licensed technology.

Under the June 2012 amendment, the Company received exclusive rights to all of Purpose's technology related to the exogenous tissue processor, continued supply of exogenous tissue processors during the Company's clinical trials, and rights to manufacture the exogenous tissue processors at any location the Company chooses. In exchange for such consideration, the Company named Purpose the sole manufacturer of equipment and also clarified the geographic territories of the exclusive license that Purpose was granted for use of the Company's technology. In addition, the Company agreed to reimburse Purpose for $0.3 million of development costs on a next generation tissue processer. Refer to the discussion under Note 5, Commitments and Contingencies – License Agreements – *Tissue Processor Sub-License*.

In May 2016, the Company acquired the development and commercialization rights to NeoCart for the Japanese market from Purpose. Under the terms of the amended agreement, the Company assumes sole responsibility for and rights to the development and commercialization of NeoCart in Japan. In exchange for the transfer of development and commercialization rights, the Company will pay a success-based milestone to Purpose upon conditional approval of NeoCart in Japan, as well as commercial milestones and a low single digit royalty on Japanese sales of NeoCart, upon full approval, if any, in Japan.

The Company paid Purpose $0.1 million in the six months ended June 30, 2019.

11. RESTRUCTURING

In connection with the aforementioned restructuring plans implemented in January 2019 and March 2019, the Company severed all of its employees before June 30, 2019. The Company incurred a restructuring charge of approximately $2.8 million, all of which has been paid. The restructuring charges were comprised solely of employee severance packages which included salary, healthcare benefits and guaranteed bonuses.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.

You should read the following discussion and analysis of our financial condition and results of operations in conjunction with the financial statements and the notes thereto included elsewhere in this Quarterly Report on Form 10-Q and with our audited financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2018, filed with the SEC on March 22, 2019. Some of the information contained in this discussion and analysis, including information with respect to our plans and strategy for our business and related financing, include forward-looking statements that involve risks, uncertainties and assumptions. You should read the "Risk Factors" and "Information Regarding Forward-Looking Statements" sections of this Quarterly Report on Form 10-Q for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Overview

We historically focused on the development of restorative cell therapies (RCTs). We use the term RCT to refer to a new class of products that are designed to offer patients rapid-onset pain relief and restored function through the repair of damaged or worn tissue. Our product, NeoCart®, is an innovative cell therapy that utilizes various aspects of our RCT platform to treat tissue injury in the field of orthopedics, specifically cartilage damage in the knee.

NeoCart is based on our RCT platform, which we believe has the potential to be used for a broad range of additional therapeutic indications and combines expertise in the following areas:

- Cell therapy and processing: the handling of tissue biopsies and the extraction, isolation and expansion of the cells;
- Biomaterials and Scaffold: three-dimensional biomaterials structures that enable the proper delivery, distribution and organization of cells in their natural environment to support tissue formation;
- Tissue engineering: the use of a combination of cells, engineering and biomaterials to improve or restore biological functions; and
- Bioadhesives: natural, biocompatible materials that act as adhesives for biological tissue and allow for natural cell and tissue infiltration and integration with native cells.

In the third quarter of 2018, we announced that our Phase 3 clinical trial of NeoCart did not meet the primary endpoint of a statistically significant improvement in pain and function in a dual threshold responder analysis one year after treatment as compared to microfracture. In the modified Intent to Treat (mITT) population (which excludes those patients who were randomized but not treated with NeoCart), 74.2% of the NeoCart patients exhibited clinically meaningful improvements in pain and function compared to 62.0% of microfracture patients at one year (p=0.071). However, in this mITT population, patients treated with NeoCart achieved a statistically significant improvement in pain and function (p=0.018) six months after treatment as compared to patients treated with microfracture. In addition, NeoCart achieved a statistically significant improvement in pain and function at one year in certain patient populations including patients with lesion sizes greater than 2.2 cm^2 and those with a Body Mass Index, or BMI, of greater than 28. Both NeoCart and microfracture were well tolerated and exhibited strong safety profiles.

Based on the totality of the data, we initiated a dialogue with the United States Food and Drug Administration (FDA) in the third quarter of 2018 to discuss the regulatory path forward for NeoCart. Our primary objective in these discussions was to determine whether the FDA would accept a submission of a Biologics License Application (BLA) for NeoCart without data from an additional clinical trial. We had a constructive dialogue with the FDA, which included requests for and review of additional statistical analyses, different subgroup analyses, and secondary endpoints. These additional analyses, while compelling, did not change the conclusion that the NeoCart Phase 3 trial failed to meet its primary and secondary endpoints. In December 2018, we received final feedback from the FDA indicating that while the NeoCart Phase 3 clinical trial resulted in certain compelling data, particularly the early response in pain and function and the data in certain lesion sizes, an additional Phase 3 clinical trial would need to be completed before the FDA would accept the submission of a BLA for NeoCart. The FDA indicated receptivity to novel clinical trial methodologies and regenerative medicine advanced therapy designations in order to support additional data for a future potential submission. However, considering the time and funding required to conduct such a trial, we discontinued the development of NeoCart and are not planning to submit a BLA.

In connection with our decision to discontinue the development of NeoCart, our board of directors engaged a financial advisory firm to help explore our available strategic alternatives, including possible mergers and business combinations, a sale of part or all of our assets, and collaboration and licensing arrangements. In January 2019 and March 2019, we implemented restructuring plans that were approved by our Board involving reductions in headcount to reduce operating costs. The positions eliminated together represented all but one employee, and included our Chief Executive Officer, Chief Operating Officer, Chief Medical Officer and Chief Business Officer. We engaged Mr. Adam Gridley, our former Chief Executive Officer, Mr. Stephen Kennedy, our former Chief Operating Officer, along with up to four additional employees as consultants to assist with our preparation for a potential merger or wind-down of operations. We terminated the final remaining employee in May 2019.

The process culminated in a planned merger (the Merger), between us and Ocugen, Inc. (Ocugen), pursuant to the Agreement and Plan of Merger and Reorganization, dated April 5, 2019, by and among Histogenics, Restore Merger Sub, Inc., a wholly-owned subsidiary of Histogenics, and Ocugen that was announced on April 8, 2019, and was subsequently amended on June 14, 2019 (as amended, the Merger Agreement). Subject to the satisfaction of the conditions described in the Merger Agreement, including approval of the transaction by our stockholders and Ocugen's stockholders, a wholly-owned subsidiary of Histogenics will be merged with and into Ocugen, with Ocugen surviving the Merger as a wholly-owned subsidiary of Histogenics.

The proposed Merger is structured as a stock-for-stock transaction whereby all of Ocugen's outstanding shares of common stock and securities convertible into or exercisable for Ocugen's common stock will be converted into the right to receive our common stock and securities convertible into or exercisable for our common stock. Under the exchange ratio formula in the Merger Agreement, the former Ocugen equity holders immediately before the Merger are expected to own approximately 83% of the outstanding capital stock of Histogenics, and the stockholders of Histogenics immediately before the Merger are expected to own approximately 17% of the outstanding capital stock of Histogenics, each as calculated immediately prior to an approximately $25 million financing described below of the combined company contemplated in connection with the closing of the proposed Merger (the "Closing"). The exchange ratio formula includes Ocugen's outstanding stock options and warrants and Histogenics' outstanding stock options, warrants and Series A Convertible Preferred Stock. In connection with the proposed Merger, on June 13, 2019, Ocugen and Histogenics entered into a securities purchase agreement (the Securities Purchase Agreement) with certain accredited investors (the Investors) pursuant to which, among other things, Ocugen agreed to issue to the Investors shares of Ocugen common stock immediately prior to the Merger and Histogenics agreed to issue to the Investors warrants to purchase shares of Histogenics common stock on the fifth trading day following the consummation of the merger (the Investor Warrants) in a private placement transaction for an aggregate purchase price of approximately $25.0 million (subject to setoff for amounts outstanding of approximately $2.4 million under certain senior secured notes previously issued to certain of the Investors by Ocugen) (the Pre-Merger Financing). Immediately after the Merger, after giving effect to the Pre-Merger Financing and based on the exchange ratio of 28.7650, current holders of Ocugen's capital stock and options and warrants to purchase shares of Ocugen common stock, are expected to own, or hold rights to acquire, in the aggregate approximately 86.24% of the fully-diluted common stock of Histogenics, which for these purposes is defined as the outstanding common stock of Histogenics plus Series A Convertible Preferred Stock and outstanding warrants of Histogenics, excluding the Investor Warrants (the Fully-Diluted Common Stock of Histogenics), and Histogenics' current stockholders and warrantholders are expected to own, or hold rights to acquire, in the aggregate approximately 13.76% of the Fully-Diluted Common Stock of Histogenics.

Historically, we devoted substantially all of our resources to the development of our RCT platform, the preclinical and clinical advancement of our product candidates, the creation and protection of related intellectual property and the provision of general and administrative support for these operations. We have funded our operations primarily through the private placement of preferred stock and convertible promissory notes, commercial bank debt, sales of common stock and our collaboration with MEDINET.

We have never been profitable and incurred net losses in each year since inception. Our accumulated deficit was $229.5 million as of June 30, 2019. Substantially all of our net losses resulted from costs incurred in connection with our research and development programs and from general and administrative costs associated with our operations. Our net losses may fluctuate significantly from quarter to quarter and year to year. We expect that our existing cash and cash equivalents will be sufficient to fund our projected cash needs through the closing of the Merger which is expected in the third quarter of 2019 but our expenses may be greater than forecasted and the closing of the Merger could be delayed. If we need to raise additional capital to complete the Merger, we would need to pursue a debt or equity financing or other strategic transactions. However, we may be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all. Our failure to raise capital or enter into such other arrangements when needed would have a negative impact on our financial condition and could result in the need to pursue an immediate dissolution of Histogenics.

Financial Operations Overview

We conduct operations in two geographic regions: Histogenics Corporation, a Delaware corporation, at our facilities in Waltham and Lexington, Massachusetts, and ProChon Biotech Ltd. (ProChon) in Tel Aviv, Israel. We own 100% of the voting shares of ProChon. As the nature of the products, customers and methods to distribute products are the same and the nature of the regulatory environment, the production processes and historical and estimated future margins are similar, the two operations have been aggregated into one reporting segment.

In September 2016, we completed a private placement (the Private Placement) where we issued 2,596,059 shares of our common stock at a per share price of $2.25 and 24,158.8693 shares of our newly-created Series A Convertible Preferred Stock, which shares of preferred stock are convertible into approximately 10,737,275 shares of common stock. The Series A Convertible Preferred Stock became convertible into shares of our common stock following approval of the private placement by our stockholders in the fourth quarter of 2016. As of December 31, 2018, 400.4910 shares of Series A Convertible Preferred Stock that are convertible into 177,996 shares of common stock were outstanding. The net proceeds after deduction of placement agent fees and other transaction-related expenses were $27.6 million. As part of the Private Placement, the investors received warrants to purchase up to 13,333,334 shares of our common stock at an exercise price of $2.25 per share (the 2016 Warrants). The 2016 warrants include a cashless-exercise feature that may be exercised solely in the event there is no effective registration statement registering, or no current prospectus available for, the resale of the shares of common stock underlying the warrants as of the six-month anniversary of the closing of the Private Placement. The 2016 warrants became exercisable following approval of the Private Placement by our stockholders in the fourth quarter of 2016 and expire five years after the date of such stockholder approval.

In January 2018, we completed an underwritten registered direct offering of 2,691,494 shares of common stock at a price of $2.35 per share. The total net proceeds of the offering were $5.7 million after deducting underwriter’s discounts and commissions, and expenses related to the offering.

In March 2018, we entered into an equity distribution agreement (the Equity Distribution Agreement) with Canaccord Genuity Inc. (Canaccord), pursuant to which we may, from time to time, sell shares of our common stock (the Shares), having an aggregate offering price of up to $10 million through Canaccord, as our sales agent. The Shares will be offered and sold by us pursuant to our previously filed and currently effective Registration Statement on Form S-3 (Reg. No. 333-216741) (the Registration Statement). The Shares may only be offered and sold by means of a prospectus, including a prospectus supplement, forming part of the effective Registration Statement. Sales of the common stock, if any, will be made at market prices by methods deemed to be an “at the market offering” as defined in Rule 415 promulgated under the Securities Act of 1933, as amended (the Securities Act), including sales made directly on The Nasdaq Capital Market, on any other existing trading market for the common stock, or to or through a market maker other than on an exchange. During the year ended December 31, 2018, we sold an aggregate of 6,633,903 shares of common stock and received $4.5 million after deducting commissions. There were no sales under the Equity Distribution Agreement in 2019.

On October 10, 2018, we closed an underwritten public offering of 26,155,000 shares of our common stock and warrants to purchase up to 19,616,250 shares of common stock (the 2018 Warrants), at a combined purchase price of $0.65 per share of common stock and accompanying warrant. The gross proceeds from this offering were $17.0 million, before deducting underwriting discounts and commissions, and offering expenses payable by us. The 2018 Warrants were exercisable immediately upon issuance at a price of $0.70 per share of common stock and have a term of five years commencing on the date of issuance.

In the first quarter of 2019, we and certain holders of the 2016 Warrants (the Participating 2016 Holders) entered into a Warrant Amendment and Exercise Agreement (the 2016 Exercise Agreement) pursuant to which we agreed to reduce the exercise price of the 2016 Warrants held by such Participating 2016 Holders from $2.25 to $0.01 per share (the 2016 Reduced Exercise Price) in consideration for the exercise of the 2016 Warrants held by such Participating 2016 Holders in full at the 2016 Reduced Exercise Price for cash. In connection with the exercise of the 2016 Warrants by the Participating 2016 Holders, we received aggregate gross proceeds of approximately $0.1 million. After the exercise of the 2016 Warrants held by the Participating 2016 Holders, 2016 Warrants to purchase approximately 508,714 shares of the Company’s Common Stock remain outstanding.

Also in the first quarter of 2019, we reduced the exercise price of the 2018 Warrants from $0.70 to $0.01 per share (the 2018 Reduced Exercise Price) and all of the holders of the 2018 Warrants (the Participating 2018 Holders) entered into a Warrant Exercise Agreement (the 2018 Exercise Agreement) pursuant to which in consideration for the 2018 Reduced Exercise Price, the Participating 2018 Holders agreed to exercise the 2018 Warrants held by such Participating 2018 Holders in full at the 2018 Reduced Exercise Price for cash. In connection with the exercise of the 2018 Warrants by the Participating 2018 Holders, we received aggregate gross proceeds of approximately $0.2 million.

The consolidated financial statements and the following information include the accounts of Histogenics, ProChon and Histogenics Securities Corporation. All intercompany accounts and transactions have been eliminated in consolidation.

Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of our consolidated financial condition and results of operations are based on our consolidated financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles. The preparation of these consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenue and expenses and the disclosure of contingent assets and liabilities in our consolidated financial statements. On an ongoing basis, we evaluate our estimates and judgments, including those related to accrued expenses and stock-based compensation. We base our estimates on historical experience, known trends and events, and various other factors that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. Other than the adoption of ASU No. 2016-02, there have been no material changes to our critical accounting policies and estimates from those previously disclosed in our 2018 Annual Report on Form 10-K for the year ended December 31, 2018 (see Note 2 of the Notes to the Consolidated and Combined Financial Statements).

Other Company Information

Net Operating Loss Carryforwards

Utilization of the net operating loss (NOL) and research and development credit carryforwards may be subject to a substantial annual limitation due to ownership change limitations that have occurred or that could occur in the future, as required by Section 382 and 383 of the Internal Revenue Code (Code), as well as similar state and foreign provisions. These ownership changes may limit the amount of NOL and research and development credit carryforwards that can be utilized annually to offset future taxable income and tax, respectively. In general, an "ownership change" as defined by Section 382 of the Code results from a transaction or series of transactions over a three-year period resulting in an ownership change of more than 50% of the outstanding stock of a company by certain stockholders. We have completed a study prior to December 31, 2017, to assess whether an ownership change has occurred and the results of this study indicated we experienced ownership changes, as defined by Section 382 of the Code, in each of 2006, 2011, 2012, 2013 and 2016. We have not recorded NOLs that as a result of these restrictions will expire unused. The limitations are an aggregate of $312.8 million for the years 2010 to 2016.

As of December 31, 2018 and 2017, we had U.S. federal NOL carryforwards of $67 million and $43.9 million, respectively, which may be available to offset future income tax liabilities and expire at various dates through 2037. As of December 31, 2018, and 2017, we also had U.S. state NOL carryforwards of $66.9 million and $43.6 million, respectively, which may be available to offset future income tax liabilities and expire at various dates through 2037. As of December 31, 2018 and 2017, we also had $26.2 million and $26.1 million, respectively, of foreign NOL carryforwards which may be available to offset future income tax liabilities, which carryforwards do not expire.

As of June 30, 2019, we have provided a full valuation allowance for deferred tax assets.

JOBS Act

On April 5, 2012, the Jumpstart Our Business Startups Act (JOBS Act) was enacted. Section 107 of the JOBS Act permits an "emerging growth company" or a "smaller reporting company" to delay the adoption of new or revised accounting standards until those standards would otherwise apply to private companies. We plan to avail ourselves of this exemption from new or revised accounting standards and, therefore, we may not be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

For so long as we are an "emerging growth company" or "smaller reporting company," we intend to rely on exemptions relating to: (1) providing an auditor's attestation report on our system of internal control over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act and (2) complying with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report

providing additional information about the audit and the financial statements, known as the auditor discussion and analysis. We will remain an emerging growth company until the earliest of: (a) the last day of the fiscal year in which we have total annual gross revenue of $1.0 billion or more, (b) December 31, 2019, the last day of our fiscal year following the fifth anniversary of the date of the completion of our initial public offering (IPO), (c) the date on which we have issued more than $1.0 billion in non-convertible debt during the previous three years and (d) the date on which we are deemed to be a large accelerated filer under the rules of the SEC.

Results of Operations

Three Month Periods Ended June 30, 2019 and 2018

The following table summarizes the results of our operations for the three-month period ended June 30, 2019 and 2018:

	Three Months Ended June 30,		Change	
	2019	2018	$	%
	(in thousands)			
Research and development expenses	$ 446	$ 4,458	$(4,012)	(90)%
General and administrative expenses	2,614	2,826	(212)	(8)%
Other income (expense), net	(176)	3,507	(3,678)	(105)%

Research and Development Expenses. Research and development expenses were $0.4 million for the three months ended June 30, 2019 as compared to $4.5 million for the three months ended June 30, 2018. The decrease of $4.0 million was due to the discontinuation of the NeoCart development program and the related restructuring plans that we implemented in January 2019 and March 2019. We expect no additional research and development expenses until the anticipated closing of the Merger.

General and Administrative Expenses. General and administrative expenses were $2.6 million for the three months ended June 30, 2019 compared to $2.8 million for the three months ended June 30, 2018. We expect a lower level of ongoing general and administrative expenses until the anticipated closing of the Merger.

Other Income (Expense), Net. Net other expense was $0.2 million for the three months ended June 30, 2019 as compared to net other income of $3.5 million for the three months ended June 30, 2018. In the three months ended June 30, 2019, the net expense is primarily comprised of a loss of on the extinguishment of lease obligations of $0.3 million. In the three months ended June 30, 2018, the other income is primarily comprised of a change in warrant liability caused by an increase in our stock price during the period.

Six Month Periods Ended June 30, 2019 and 2018

The following table summarizes the results of our operations for the six month period ended June 30, 2019 and 2018:

	Six Months Ended June 30,		Change	
	2019	2018	$	%
	(in thousands)			
Research and development expenses	$ 2,029	$ 7,744	$(5,715)	(74)%
General and administrative expenses	5,543	5,633	(90)	(2)%
Restructuring	2,789	—	2,789	—
Loss due to asset impairment	750	—	750	—
Other income (expense), net	(1,540)	(5,252)	3,712	71%

Research and Development Expenses. Research and development expenses were $2.0 million for the six months ended June 30, 2019 as compared to $7.7 million for the six months ended June 30, 2018. The decrease of $5.7 million was primarily due to the discontinuation of the NeoCart development program and the related restructuring plans that we implemented in January 2019 and March 2019. We expect no additional research and development expenses until the anticipated closing of the Merger.

General and Administrative Expenses. General and administrative expenses were $5.5 million for the six months ended June 30, 2019 compared to $5.6 million for the six months ended June 30, 2018. We expect a lower level of ongoing general and administrative expenses until the anticipated closing of the Merger.

Restructuring. During the six months ended June 30, 2019, the Company implemented two restructurings that resulted in the severance of all of its employees. In connection with the employee severances, the Company incurred approximately $2.8 million in severance-related expenses. All of the severance activity was incurred and paid as of June 30, 2019.

Loss due to asset impairment. The Company incurred a loss of $0.8 million in 2019 on the impairment of an asset related to the License Agreement with MEDINET. Given the decision to discontinue the development of NeoCart and terminate manufacturing operations, we concluded that the asset was fully impaired and the full asset value was written off in the first quarter of 2019.

Other Income (Expense), Net. Other expense, net was $1.5 million for the six months ended June 30, 2019 as compared to $5.3 million for the six months ended June 30, 2018. In both periods, the charges were primarily due to changes in warrant liability caused by a decrease in our stock price during the respective periods.

Liquidity and Capital Resources

We have incurred losses and negative cash flows from operations resulting in an accumulated deficit at June 30, 2019 of $229.5 million. We anticipate that we will continue to incur net losses for the next several years. Through June 30, 2019, we have funded our consolidated operations primarily through funds from the sale of equity securities, commercial bank debt, payments from collaboration activities, and, to a limited extent, revenue from product sales and grants. As of June 30, 2019, we had cash and cash equivalents $2.8 million.

We believe that our existing cash and cash equivalents will be sufficient to fund our projected cash needs through the third quarter of 2019 and enable us to complete our planned merger with Ocugen. However, if we experience a delay in completing the Merger, we will require additional capital to sustain our operations through such completion or we will need to pursue an immediate dissolution of the Company. If we need additional capital, we would need to raise such capital through debt or equity financings, asset sales or other strategic transactions. However, there can be no assurances that we will be able to complete any such transaction on acceptable terms or otherwise. The failure to obtain sufficient funds on commercially acceptable terms when needed could have a material adverse effect on our business, results of operations and financial condition and may prevent us from completing the Merger. Accordingly, these factors, among others, raise substantial doubt about our ability to continue as a going concern.

The following table sets forth a summary of the net cash flow activity for each of the periods indicated:

	Six Months Ended June 30,		Change	
	2019	2018	$	%
	(in thousands)			
Net cash used in operating activities	$ (11,549)	$ (1,927)	$ (9,622)	—
Net cash provided by (used in) investing activities	110	(1,834)	1,944	105%
Net cash provided by (used in) financing activities	(1,454)	5,452	(6,906)	(127)%
Net increase (decrease) in cash and cash equivalents	$ (12,893)	$ 1,691	$(14,584)	—

Operating Activities

Cash from operating activities decreased from a use of $1.9 million to a use of $11.6 million for the six months ended June 30, 2018 compared to the six months ended June 30, 2019. During the six months ended June, 2019, net cash used in operating activities was driven primarily by our net loss of $12.7 million and a combined reduction in accounts payable and accrued expenses of $1.9 million, partially offset by non-cash charges for the change in the fair value of warrant liability of $1.5 million and loss on asset impairment of $0.8 million. During the six months ended June 30, 2018, the Company's net cash provided by operations was favorably impacted by the receipt of $10 million of deferred revenue associated with the MEDINET License Agreement.

Investing Activities

The Company's cash flow provided by investing activities of $0.1 million for the six months ended June 30, 2019 reflected cash proceeds from the sale of fixed assets, compared to a net use of $1.8 million for the same six-month period of 2018 which reflected purchases of property and equipment of $2.7 million, offset by proceeds from the maturity of marketable securities of $0.9 million.

Financing Activities

Cash used by financing activities of $1.4 million for the six months ended June 30, 2019 was primarily comprised of payments of $ 1.8 million to extinguish lease obligations, partially offset by proceeds from the exercise of common stock warrants of $0.3 million. Cash provided by financing activities of $5.5 million was primarily due to the issuance of common stock.

Operating Capital Requirements

We anticipate that we will continue to incur losses for the next several quarters and we may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. We may also need additional funding in the future in connection with our continuing operations if our Merger with Ocugen is delayed.

If we raise additional funds through the issuance of additional debt or equity securities, it could result in dilution to our existing stockholders, increased fixed payment obligations and the existence of securities with rights that may be senior to those of our common stock. If we incur indebtedness, we could become subject to covenants that would restrict our operations and potentially impair our competitiveness, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. Any of these events could significantly harm our business, financial condition and prospects.

Our forecast of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement and involves risks and uncertainties, and actual results could vary as a result of a number of factors. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect. The amount and timing of future funding requirements, both near- and long-term, will depend on many factors, including:

- the accuracy of our estimates regarding expenses and any capital requirements;
- the timely completion of the Merger with Ocugen;
- the cost of retaining key consultants;
- the timing, completion and funds received from any asset sales we make in connection with the Merger;
- any unexpected expenses and liabilities that related to the wind-down of our operations and preparation for the Merger;
- the cost of establishing and maintaining development and commercialization partnerships and or licensing transactions we may pursue;
- the extent to which we are required to pay milestone or other payments under our in-license agreements and the timing of such payments; and
- the cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights.

If we cannot capitalize on our business opportunities because we lack sufficient capital, our business, financial condition and results of operations could be materially adversely affected.

As previously announced, on October 17, 2018, Nasdaq notified the Company that it did not meet Nasdaq's $1.00 per share minimum bid price requirement under Nasdaq Listing Rule 5550(a)(2) for continued listing on The Nasdaq Capital Market, and the Company was given an initial grace period of 180 days, or until April 15, 2019, to regain compliance with this Rule. On April 16, 2019, the Company received a letter (the Letter) from the Nasdaq Listing Qualifications Staff (the Staff) notifying the Company that, based upon the Company's continuing non-compliance with Rule 5550(a)(2), the Staff had determined that the Company's common stock would be delisted from Nasdaq unless the Company timely requests a hearing before a Nasdaq Hearings Panel (the Panel). The Letter also noted that the Company was not eligible for a second 180 day grace period as it does not comply with the stockholders' equity initial listing requirement for The Nasdaq Capital Market.

Subsequently, the Company requested a hearing before the Panel, which was held in May 2019. On May 31, 2019, the Company received a decision letter from the Panel (the Decision), indicating that the Panel had granted the Company's request to continue its listing on The Nasdaq Capital Market in order to complete the proposed Merger with Ocugen. The Decision specifies that the Company shall complete the Merger no later than September 30, 2019, and demonstrate to the

satisfaction of the Staff and the Panel that the combined entity meets all of the applicable requirements for initial listing on The Nasdaq Capital Market. The Panel reserved the right to reconsider the terms of this extension based on any event, condition or circumstance that exists or develops that would, in the opinion of the Panel, make continued listing of the Company's common stock on The Nasdaq Capital Market inadvisable or unwarranted. The Company's common stock will continue to trade on The Nasdaq Capital Market under the symbol "HSGX" through the earlier of the expiration of the extension period granted by the Panel or the Closing of the Merger.

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

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

Off-Balance Sheet Arrangements

We did not have any off-balance sheet arrangements during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined in the rules and regulations of the SEC.

Item 3. Quantitative and Qualitative Disclosures about Market Risk.

Not applicable.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the Exchange Act), are controls and other procedures designed to ensure that information required to be disclosed in reports filed or submitted under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified by the rules and forms promulgated by the SEC. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that such information is accumulated and communicated to management, including the chief executive officer and the chief financial officer, as appropriate, to allow timely decisions regarding required disclosure.

In connection with the preparation of this Quarterly Report on Form 10-Q, we completed an evaluation, as of June 30, 2019, under the supervision of and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, as to the effectiveness of our disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act). Based upon our evaluation, our principal executive officer and principal financial officer have concluded that our disclosure controls and procedures were not effective as of June 30, 2019 as a result of the material weakness described below. It should be noted that any system of controls, however well designed and operated, can provide only reasonable, and not absolute, assurance that the objectives of the system will be met. In addition, the design of any control system is based in part upon certain assumptions about the likelihood of future events.

We have identified a material weakness in our internal controls relating to the accounting for transactions that are either highly complex and/or unusual in nature. In such instances, we seek to augment our internal accounting capabilities by obtaining assistance from third-parties who have greater expertise in such areas. Examples of situations such as these include (but are not limited to) the determination of the initial and periodic fair value of warrants that are liability classified and the accounting treatment for the termination of the Company's collaboration agreement with Intrexon Corporation ("Intrexon").

For example, during the third quarter of 2018, we identified a material weakness in our internal controls relating to the valuation of the warrant liability. Because the valuation of the warrants is exceedingly complex and requires highly specialized skills to perform and review, we use the assistance of a third-party service provider to perform such valuation. In the third quarter of 2018, the third-party service provider made an error in the valuation that was not detected by management in its review process but was identified by our independent registered public accounting firm. In the fourth quarter of 2018, we identified a material weakness in our internal controls related to the accounting treatment for the contingent liability

associated with the termination agreement entered into with Intrexon which terminated the Company's collaboration agreement with Intrexon. In this instance, we concluded after numerous discussions with our independent registered public accounting firm that we had incorrectly accounted for the contingent liability. In both cases these items were discovered prior to the issuance of the financial statements.

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis. The identified material weakness did not result in a misstatement in our final consolidated financial statements or disclosures; however, it could result in misstatements of certain account balances (such as warrant liability and change in fair value of warrant liability or the accrued expenses due to Intrexon) or disclosures that would result in a material misstatement to the annual or interim consolidated financial statements that would not be prevented or detected. We have implemented additional review procedures, including engaging a second third-party service provider to assist in our review of the work of the third-party service provider preparing the warrant valuation analysis and will seek to implement a similar procedure for other unusual or complex transactions going forward. We believe these actions will be sufficient to remediate the identified material weakness and strengthen our internal control over financial reporting, as well as our disclosure controls and procedures. However, while certain remediation steps have been completed in the fourth quarter of 2018 and the first quarter of 2019, the enhanced controls relating thereto are not all yet fully operational, and we may determine to take additional measures to address our control deficiencies or to modify the remediation plans described above. The identified material weakness in our internal control over financial reporting will not be considered remediated until the new controls are fully implemented, in operation for a sufficient period of time, tested and concluded by management to be designed and operating effectively.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) that occurred during the period covered by this report that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II – OTHER INFORMATION

Item 1. Legal Proceedings.

From time to time, we are subject to claims in legal proceedings arising in the normal course of its business. We do not believe that we are currently party to any pending legal actions that could reasonably be expected to have a material adverse effect on our business, financial condition, results of operations or cash flows.

Item 1A. Risk Factors.

The following description of risk factors include any material changes to, and supersedes the description of, risk factors associated with our business previously disclosed in Part I, Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2018, filed with the Securities and Exchange Commission (SEC) on March 22, 2019, under the heading "Risk Factors." Our business, financial condition and operating results can be affected by a number of factors, whether currently known or unknown, including but not limited to those described below, any one or more of which could, directly or indirectly, cause our actual operating results and financial condition to vary materially from past, or anticipated future, operating results and financial condition. Any of these factors, in whole or in part, could materially and adversely affect our business, financial condition, operating results and the price of our common stock.

The following discussion of risk factors contains forward-looking statements. These risk factors may be important to understanding any statement in this Quarterly Report on Form 10-Q or elsewhere. The following information should be read in conjunction with the consolidated financial statements and related notes in Part I, Item 1, "Financial Statements" and Part I, Item 2, "Management's, Discussion and Analysis of Financial Condition and Results of Operations."

Because of the following factors, as well as other factors affecting our financial condition and operating results, past financial performance should not be considered to be a reliable indicator of future performance, and investors should not use historical trends to anticipate results or trends in future periods.

Risks Related to the Proposed Merger

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

The Merger Agreement has set the exchange ratio for the Ocugen capital stock at 28.7650, subject to adjustment for the reverse stock split of Histogenics common stock to be implemented prior to the consummation of the Merger. Applying the exchange ratio of 28.7650, current holders of Ocugen's capital stock and options and warrant to purchase shares of Ocugen common stock, are expected to own, or hold rights to acquire, in the aggregate approximately 83% of the fully-diluted common stock of Histogenics, which for these purposes is defined as the outstanding common stock of Histogenics plus Series A Convertible Preferred Stock and outstanding warrants of Histogenics excluding the Investor Warrants (the Fully-Diluted Common Stock of Histogenics) and Histogenics' current stockholders and warrantholders are expected to own, or hold rights to acquire, in the aggregate approximately 17% of the Fully-Diluted Common Stock of Histogenics, prior to giving effect to the Pre-Merger Financing (as defined below). In connection with the proposed Merger, on June 13, 2019, Ocugen and Histogenics entered into a securities purchase agreement, which was subsequently amended on June 28, 2019 (the Securities Purchase Agreement), with certain accredited investors (the Investors) pursuant to which, among other things, Ocugen agreed to issue to the Investors shares of Ocugen common stock immediately prior to the Merger and Histogenics agreed to issue to the Investors warrants to purchase shares of Histogenics common stock on the fifth trading day following the consummation of the merger (the Investor Warrants) in a private placement transaction for an aggregate purchase price of approximately $25.0 million (subject to setoff for amounts outstanding of approximately $5.29 million under certain senior secured notes previously issued or to be issued prior to the consummation of the Merger to certain of the Investors by Ocugen) (the Pre-Merger Financing). Immediately after the Merger, after giving effect to the Pre-Merger Financing and based on the exchange ratio of 28.7650, current holders of Ocugen's capital stock and options and warrants to purchase shares of Ocugen common stock, are expected to own, or hold rights to acquire, in the aggregate approximately 86.24% of the Fully-Diluted Common Stock of Histogenics, and Histogenics' current stockholders and warrantholders are expected to own, or hold rights to acquire, in the aggregate approximately 13.76% of the Fully-Diluted Common Stock of Histogenics.

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

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

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

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

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

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

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

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

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

- the taking of any action, or the failure to take any action, by either Histogenics or Ocugen required to comply with the terms of the Merger Agreement.

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

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

Certain officers and directors of Histogenics and Ocugen participate in arrangements that provide them with interests in the proposed Merger that are different from the interests of the respective stockholders of Histogenics and Ocugen, including, among others, the continued service as an officer or director of the combined organization, severance benefits, the acceleration of stock option vesting, continued indemnification and the potential ability to sell an increased number of shares of common stock of the combined organization in accordance with Rule 144 under the Securities Act of 1933, as amended.

For example, certain of Ocugen's directors and executive officers have options, subject to vesting, to purchase shares of Ocugen's common stock which, at the closing of the Merger, shall be converted into and become options to purchase shares of our common stock, certain of Ocugen's directors and executive officers are expected to become directors and executive officers of Histogenics upon the closing of the Merger, and all of Histogenics' and Ocugen's directors and executive officers are entitled to certain indemnification and liability insurance coverage pursuant to the terms of the Merger Agreement. These interests, among others, may influence the officers and directors of Histogenics and Ocugen to support or approve the proposed Merger.

The market price of our common stock following the Merger may decline as a result of the Merger.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

If the conditions to the Merger are not met, the Merger will not occur.

Even if the Merger is approved by the stockholders of Histogenics and Ocugen, specified conditions must be satisfied or waived to complete the Merger. We cannot assure you that all of the conditions will be satisfied or waived. If the conditions are not satisfied or waived, the Merger will not occur or will be delayed, and Histogenics and Ocugen each may lose some or

all of the intended benefits of the proposed Merger. Additionally, if the Merger does not occur, we may not have sufficient cash to conduct an orderly wind-down and dissolution of Histogenics. We would not be able to raise additional capital through the sale of our NeoCart program prior to approval from our stockholders as such assets constitute substantially all of our assets. Histogenics may seek an immediate dissolution, subject to a vote of our stockholders, in the event the Merger is not completed.

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

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

Risks Related to Our Financial Condition and Our Need for Additional Financing, and Additional Risks Related to the Merger

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

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

- we have incurred and expect to continue to incur significant expenses related to the proposed Merger even if the Merger is not consummated;
- we could be obligated to pay Ocugen a termination fee of up to $0.6 million under certain circumstances set forth in the Merger Agreement;
- the market price of our common stock may decline to the extent that the current market price reflects a market assumption that the proposed Merger will be completed; and
- matters relating to the proposed Merger have required and will continue to require substantial commitments of time and resources by our remaining consultants, which could otherwise have been devoted to other opportunities that may have been beneficial to us.

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

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

Our assets currently consist primarily of cash and cash equivalents, our NeoCart assets, the remaining value, if any, of our deferred tax assets, our listing on The Nasdaq Capital Market and the Merger Agreement with Ocugen. While we have entered into the Merger Agreement with Ocugen, the closing of the proposed Merger may be delayed or may not occur at all and there can be no assurance that the proposed Merger will deliver the anticipated benefits we expect or enhance stockholder value. If we are unable to consummate the proposed Merger, our board of directors may elect to pursue an alternative strategy, one of which may be a strategic transaction similar to the proposed Merger. Attempting to complete an alternative transaction like the proposed Merger will be costly and time consuming, and we can make no assurances that such an alternative transaction would occur at all. Alternatively, our board of directors may elect to resume our efforts to seek

potential collaborative, partnering or other strategic arrangements for our NeoCart assets, including a sale or other divestiture of our NeoCart assets, or our board of directors could instead decide to pursue a dissolution and liquidation of our company. In such an event, the amount of cash available for distribution to our stockholders will depend heavily on the timing of such decision, as with the passage of time the amount of cash available for distribution will be reduced as we continue to fund our operations. In addition, if our board of directors were to approve and recommend, and our stockholders were to approve, a dissolution and liquidation of our company, we would be required under Delaware corporate law to pay our outstanding obligations, as well as to make reasonable provision for contingent and unknown obligations, prior to making any distributions in a liquidation to our stockholders. Our commitments and contingent liabilities may include severance obligations, regulatory, clinical and preclinical obligations, and fees and expenses related to the proposed Merger. As a result of this requirement, a portion of our assets would need to be reserved pending the resolution of such obligations. In addition, we may be subject to litigation or other claims related to a dissolution and liquidation. If a dissolution and liquidation were pursued, our board of directors, in consultation with its advisors, would need to evaluate these matters and make a determination about a reasonable amount to reserve. Accordingly, holders of our common stock could lose all or a significant portion of their investment in the event of a liquidation, dissolution or winding up of the company.

The issuance of shares of our common stock to Ocugen stockholders in the proposed Merger will substantially dilute the voting power of our current stockholders.

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

We have incurred significant losses since our inception and anticipate that we will continue to incur substantial losses for the next several years.

We have incurred net losses in each year since our inception, including net losses of $8.6 million in 2018 and $26.4 million in 2017. As of June 30, 2019 we had an accumulated deficit of $229.5 million. We anticipate that our existing cash, cash equivalents and marketable securities will be sufficient to fund our operations through the consummation of the proposed Merger, which is anticipated to occur in the third quarter of 2019. Accordingly, these factors, among others, raise substantial doubt about our ability to continue as a going concern. The amount of our future net losses will depend, in part, on the amount and timing of our expenses. These net losses have had, and will continue to have, an adverse effect on our stockholders' equity and working capital.

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

If the Merger is not completed and we are unable to raise sufficient additional funds for the development of NeoCart, whether through potential collaborative, partnering or other strategic arrangements or otherwise, which we do not believe we could do on reasonable terms, we will likely cease operations, wind-down and dissolve (whether in or out of a bankruptcy or court proceeding to do so).

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

At June 30, 2019, Histogenics had cash and cash equivalents of $2.8 million. Based on Histogenics' current business plan and spending assumptions as a standalone company, we estimate that our current cash and cash equivalents together with interest thereon, will be sufficient to meet our projected operating requirements through the third quarter of 2019. Histogenics has based its cash sufficiency estimates on its current business plan and its assumptions that may prove to be wrong. Histogenics could utilize its available capital resources sooner than it currently expects, and it could need additional funding sooner than currently anticipated.

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

- its ability to successfully complete the proposed Merger;
- the terms and timing of any potential collaborative, partnering and other strategic arrangements that Histogenics may establish; and
- the amount and timing of any licensing fees, milestone payments and royalty payments from potential collaborators, if any.

While Histogenics has been able to fund its operations to date, Histogenics has no source of revenue, nor does it expect to generate product revenue of product revenue, it will need to finance future cash needs through potential collaborative, partnering or other strategic arrangements, as well as through public or private equity offerings or debt financings or a combination of the foregoing. If Histogenics is unable to raise additional funds, it will need to continue to reduce its expenditures in order to preserve its cash. Further cost-cutting measures that Histogenics may take may not be sufficient to enable it to meet its cash requirements, and they may negatively affect Histogenics' business and its ability to derive any value from its NeoCart program. In any event, in order to restart the NeoCart development program, Histogenics will need to raise substantial additional capital, which it does not currently believe it will be able to do on reasonable terms, if at all. Histogenics' failure to do so would likely result in it determining to cease operations.

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

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

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

We are substantially dependent on our remaining consultants to facilitate the consummation of the proposed Merger.

In connection with our restructuring in January 2019 and a further restructuring in March of 2019, we terminated all but one employee, and we subsequently terminated our final employee in May 2019. Our ability to successfully complete a strategic transaction depends in large part on our ability to retain the consulting services of certain of our former personnel, particularly Adam Gridley, our President and Jonathan Lieber, our Interim Chief Financial Officer. Despite our efforts to retain these individuals as consultants following their separation of service from the Company, one or more may terminate their engagement with us on short notice. The loss of the services of any of these individuals could potentially harm our ability to consummate the proposed Merger, as well as fulfill our reporting obligations as a public company.

The pendency of the proposed Merger could have an adverse effect on the trading price of our common stock and our business, financial condition and prospects.

While there have been no significant adverse effects to date, the pendency of the proposed Merger could disrupt our business in many ways, including:

- the attention of our remaining service providers may be directed toward the completion of the proposed Merger and related matters and may be diverted from our day-to-day business operations; and
- third parties may seek to terminate or renegotiate their relationships with us as a result of the proposed Merger, whether pursuant to the terms of their existing agreements with us otherwise.

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

Risks Related to Our Historical Business

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

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

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

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

Our inability to utilize our net operating loss carryforwards before they expire may adversely affect our results of operations and financial condition.

As of December 31, 2018 we had federal and state net operating loss carryforwards of approximately $67 million and $67 million, respectively, which may be utilized against future federal and state income taxes. In general, a corporation that undergoes an “ownership change” is subject to limitations on its ability to utilize its pre-change net operating loss carryforwards (NOLs) to offset future taxable income. In general, an ownership change occurs if the aggregate stock ownership of certain stockholders, generally stockholders beneficially owning five percent or more of our common stock,

applying certain look-through and aggregation rules, increases by more than 50% over such stockholders' lowest percentage ownership during the testing period, generally three years. Purchases of our common stock in amounts greater than specified levels, which will be beyond our control, could create a limitation on our ability to utilize our NOLs for tax purposes in the future. In addition, the closing of a strategic transaction may result in the limitation of our NOLs, which may affect the value we receive in such a strategic transaction. Limitations imposed on our ability to utilize NOLs could cause us to pay U.S. federal and state income taxes earlier than we would otherwise be required if such limitations were not in effect and could cause such NOLs to expire unused. Furthermore, we may not be able to generate sufficient taxable income to utilize our NOLs before they expire beginning in 2037. In addition, at the state level there may be periods during which the use of NOLs is suspended or otherwise limited, which would accelerate or may permanently increase state taxes owed. If any of these events occur, we may not derive some or all of the expected benefits from our NOLs, and our results of operations and financial condition may be adversely affected as a result.

We may fail to comply with any of our obligations under existing agreements pursuant to which we license rights or technology, which could result in the loss of rights or technology that are material to our business and as a result possibly material to a potential strategic partner.

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

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

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

- increased costs due to related litigation;
- distraction of management's attention from our primary business;
- substantial monetary awards to patients or other claimants; and
- potential impairment of our ability to successfully complete a potential strategic transaction.

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

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

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

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

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

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

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

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

We have identified material weaknesses in our internal controls over financial reporting and may identify additional material weaknesses in the future that may cause us to fail to meet our reporting obligations or result in material misstatements of our financial statements.

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

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

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

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

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

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

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

Our research and development and manufacturing processes involve the controlled use of hazardous materials, including chemicals and biological materials. Our operations produce hazardous waste products. We cannot eliminate the risk of accidental contamination or discharge and any resultant injury from these materials. We may be sued for any injury or

contamination that results from our use or the use by third parties of these materials, and our liability may exceed our insurance coverage and our total assets. Federal, state and local laws and regulations govern the use, manufacture, storage, handling and disposal of these hazardous materials and specified waste products, as well as the discharge of pollutants into the environment and human health and safety matters.

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

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

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

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

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

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

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

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

A significant natural disaster, such as an earthquake, fire or flood, or a significant power outage, could have a material adverse impact on our business, operating results and financial condition. If any of our manufacturing, processing or storage facilities, or any of the equipment in such facilities were to be damaged or destroyed, it may result a lack of any definitive offer to consummate a strategic transaction, or, if we receive such a definitive offer, the terms may not be as favorable as anticipated or may not result in the consummation of a transaction.

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

We are increasingly dependent on information technology systems, infrastructure and data.

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

Risks Related to Regulatory Approval

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

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

Risks Related to Our Intellectual Property

Our ability to execute a strategic transaction may depend on our ability to protect our intellectual property and our proprietary technologies.

Our ability to execute a strategic transaction may depend in part on our ability to maintain patent protection and trade secret protection for our product candidates, proprietary technologies and their uses as well as our ability to operate without infringing upon the proprietary rights of others. There can be no assurance that our patent applications or those of our licensors will result in additional patents being issued or that issued patents will afford sufficient protection against

competitors with similar technology, nor can there be any assurance that the patents issued will not be infringed, designed around, or invalidated by third parties. Even issued patents may later be found unenforceable or may be modified or revoked in proceedings instituted by third parties before various patent offices or in courts. The degree of future protection for our proprietary rights is uncertain. Only limited protection may be available and may not adequately protect our rights or permit us to gain or keep any competitive advantage. This failure to properly protect the intellectual property rights relating to these product candidates could have a material adverse effect on our financial condition and results of operations and ability to complete the Merger.

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

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

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

In addition, we rely on the protection of our trade secrets and proprietary know-how. Although we have taken steps to protect our trade secrets and unpatented know-how, including entering into confidentiality agreements with third parties, and confidential information and inventions agreements with employees, consultants and advisors, third parties may still obtain this information or may come upon this or similar information independently. If any of these events occurs or if we otherwise lose protection for our trade secrets or proprietary know-how, the value of this information may be greatly reduced.

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

Our success also depends on our ability and the ability of our current or future development or collaborative partners to develop, manufacture, market and sell our product candidates without infringing upon the proprietary rights of third parties. Numerous U.S. and foreign-issued patents and pending patent applications owned by third parties exist in the fields in which we are developing product candidates, some of which may contain claims that overlap with the subject matter of our

intellectual property or are directed at our product candidates, technologies or methods of manufacture. When we become aware of patents held by third parties that may implicate the manufacture, development or commercialization of our product candidates, we evaluate our need to license rights to such patents. If we need to license rights from third parties to manufacture, develop or commercialize our product candidates, there can be no assurance that we will be able to obtain a license on commercially reasonable terms or at all. Failure to obtain a license on commercially reasonable terms or at all could impair our ability to successfully complete the Merger or any potential strategic transaction on terms that are favorable to our stockholders, or at all.

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

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

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

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

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

Most of our competitors are larger than we are and have substantially greater resources. They are, therefore, likely to be able to sustain the costs of complex patent litigation longer than we could. In addition, the uncertainties associated with litigation could have a material adverse effect on our ability to raise the funds necessary to continue our clinical trials, continue our internal research programs, in-license needed technology, or enter into development partnerships that would help us bring our product candidates to market.

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

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

If we or any of our future development partners were to initiate legal proceedings against a third party to enforce a patent covering one of our product candidates or one of our future product candidates, technologies or methods of manufacture, the defendant could counterclaim that our patent is invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness or non- enablement. Grounds for

an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the U.S. Patent and Trademark Office, or made a misleading statement, during prosecution. Third parties may also raise similar claims before the U.S. Patent and Trademark Office even outside the context of litigation. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection on such product candidate. Such a loss of patent protection would have a material adverse impact on our business and could impair our ability to successfully complete the Merger or any potential strategic transaction on terms that are favorable to our stockholders, or at all.

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

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

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

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

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

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

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to biotechnology, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially

meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license and may adversely affect our business and could significantly impair our ability to successfully complete the Merger or any potential strategic transaction on terms that are favorable to our stockholders, or at all.

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

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

Risks Related to Our Common Stock

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

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

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

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

Further, on December 19, 2018, Histogenics received a deficiency letter from the Staff notifying it that for the last 30 consecutive business days prior to December 18, 2018, the market value of its listed securities were less than $35 million, which does not meet the requirement for continued listing on The Nasdaq Capital Market under Nasdaq Listing Rule 5550(b)(2) (Rule 5550(b)(2)). In accordance with Nasdaq Listing Rule 5810(c)(3)(C), Nasdaq provided Histogenics until June 17, 2019 to regain compliance with Rule 5550(b)(2). On June 19, 2019, Histogenics received a letter (the June Letter) from the Staff notifying Histogenics that it had failed to regain compliance with Rule 5550(b)(2) and that such compliance failure serves as an additional basis for delisting Histogenics' common stock from The Nasdaq Capital Market. The June Letter also noted that such letter served as formal notification that the Panel will consider the failure to regain compliance with Rule 5550(b)(2)in its decision regarding Histogenics' continued listing on The Nasdaq Capital Market, and that Histogenics should present its views with respect to this additional compliance deficiency to the Panel in writing no later than June 26, 2019, which Histogenics did on June 26, 2019.

We may not satisfy The Nasdaq Capital Market's other requirements for continued listing. If we cannot satisfy these requirements, Nasdaq could delist our common stock and could impact our ability to consummate the proposed Merger.

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

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

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

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

- our ability to consummate a strategic transaction, the value of such transaction including whether it is deemed to enhance stockholder value or deliver expected benefits;
- announcements about us or about our competitors including clinical trial results, regulatory approvals, or new product candidate introductions and the revenue and growth potential of such new products;
- developments concerning our current or future development partners, licensors or product candidate manufacturers;
- litigation and other developments relating to our patents or other proprietary rights or those of our competitors;
- conditions in the pharmaceutical or biotechnology industries, regulations or concerns related to cell and gene therapies, and the economy as a whole;
- governmental regulation and legislation;
- the recruitment or departure of members of our Board, management team or other key personnel;
- changes in our operating results;
- any changes in the financial projections we may provide to the public, our failure to meet these projections, or changes in recommendations by any securities analysts that elect to follow our common stock;
- any change in securities analysts' estimates of our performance, or our failure to meet analysts' expectations;
- the expiration of market standoff or contractual lock-up agreements;
- sales or potential sales of substantial amounts of our common stock; and
- price and volume fluctuations in the overall stock market or resulting from inconsistent trading volume levels of our shares.

In recent months and years, the stock market in general, and the market for pharmaceutical and biotechnological companies in particular, has experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to changes in the operating performance of the companies whose stock is experiencing those price and volume fluctuations. In

addition, Brexit or actions taken by the current presidential administration and Congress could adversely affect United States, European or worldwide economic or market conditions and could contribute to instability and volatility in global financial markets. Broad market and industry factors may seriously affect the market price of our common stock, regardless of our actual operating performance.

Our quarterly operating results may fluctuate substantially, which may cause the price of our common stock to fluctuate substantially.

We expect our quarterly operating results to be subject to fluctuations. Our net income or loss and other operating results may be affected by numerous factors, including:

- our ability to complete the Merger or any strategic transaction;
- derivative instruments recorded at fair value, including but not limited to the change in fair value of warrants issued in connection with a private placement we completed in 2016 and the common stock offering we completed in 2018;
- asset impairments, severance costs, lease termination costs, transaction and other costs triggered by a wind down of our operations; and
- any lawsuits in which we may become involved.

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

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

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

If securities analysts do not publish research, publish unfavorable research about our business or cease coverage of our company, our stock price and trading volume could decline.

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

Raising additional funds by issuing securities or through licensing or lending arrangements may cause dilution to our existing stockholders, restrict our operations or require us to relinquish proprietary rights.

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

We have never paid and do not intend to pay cash dividends and, consequently, your ability to achieve a return on your investment will depend on appreciation in the price of our common stock.

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

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

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

- establish a classified board of directors so that not all members of our board are elected at one time;
- permit the board of directors to establish the number of directors;
- provide that directors may only be removed "for cause";
- require super-majority voting to amend some provisions in our certificate of incorporation and bylaws;
- authorize the issuance of "blank check" preferred stock that our board of directors could use to implement a stockholder rights plan;
- eliminate the ability of our stockholders to call special meetings of stockholders;
- prohibit stockholder action by written consent, which requires all stockholder actions to be taken at a meeting of our stockholders;
- provide that the board of directors is expressly authorized to make, alter or repeal our bylaws; and
- establish advance notice requirements for nominations for election to our board of directors or for proposing matters that can be acted upon by stockholders at annual stockholder meetings.

In addition, Section 203 of the Delaware General Corporation Law may discourage, delay or prevent a change in control of our company. Section 203 imposes certain restrictions on merger, business combinations and other transactions between us and holders of 15% or more of our common stock.

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

We are an emerging growth company. Under the Jumpstart Our Business Startups Act, emerging growth companies can delay adopting new or revised accounting standards until such time as those standards apply to private companies. We plan to avail ourselves of this exemption from new or revised accounting standards and, therefore, we may not be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

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

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

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

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.

None.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not Applicable.

Item 5. Other Information.

None.

Item 6. Exhibits.

Exhibit	Description
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	Amended and Restated Bylaws (filed as Exhibit 3.2 to the Registrant's Current Report on Form 8-K as filed on December 8, 2014, and incorporated herein by reference)
4.1	Form of Series A/B Investor Warrants (filed as Exhibit 4.1 to the Registrant's Current Report on Form 8-K as filed on June 14, 2019, and incorporated herein by reference)
4.2	Form of Series C Investor Warrants (filed as Exhibit 4.2 to the Registrant's Current Report on Form 8-K as filed on June 14, 2019, and incorporated herein by reference)
4.3	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)
10.1	Asset Purchase Agreement dated May 8, 2019 by and between the Registrant and Medavate Corp. (filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K as filed on May 13, 2019, and incorporated herein by reference)
10.2	Securities Purchase Agreement, dated as of June 13, 2019, by and among Ocugen, Inc., the Registrant and the investors party thereto (filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K as filed on June 14, 2019, and incorporated herein by reference)
10.3	Form of Lock-Up Agreement (filed as Exhibit 10.2 to the Registrant's Current Report on Form 8-K as filed on June 14, 2019, and incorporated herein by reference)
10.4	Form of Amendment to Securities Purchase Agreement, dated as of June 28, 2019, by and among Histogenics Corporation, Ocugen, Inc. and the investor named therein (filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K as filed on July 3, 2019, and incorporated herein by reference)
31.1*	Certification of the Chief Executive Officer, as required by Section 302 of the Sarbanes-Oxley Act of 2002
31.2*	Certification of the Chief Financial Officer as required by Section 302 of the Sarbanes-Oxley Act of 2002
32.1*	Certifications of the Chief Executive Officer and Chief Financial Officer as required by 18 U.S.C. 1350
101.INS*	XBRL Instance Document
101.SCH*	XBRL Taxonomy Extension Schema Document
101.CAL*	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	XBRL Taxonomy Extension Presentation Linkbase Document

* Filed herewith.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Histogenics Corporation

Dated: August 9, 2019

/s/ Adam Gridley

Adam Gridley
President
(Principal Executive Officer)

Dated: August 9, 2019

/s/ Jonathan Lieber

Jonathan Lieber
Interim Chief Financial Officer
(Principal Financial Officer and Principal Accounting Officer)

EXHIBIT 31.1

CERTIFICATION

I, Adam Gridley, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Histogenics Corporation;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a. designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b. designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c. evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d. disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a. all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b. any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 9, 2019

/s/ Adam Gridley

Adam Gridley
President
(Principal Executive Officer)

EXHIBIT 31.2

CERTIFICATION

I, Jonathan Lieber, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Histogenics Corporation;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a. designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b. designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c. evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d. disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a. all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b. any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 9, 2019

/s/ Jonathan Lieber

Jonathan Lieber
Interim Chief Financial Officer
(Principal Financial and Accounting Officer)

EXHIBIT 32.1

Certification

Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

(Subsections (a) and (b) of Section 1350, Chapter 63 of Title 18, United States Code)

Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (subsections (a) and (b) of section 1350, chapter 63 of title 18, United States Code), each of the undersigned officers of Histogenics Corporation (the Company), does hereby certify, to the best of such officer's knowledge, that:

The Quarterly Report on Form 10-Q for the quarter ended June 30, 2019 (the Form 10-Q) of the Company fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, and the information contained in the Form 10-Q fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: August 9, 2019

/s/ Adam Gridley

Adam Gridley
President
(Principal Executive Officer)

Date: August 9, 2019

/s/ Jonathan Lieber

Jonathan Lieber
Interim Chief Financial Officer
(Principal Financial and Accounting Officer)

A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request. This certification "accompanies" the Form 10-Q to which it relates, is not deemed filed with the SEC and is not to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing.