UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2018

or

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

For the transition period from _____ to _____

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 Number)**
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)

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

Common Stock, $0.01 par value per share	**The Nasdaq Stock Market LLC**
(Title of each class)	**(Name of each exchange on which registered)**

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

None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

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 (§ 229.405 of this chapter) 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 if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☐

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

Large accelerated filer	☐	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 13(a) of the Exchange Act. ☒

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

As of June 30, 2018, the last business day of the registrant's last completed second quarter, the aggregate market value of the Common Stock held by non-affiliates of the registrant was approximately $63.6 million, based on the closing price of the registrant's Common Stock, as reported by the Nasdaq Capital Market. For purposes of this disclosure, shares of Common Stock held by each executive officer, director, stockholders known by the registrant to be affiliates of such executive officers and directors based on public filings and stockholders known by the registrant to own 20% or more of the outstanding stock based on public filings and other information known to the registrant have been excluded since such persons may be deemed affiliates. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

As of March 20, 2019 there were 94,599,601 shares of the registrant's Common Stock issued and outstanding.

Histogenics Corporation

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PART I

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

Various statements in this report are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements involve substantial risks and uncertainties. All statements, other than statements of historical facts, included in this report regarding our strategy, future operations, future financial position, projected costs, prospects, plans and objectives of management are forward-looking statements. These statements are subject to risks and uncertainties and are based on information currently available to our management. Words such as, but not limited to, "anticipate," "believe," "contemplates," "continue," "could," "design," "estimate," "expect," "intend," "likely," "may," "ongoing," "plan," "potential," "predict," "project," "will," "would," "seek," "should," "target," or the negative of these terms and similar expressions or words, identify forward-looking statements. The events and circumstances reflected in our forward-looking statements may not occur and actual results could differ materially from those projected in our forward-looking statements. Meaningful factors which could cause actual results to differ include, but are not limited to:

- our evaluation of strategic alternatives with a goal to enhance stakeholder value, including the possibility of a merger or sale of the Company, the sale of the Company's assets in one or more transactions to one or more third parties or a liquidation and dissolution of the Company;
- our ability to obtain funding for our operations;
- our ability to establish and maintain development and commercialization partnerships;
- our technology, manufacturing capacity, location and partners;
- the accuracy of our estimates regarding expenses, capital requirements and need for additional financing;
- updated or refined data based on continuing review and quality control analysis of clinical data, including the NeoCart Phase 3 clinical trial data;
- our securities' or industry analysts' expectations regarding the commercial success of NeoCart, if approved, and the timing and success of any clinical trials we may initiate in the future;
- the anticipated trends and challenges in our business and the market in which we operate;
- our ability to retain key personnel;
- regulatory developments in the United States and foreign countries; and
- our plans for the use of our cash and cash equivalents.

All written and verbal forward-looking statements attributable to us or any person acting on our behalf are expressly qualified in their entirety by the cautionary statements contained or referred to in this section. We caution investors not to rely too heavily on the forward-looking statements we make or that are made on our behalf. We undertake no obligation, and specifically decline any obligation, to update or revise publicly any forward-looking statements, whether as a result of new information, future events or otherwise. You are advised, however, to consult any further disclosures we make on related subjects in any annual, quarterly or current reports that we may file with the Securities and Exchange Commission.

We encourage you to read the discussion and analysis of our financial condition and our consolidated financial statements contained in this annual report on Form 10-K. We also encourage you to read Item 1A of Part 1 of this annual report on Form 10-K, entitled "Risk Factors," which contains a more complete discussion of the risks and uncertainties associated with our business. In addition to the risks described above and in Item 1A of this report, other unknown or unpredictable factors also could affect our results. There can be no assurance that the actual results or developments anticipated by us will be realized or, even if substantially realized, that they will have the expected consequences to, or effects on, us. Therefore no assurance can be given that the outcomes stated in such forward-looking statements and estimates will be achieved.

As used in this annual report on Form 10-K, the terms “Histogenics,” “Company,” “registrant,” “we,” “us,” and “our” mean Histogenics Corporation and its subsidiaries unless the context indicates otherwise.

INDUSTRY AND MARKET DATA

We obtained the industry, market and competitive position data used throughout this annual report on Form 10-K from our own internal estimates and research, as well as from industry and general publications, in addition to research, surveys and studies conducted by third parties in certain instances. Internal estimates are derived from publicly-available information released by industry analysts and third-party sources, our internal research and our industry experience, and are based on assumptions made by us based on such data and our knowledge of our industry and market, which we believe to be reasonable. In addition, while we believe the industry, market and competitive position data included in this annual report on Form 10-K are reliable and are based on reasonable assumptions, such data involves risks and uncertainties and are subject to change based on various factors, including those discussed in “Risk Factors.” These and other factors could cause results to differ materially from those expressed in the estimates made by the independent parties and by us.

ITEM 1. *BUSINESS*

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.

Recent Developments

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.

Current Strategy

As a result of the FDA feedback, we initiated a process to evaluate strategic alternatives to maximize value for all of our stakeholders. We are conducting the process with the assistance of financial and legal advisors and are evaluating the full range of potential strategic alternatives, including but not limited to, acquisitions, business combinations, joint ventures, public and private capital raises and recapitalization and sale transaction options, including a sale of assets or intellectual property. Since these efforts may not be successful and given our limited cash reserves, we are also considering other possible alternatives, including a wind-down of operations and a liquidation and dissolution of the Company, or Chapter 11 bankruptcy protection to complete or execute a restructuring transaction or liquidation. Our strategic process is ongoing and includes a range of interactions with transaction counterparties. Thus, we believe it is in our stockholders' best interest to allow sufficient opportunity to pursue and consummate one or more such transactions and to consider additional alternatives that may materialize in the future before making a decision regarding a liquidation of the Company. There is no guarantee that any cash (or other securities representing any value) will be returned to stockholders and there is the possibility that the Company's common stock will be worthless in a bankruptcy, wind-down or other liquidation scenario.

In January and March 2019, we implemented restructuring plans that were approved by our Board of Directors (the Board) involving reductions in headcount to reduce operating costs and conserve cash, along with other cash

conservation measures relating to our facilities. The positions eliminated as part of the restructuring plans together represented all but one member of our of our workforce, including our Chief Executive Officer, Chief Operating Officer, Chief Medical Officer and Chief Business Officer. We intend to engage, Mr. Adam Gridley, our Chief Executive Officer, Mr. Stephen Kennedy, our Chief Operating Officer, along with up to four additional employees as consultants to assist with our continuing evaluation of strategic alternatives. Mr. Gridley will retain his statutory titles of president, treasurer and secretary of the Company while he continues to provide consulting services to us, and will remain a director of the Company.

NeoCart Phase 3 Clinical Trial

The NeoCart Phase 3 clinical trial is believed to be the largest and first prospectively designed, randomized clinical trial in North America evaluating the safety and efficacy of a restorative cell therapy to treat knee cartilage damage. It is also believed to be the only trial with a dual threshold responder analysis endpoint.

As part of the prospective data analysis, we collected a variety of patient reported outcome endpoints, including all measures of the Knee Injury and Osteoarthritis Outcomes Score (KOOS) and the International Knee Documentation Committee (IKDC) score, which are validated, patient-centered assessments of pain and function that are commonly used in current clinical trials of cartilage therapies. On almost all of these measures, two of which are being utilized as primary endpoints in ongoing clinical trials by third parties in the U.S. for other therapies, NeoCart demonstrated statistically significant improvements versus microfracture at one and two years.

The Phase 3 clinical trial is the first study prospectively enrolled consistent with current FDA guidance, which provides for the use of microfracture as a comparator treatment in trials to repair knee cartilage damage. The published FDA guidance also specifically calls for a study population that, given the clinical limitations and variable results of microfracture, we believe provides more favorable results than what is typically seen in microfracture in both the literature and a real-world setting.

The primary endpoint for the Phase 3 clinical trial was a dual-threshold responder analysis measuring the improvement in KOOS pain and IKDC function scores for each patient treated with NeoCart compared to those treated with microfracture one year after the time of treatment. Dual-threshold responders were defined as patients who, relative to their baseline measurements, had at least a 12-point improvement in the KOOS pain sub-score assessment and a 20-point improvement in the IKDC subjective assessment. The trial also evaluated additional pain, quality of life, and function outcomes using all five measures of KOOS subscales, including Sports and Recreation. The change from baseline and the relative change between the NeoCart and microfracture arms was also measured at one year which contrasts with clinical trials of other products, either on the market or in development, that measured these changes at two years.

Demographics for both study arms were similar and represent a patient population that was intended to ensure that microfracture would respond favorably, including patients with an average age of approximately 39 years old and a Body Mass Index of approximately 27. Furthermore, the mean lesion size was 2.1 cm in the NeoCart arm and 1.8 cm in the microfracture arm. There were no other significant differences between the treatment arms.

The results with respect to the primary endpoint (dual threshold responder analysis one year after treatment) are summarized below:

	NeoCart			Microfracture				
	Positive Responders	Responder Rate		Positive Responders	Responder Rate		Difference	
ITT	121/170	71.2	%	49/79	62.0	%	9.2	p=0.1877
mITT	121/163	74.2	%	49/79	62.0	%	12.2	P=0.0714
As Treated	120/162	74.1	%	50/80	62.5	%	11.6	p=0.0735
Per Protocol	118/155	76.1	%	43/65	66.2	%	10.0	p=0.1362

Key additional findings from the clinical trial include:

NeoCart demonstrated statistically significant improvements in pain and function at both one and two years after treatment as measured by changes in the KOOS and IKDC scores.

KOOS pain score (mITT Population)
Change from Baseline
(NeoCart Baseline = 54.0; Microfracture Baseline = 52.4)

	NeoCart		Microfracture			
Visit	**N**	**Mean**	**N**	**Mean**	**P-Value**	
3-months	160	24.1	75	22.4	0.0487	*
6-months	157	28.6	75	27.0	0.0819	
1-year	158	31.4	72	28.7	0.0239	*
2-years	87	32.2	34	28.9	0.0080	*
3-years	39	34.3	16	30.7	0.1071	

* *Statistically significant*

IKDC subjective knee exam score (mITT Population)
Change from Baseline
(NeoCart Baseline = 40.3; Microfracture Baseline = 40.0)

	NeoCart		Microfracture			
Visit	**N**	**Mean**	**N**	**Mean**	**P-Value**	
3-months	159	13.7	76	14.5	0.9686	
6-months	156	24.4	74	22.4	0.1572	
1-year	158	33.1	71	28.3	0.0126	*
2-years	87	35.3	34	30.2	0.0366	*
3-years	38	39.9	16	32.6	0.2691	

* *Statistically significant*

NeoCart is based on 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 and structures that enable the proper delivery, distribution and organization of cells in their natural environment to support tissue formation;
- Tissue engineering: the use of a combination of cells, engineering and biomaterials to improve or restore biological functions; and
- Bioadhesives: natural, biocompatible materials that act as adhesives for biological tissue and allow for natural cell and tissue infiltration and integration with native cells.

Intellectual Property

Patent and trade secret protection is critical to our business. We protect our cell processing technology, materials science and products for tissue repair through a variety of methods, including seeking, maintaining and defending patents and other intellectual property intended to cover our products and compositions, their methods of use and processes for their manufacture, our platform technologies, our trade secrets and any other inventions that are commercially important to the development of our business. We actively seek patent protection in the United States and select foreign countries.

Our intellectual property portfolio is currently composed of 34 issued patents and 11 patent applications in the United States that we own, and 15 issued patents and one patent application in the United States that we license from academic institutions and business entities. We also have approximately 100 counterpart patent and patent applications owned or licensed in certain foreign jurisdictions. This portfolio of owned and in-licensed patents and patent applications covers aspects of: our implants, including NeoCart and our protein implants; our tissue engineering processor; our adhesives; our growth factors, methods of delivery of therapeutic agents and promoters for increased expression of protein; our method for treatment of ligament and tendon injuries; surgical tools for placing our implants; and our bone composites. The patents that cover the listed technologies have statutory expiration dates between 2019 and 2031.

We have entered into license agreements with various academic institutions and business entities to obtain the rights to use certain patents and patent applications for the development and commercialization of our technology and products. We also rely on know-how and continuing technological innovation to develop and maintain our proprietary position.

We license from Purpose Co., Ltd. (f/k/a Takagi Sangyo Co. Ltd. and f/k/a Takagi Industrial Co., Ltd.) (Purpose) an exclusive right to 39 issued patents and 6 pending patent applications worldwide relating to an exogenous tissue processor. Through this agreement, we have a sublicense to three issued U.S. patents and eight issued foreign patents owned by The Brigham and Women's Hospital, Inc. (BWH) and Purpose that relate to methods of cultivating a cell or tissue of a living body to be cultivated inside a culture chamber and apparatuses for cultivating a cell or tissue. We also have an exclusive license to two issued U.S. patents and one pending U.S. patent application for restoration of articular cartilage matrix from the Board of Trustees of The Leland Stanford Junior University. The patents that have issued or may yet issue that have been licensed to us under these agreements will have statutory expiration dates between 2020 and 2031.

We have an exclusive license to a portfolio consisting of two families of issued patents and pending patent applications owned by Angiotech Pharmaceuticals (US), Inc. and Angiodevice International GmbH. This exclusivity is for the use of CT3, our proprietary adhesive, for use in combination with intellectual property for the repair of articular cartilage, ligament, meniscus or tendon damage. The patents relate to methods of preparing biocompatible gels, biocompatible gel-forming compositions, methods of treating tissues by administering biocompatible gel-forming compositions, composition for forming a matrix useful as a high strength medical sealant, biocompatible polymer device for use in treating tissues, systems for forming a high strength medical sealant, methods for providing a high strength medical sealant on a surface, methods for applying a sealing layer to a native tissue surface, methods for effecting surgical adhesion, and methods for providing a sealant coating on the surface of a synthetic implant. Any patents within this portfolio that have issued or may yet issue will have statutory expiration dates between 2019 and 2022.

We have an exclusive license to one patent family relating to growth factors and high level expression of heterologous proteins owned by Yeda Research and Development Co., Ltd. Any patents within this portfolio that have issued or may yet issue will have statutory expiration dates between 2021 and 2023.

We continually assess and refine our intellectual property strategy in order to fortify our position in our target markets. We cannot ensure that patents will be granted with respect to any of our pending owned or in-licensed patent applications or with respect to any patent applications we may own or license in the future, nor can we be sure that any of our existing owned or in-licensed patents or any patents we may own or license in the future will be useful in protecting our technology. Please see "Risk Factors—Risks Related to Our Intellectual Property" for additional information on the risks associated with our intellectual property strategy and portfolio.

Material Technology License Agreements

MEDINET Co., Ltd.

In December 2017, we entered into a License and Commercialization Agreement (the MEDINET Agreement) with MEDINET Co., Ltd. (MEDINET) with regards to the commercialization of NeoCart in Japan. Pursuant to the terms of the MEDINET Agreement, we are eligible to receive up to an aggregate of approximately $86.9 million in milestone payments plus royalties, consisting of (i) a non-refundable upfront payment of $10.0 million which we received in January 2018, (ii) potential regulatory and development milestone payments of up to an aggregate of $10.5 million, (iii) overall sales-dependent milestones of up to an aggregate of $66.4 million and (iv) tiered royalties on net sales of NeoCart in Japan. In return for such consideration, we granted to MEDINET exclusive commercialization rights to NeoCart in Japan for the replacement or repair of damaged, worn or defective cartilage in humans and non-human animals.

The MEDINET Agreement will remain in effect until the later of (i) expiration of the last-to-expire valid and enforceable patent covering NeoCart in Japan and (ii) ten years from the first commercial sale of NeoCart in Japan. MEDINET has an option to extend the term for five years upon written notice to us prior to the end of the initial term. MEDINET has the right to terminate the MEDINET Agreement for any or no reason at any time, and we may terminate the MEDINET Agreement in the event MEDINET or one of its affiliates or sublicensees challenges a patent covering NeoCart in Japan. Additionally, either party may terminate the MEDINET Agreement for an uncured material breach by the other party or upon certain insolvency or bankruptcy proceedings involving the other party. We and MEDINET have agreed to indemnify each other for third-party claims arising out of either our or our affiliates' willful misconduct or negligence, breaches of representations, warranties, covenants, obligations or agreements contained in the MEDINET Agreement, or MEDINET's exploitation of NeoCart in its respective territory, subject to specified exclusions.

We and MEDINET have agreed to enter into supply, quality and pharmacovigilance agreements (the MEDINET Supply Agreements), pursuant to which MEDINET will purchase its requirements of NeoCart and the related biopsy kit from us. Pursuant to the terms of the MEDINET Agreement, the MEDINET Supply Agreements will contain provisions addressing several topics, including those set forth in the MEDINET Agreement.

Purpose Co., Ltd.

In May 2016, we amended our license agreement (the Amendment) with Purpose whereby we acquired the development and commercialization rights to NeoCart in Japan. Under the Amendment, we assumed sole responsibility for the development and commercialization of all or any portion our products in Japan. In addition, the amended agreement provides us with an exclusive, perpetual (with respect to patent rights, for the full term of each patent licensed) and sublicensable license, under Purpose's patent rights and technology relating to their tissue processor, in Japan, to make, use, sell, import and otherwise exploit products or services covered by claims of such Purpose patents or Purpose's technology, in connection with articular cartilage, ligaments, tendons and meniscus. The Amendment also terminates the license that Purpose held under the original license agreement to develop and commercialize Histogenics' patents and technology in Japan.

Pursuant to the Amendment, we are obligated to pay Purpose payments of up to $10 million in the event certain milestones are satisfied as well as a royalty payment in the low single digits on the net sales in Japan for Histogenics products that rely on a Purpose patent or incorporate or necessarily rely upon any Purpose technology. Such royalty payment shall be reduced if the applicable Histogenics products do not rely on an outstanding Purpose patent.

The other terms of the agreement with Purpose remain in effect including our ability outside of Japan to (1) make, use and sell products or services covered by claims of Purpose's patents and (2) use and create derivative works of Purpose's technology for the design, development, manufacture, testing, support and commercialization of any product or service that incorporates or builds upon Purpose's technology, in each case, only in connection with articular cartilage, ligaments, tendons and meniscus. Purpose retained the right to sell its single unit exogenous tissue processer machines to research institutes for general but noncommercial use anywhere in the world.

As part of our agreement with Purpose, they continue to manufacture and sell single unit exogenous tissue processor machines to us. In addition, Purpose exclusively sublicensed to us its rights and obligations under the BWH-Purpose

license, as amended from time to time. Under the Purpose-BWH license agreement, BWH granted Purpose an exclusive, royalty-bearing, worldwide, sublicensable license, under its rights in licensed patents and patent applications co-owned by BWH and Purpose, to make, use and sell (1) apparatuses for cultivating a cell or tissue, (2) tissue or cell products made using such apparatuses, (3) tissue or cell products made using processes for cultivating a cell or tissue as disclosed in the licensed patents and patent applications and (4) any apparatus that cultivates cells or tissues using such processes, in each case, whose manufacture, use, or sale is covered by the claims of the licensed patents and patent applications, only for therapeutic use. BWH may terminate this agreement if Purpose, itself or through its sublicensees, does not achieve commercial distribution and sale of the licensed products in the United States by December 31, 2019. In return for extending the termination period through December 31, 2019 pursuant to an amendment effective November 2015, we agreed to pay BWH $50,000 in November 2015 and three annual payments of $30,000 on the anniversary of the effective date of such amendment for the three years thereafter.

Pursuant to our sublicense from Purpose, we are obligated to pay royalties and milestone payments and sublicense payments due on the BWH-Purpose license agreement. We have paid minimum royalty amounts of $200,000 and sublicense payments of $285,000 through December 31, 2018. Purpose agreed to pay BWH a royalty rate in the low single digits of our net sales of licensed products, subject to a minimum of $20,000 annually, until the license agreement terminates or until royalty payments no longer have to be made. Purpose is obligated to make one additional sublicense payment of $25,000 and milestone payments to BWH of (1) $75,000 upon the first patient treated in Phase 3 clinical trials for each licensed product or licensed process and (2) $75,000 upon final FDA approval for each licensed product or licensed process.

The agreement remains in effect for the life of the licensed patents, expected to be until October 19, 2028. Purpose may terminate the agreement by providing written notice to BWH at least 60 days in advance. BWH has the right to terminate the agreement if Purpose fails to make minimum royalty payments or other payments or otherwise breaches the agreement and such breach is not cured within 30 days of BWH providing notice to Purpose. Upon termination of the BWH-Purpose license agreement, our sublicense will convert to a nonexclusive license to Purpose's interest in the licensed products or processes. Upon written notice to Purpose of our intent to stop using the technology sublicensed to us in the BWH-Purpose license, Purpose will reassume all responsibility under the BWH-Purpose license.

Angiotech Pharmaceuticals (US), Inc. and Angiodevice International GmbH

In May 2005, we entered into a worldwide license agreement with Angiotech Pharmaceuticals (US), Inc. and Angiodevice International GmbH (collectively, Angiotech) for the right, under Angiotech's licensed patents and patent applications and technical information, to make, use and sell any product that includes both our intellectual property and CT3 for the repair of articular cartilage, ligament, meniscus or tendon damage, including related osteochrondal defects. The license excludes any product in which one nonliving ingredient is included in CT3 for the primary purpose of producing a physiological, metabolic or biological effect in mammals. The license grant was made exclusive under the fifth amendment to the license agreement that came into effect in August 2010. We have obligations to supply CT3 to Angiotech under certain terms and conditions, and Angiotech is entitled to use any data and results obtained from any clinical studies conducted by us with respect to CT3.

We paid $1.0 million to Angiotech to make the license grant under the agreement exclusive. In addition, we paid four annual patent fees of $50,000 each as of December 31, 2018. We are also obligated to pay an additional fee of $3.0 million within 30 days after we receive regulatory approval from the FDA for a licensed product. As further consideration for the license, we also agreed to pay royalties at percentage rates of single digits of net sales of NeoCart and certain other products. We were able to reduce royalties from percentage rates of net sales in the double digits to this rate after making revenue share reduction payments that totaled $2.0 million.

The agreement terminates on the earlier of May 12, 2035 and expiration of all royalty payment obligations under the agreement. Either party has the right to terminate the agreement if the other party materially breaches the agreement and fails to cure such breach within 30 days from the date of notice of such breach (ten days in the case of non-payment). We may also terminate the agreement by giving at least one year's notice. Angiotech may also terminate the agreement if we or any of our affiliates or sublicensees challenge the validity of Angiotech's patents rights or rights to improvements (or directly or indirectly support any such challenge), or if we are acquired by or merge with a third party that has developed or is marketing, or has an affiliate that has developed or is marketing, a competitive

product prior to such acquisition or merger and the resulting or surviving entity post-acquisition or merger fails to either continue to develop or sell licensed product at a level reasonably similar to the development or sale that was occurring prior to the acquisition or merger, during the six-month period following the acquisition or merger. Competitive product means, in a given country, (1) a drug or biologic approved for marketing or in Phase 3 clinical development, (2) a 510(k), or foreign equivalent, device approved for marketing, or (3) an FDA Premarket Approval, or foreign equivalent, device approved for marketing or in pivotal study clinical development, other than a licensed product, that acts (or is being developed to act) for one or more target label indications substantially similar to one or more approved or target label indications for a licensed product.

Intrexon Corporation

In September 2014, we entered into an Exclusive Channel Collaboration (ECC) with Intrexon Corporation (Intrexon) governing a "channel collaboration" arrangement in which we intended to use Intrexon's proprietary technology towards the design, identification, culturing and/or production of genetically modified cells (Technology). The ECC granted us an exclusive worldwide license to utilize Intrexon's Technology to develop and commercialize allogeneic genetically modified chondrocyte cell therapeutics for the treatment or repair of damaged articular hyaline cartilage in humans.

In December 2018, we and Intrexon entered into a mutual termination and release agreement (the Mutual Termination Agreement) pursuant to which we and Intrexon mutually agreed to terminate ECC. Pursuant to the ECC, we were responsible for the research and development costs incurred by Intrexon associated with the development of product candidates under the collaboration. As of December 21, 2018, the date of termination, we had accrued approximately $3.0 million of research and development expenses under the ECC (the Accrued Expenses). In connection with the Mutual Termination Agreement, in lieu of payment of the Accrued Expenses, we agreed to pay Intrexon an aggregate of up to $1.5 million, with $0.375 million paid at the time of entering into the Mutual Termination Agreement and $1.125 million payable within one year following any submission of a BLA to the FDA for NeoCart. We adjusted the accrued expenses to reflect a $1.125 million balance as of December 31, 2018 and recorded a gain on extinguishment of liability of $1.5 million.

Competition

The cell therapy and regenerative medicine sector is characterized by innovative science, rapidly advancing technologies and a strong emphasis on proprietary products. While we believe that our technology, development experience, scientific knowledge and intellectual property portfolio provide us with competitive advantages, we face potential competition from many different sources, including major pharmaceutical, specialty pharmaceutical, biotechnology and regenerative medicine companies, academic institutions, governmental agencies and public and private research institutions.

The competitive landscape in the field of articular cartilage repair in the U.S. is emerging and has stimulated a substantial amount of interest from companies developing tissue repair solutions. Companies have employed a variety of approaches to meet the goals of cartilage repair. The approaches, which represent the scientific evolution of the field, can be generally categorized in five ways: (1) non-cell-based, such as Arthrosurface's HemiCAP and Anika's Hyalofast; (2) uncultured cell-based (with or without scaffold), such as Zimmer's DeNovo NT, Arthrex's BioCartilage and Osiris' Cartiform, distributed exclusively with Arthrex; (3) cultured cell-based (without scaffold), such as ISTO's RevaFlex; (4) cultured cell- and scaffold-based, such as Vericel's MACI and the Aesculap division of B. Braun Medical's NovoCart 3D; and (5) cultured cell- and scaffold-based incorporating tissue engineering, such as NeoCart.

In Japan, a historical cultured cell-based product, known as JACC is sold by Japan Tissue Engineering Co., Ltd (J-TEC). This product has some of the same limitations of first-generation autologous chondrocyte implantation products in the U.S. including limited efficacy, lengthy surgery and extended patient rehabilitation. Several cultured cell and cultured cell and scaffold combinations are in various stages of clinical development in Japan, with the earliest potential new competitive entries in 2023.

Government Regulation

Regulatory Background on Autologous Cellular Products

The FDA does not apply a single regulatory scheme to human tissues and the products derived from human tissue. On a product-by-product basis, the FDA may regulate such products as drugs, biologics, or medical devices, in addition to regulating them as human cells, tissues, or cellular or tissue-based products (HCT/Ps), depending on whether or not the particular product triggers any of an enumerated list of regulatory factors. A fundamental difference in the treatment of products under these classifications is that the FDA generally permits HCT/Ps that do not trigger any of those regulatory factors to be commercially distributed without marketing approval. In contrast, products that trigger those factors, such as if they are more than minimally manipulated when processed or manufactured, are regulated as drugs, biologics, or medical devices and require FDA approval. The FDA has designated NeoCart as a biologic under the jurisdiction of the Center for Biologics Evaluation and Research and market access or approval will require BLA approval.

In 1997, the FDA began requiring a BLA for autologous cellular products and approved the already-marketed Carticel contingent on further clinical trials. In 2000, Carticel's indication narrowed to second-line therapy for patients with inadequate response to prior treatment. As of December 2011, the FDA requires evidence of clinical efficacy against approved and validated endpoints and standard of care control arm as outlined in their final guidance on the subject of cartilage repair.

The grant of marketing authorization in the European Economic Area (EEA) for products containing viable human tissues or cells such as NeoCart is governed by Regulation 1394/2007/EC on advanced therapy medicinal products, read in combination with Directive 2001/83/EC of the European Parliament and of the Council, commonly known and the Community code on medicinal products. Regulation 1394/2007/EC lays down specific rules concerning the authorization, supervision and pharmacovigilance of gene therapy medicinal products, somatic cell therapy medicinal products and tissue engineered products. Manufacturers of advanced therapy medicinal products must demonstrate the quality, safety and efficacy of their products to the European Medicines Agency (EMA), which is required to provide an opinion regarding the application for marketing authorization. The European Commission grants or refuses marketing authorization in light of the opinion delivered by the EMA.

Applicants for marketing authorization for medicinal products in the EEA are required to submit applications for marketing authorization based on the ICH Common Technical Document and must demonstrate the safety, quality and efficacy of the medicinal product for which the marketing authorization is sought. The application must include the results of pre-clinical tests and clinical trials conducted with the medicinal product. The conduct of clinical trials in the EEA is governed by Directive 2001/20/EC which imposes obligations and procedures that are similar to those provided in applicable U.S. laws. The obligations provided in the European Union (EU) Good Clinical Practice rules and EU Good Laboratory Practice must also be respected during conduct of the trials. Clinical trials must be approved by the competent regulatory authorities and the competent Ethics Committees in the EU Member States in which the clinical trials take place. Moreover, applicants are required to demonstrate that studies have been conducted with the medicinal product in the pediatric population as provided by a Pediatric Investigation Plan approved by the Pediatric Committee of the EMA. Alternatively, confirmation that the applicant has obtained a waiver or deferral for the conduct of these studies must be provided.

Reimbursement

In both domestic and foreign markets, sales of any regulatory-approved products depend in part upon the availability of reimbursement from third-party payors. Third-party payors include government health programs, such as Medicare and Medicaid, private health insurers and managed care providers, and other organizations. Reimbursement policy involves coding, coverage and payment decisions and our business strategy is to produce the necessary information for optimal decision-making by payors.

Coding: While reimbursement policy for NeoCart is uncertain at this point, we believe that the existing Current Procedural Terminology, Healthcare Commission Procedure Coding System and International Classification of Diseases, Ninth Edition coding options for ACI are sufficiently broad that they could apply to NeoCart.

Coverage: Our goal is to demonstrate improved health outcomes (e.g., improved patient outcomes and quality of life on several parameters, lower total costs including lower overall utilization of healthcare services and faster return to work) for patients receiving NeoCart compared to microfracture, an important element in securing coverage decisions by payors (Medicare and private payors).

Payment: Analysis of recent trends in ACI coverage (discharge data) suggest that patients between 18 and 64 years of age constitute the majority of the market for ACI, resulting in a market dominated by private payors. Only 10% to 20% of ACI patients are estimated to be 65 years of age and older. While limited data is available for private payor reimbursement of ACI, these payors typically reimburse inpatient procedures with bundling mechanisms similar to Medicare Severity Diagnosis Related Groups. In addition, some private payors also tend to use Medicare rates as benchmarks when setting their own fee schedules.

Government Regulation Overview

United States

Overview

In the United States, the FDA regulates biological products under the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act and related regulations. Biological products are also subject to other federal, state, local, and foreign statutes and regulations. The FDA and comparable regulatory agencies in state and local jurisdictions and in foreign countries impose substantial requirements upon the clinical development, manufacture and marketing of biological products. These agencies and other federal, state, local, and foreign entities regulate research and development activities and the testing, manufacture, quality control, safety, effectiveness, packaging, labeling, storage, distribution, record keeping, reporting, approval, advertising and promotion of our products. Failure to comply with the applicable U.S. regulatory requirements at any time during the product development process, including clinical testing, approval process or after approval may subject an applicant to administrative or judicial sanctions.

Government regulation may delay or prevent marketing of product candidates for a considerable period of time and impose costly procedures upon our activities. The testing and approval process requires substantial time, effort, and financial resources, and we cannot be certain that the FDA or any other regulatory agency will grant approvals for NeoCart or any future product candidates on a timely basis, if at all. The FDA's policies may change and additional government regulations may be enacted that could prevent or delay regulatory approval of NeoCart or any future product candidates or approval of new disease indications or label changes. We cannot predict the likelihood, nature or extent of adverse governmental regulation that might arise from future legislative, judicial, or administrative action, either in the United States or abroad.

Marketing Approval

The process required by the FDA before biological products may be marketed in the United States generally involves the following:

- completion of nonclinical laboratory and animal tests according to good laboratory practices, and applicable requirements for the humane use of laboratory animals or other applicable regulations;
- submission to the FDA of an Investigational New Drug Application (IND) which must become effective before human clinical trials may begin;
- performance of adequate and well-controlled human clinical trials according to the FDA's regulations commonly referred to as good clinical practices (GCP), and any additional requirements for the protection of human research patients and their health information, to establish the safety and efficacy of the proposed biological product for its intended use or uses;
- submission to the FDA of a BLA for marketing approval that includes substantive evidence of safety, purity, and potency from results of nonclinical testing and clinical trials;
- satisfactory completion of an FDA pre-approval inspection of manufacturing facilities where the biological product is produced to assess compliance with good manufacturing practices (GMP) to assure

that the facilities, methods and controls are adequate to preserve the biological product's identity, strength, quality and purity and, if applicable, the FDA's current good tissue practices (GTP) for the use of human cellular and tissue products to prevent the introduction, transmission or spread of communicable diseases;

- potential FDA audit of the nonclinical study sites and clinical trial sites that generated the data in support of the BLA; and
- FDA review and approval, or licensure, of the BLA, which must occur before a biological product can be marketed or sold.

U.S. Biological Products Development Process

Before testing any biological product candidate in humans, the product candidate enters the nonclinical testing stage. Nonclinical tests include laboratory evaluations of product chemistry, toxicity and formulation, as well as animal studies to assess the potential safety and activity of the product candidate. The conduct of the nonclinical tests must comply with federal regulations and requirements including good laboratory practices.

Prior to commencing the first clinical trial, the clinical trial sponsor must submit the results of the nonclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and a proposed clinical protocol, to the FDA as part of an initial IND. Some nonclinical testing may continue even after the IND is submitted. The IND automatically becomes effective 30 days after receipt by the FDA unless the FDA, within the 30-day time period, raises concerns or questions about the conduct of the clinical trial and places the clinical trial on a clinical hold. In such case, the IND sponsor must resolve any outstanding concerns with the FDA before the clinical trial may begin. Further, an Institutional Review Board (IRB) for each site proposing to conduct the clinical trial must review and approve the plan for any clinical trial before it commences at that site. An IRB is charged with protecting the welfare and rights of study subjects and considers such items as whether the risks to individuals participating in the clinical trials are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the form and content of the informed consent that must be signed by each clinical trial subject or his or her legal representative and must monitor the clinical trial until completed. The FDA or IRB may impose clinical holds on a biological product candidate at any time before or during clinical trials due to safety concerns or non-compliance. If the FDA imposes a clinical hold, trials may not recommence without FDA or IRB authorization and then only under terms authorized by the FDA and IRB. Accordingly, we cannot be sure that submission of an IND will result in the FDA allowing clinical trials to begin or that, once begun, issues will not arise that will result in the suspension or termination of such trials.

Clinical trials involve the administration of the biological product candidate to healthy volunteers or patients under the supervision of qualified investigators, generally physicians not employed by or under the trial sponsor's control. Clinical trials are conducted under protocols detailing, among other things, the objectives of the clinical trial, dosing procedures, subject selection and exclusion criteria, and the parameters to be used to monitor subject safety, including stopping rules that assure a clinical trial will be stopped if certain adverse events should occur. Each protocol and any amendments to the protocol must be submitted to the FDA as part of the IND and to the IRB.

For purposes of BLA approval, human clinical trials are typically conducted in three sequential phases that may overlap:

- Phase 1—The biological product is initially introduced into healthy human patients and tested for safety. In the case of some products for severe or life-threatening diseases, especially when the product may be too inherently toxic to ethically administer to healthy volunteers, the initial human testing is conducted in patients. These trials may also provide early evidence on effectiveness.
- Phase 2—These trials are conducted in a limited number of patients in the target population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance and optimal dosage. Multiple Phase 2 clinical trials may be conducted by the sponsor to obtain information prior to beginning larger and more expensive Phase 3 clinical trials.

- Phase 3—Phase 3 trials are undertaken to provide statistically significant evidence of clinical efficacy and to further evaluate dosage, potency and safety in an expanded patient population at multiple clinical trial sites. They are performed after preliminary evidence suggesting effectiveness of the product has been obtained, and are intended to establish the overall benefit-risk relationship of the investigational product and to provide an adequate basis for product approval and labeling.

Post-approval clinical trials, sometimes referred to as Phase 4 clinical trials, may be conducted after initial marketing approval. These trials may be required by the FDA as a condition of approval and are used to gain additional experience from the treatment of patients in the intended therapeutic indication, particularly for long-term safety follow-up. The FDA now has express statutory authority to require post-market clinical trials to address safety issues. All of these trials must be conducted in accordance with GCP requirements in order for the data to be considered reliable for regulatory purposes.

During all phases of clinical development, regulatory agencies require extensive monitoring and auditing of all clinical activities, clinical data and clinical trial investigators. Annual progress reports detailing the results of the clinical trials must be submitted to the FDA. Written IND safety reports must be promptly submitted to the FDA and the investigators for serious and unexpected adverse events; any findings from other studies, tests in laboratory animals or in vitro testing that suggest a significant risk for human patients; or any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. The sponsor must submit an IND safety report within 15 calendar days after the sponsor determines that the information qualifies for reporting. The sponsor also must notify the FDA of any unexpected fatal or life-threatening suspected adverse reaction within seven calendar days after the sponsor's initial receipt of the information.

Phase 1, Phase 2 and Phase 3 clinical trials may not be completed successfully within any specified period, if at all. Regulatory authorities, a data safety monitoring board or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the participants are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the biological product has been associated with unexpected serious harm to patients.

Our ongoing and planned clinical trials for our product candidates may not begin or be completed on schedule, if at all. Clinical trials can be delayed for a variety of reasons, including delays in:

- obtaining regulatory approval to commence a trial;
- reaching agreement with third-party clinical trial sites and their subsequent performance in conducting accurate and reliable trials on a timely basis;
- obtaining IRB approval to conduct a trial at a prospective site;
- recruiting patients to participate in a trial; and
- supply of the biological product.

Typically, if a biological product is intended to treat a chronic disease, as is the case with NeoCart, safety and efficacy data must be gathered over an extended period of time, which can range from six months to three years or more. Success in early stage clinical trials does not ensure success in later stage clinical trials. Data obtained from clinical activities is not always conclusive and may be susceptible to varying interpretations, which could delay, limit or prevent regulatory approval.

Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the physical characteristics of the biological product as well as finalize a process for manufacturing the product in commercial quantities in accordance with GMP requirements. To help reduce the risk of the introduction of adventitious agents with the use of biological products, the Public Health Service Act emphasizes the importance of manufacturing control for products whose attributes cannot be precisely defined. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, the sponsor must develop methods for testing the identity, strength, quality, potency and purity of the final biological product. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the biological product candidate does not undergo unacceptable deterioration over its shelf life.

U.S. Review and Approval Processes

In order to obtain approval to market a biological product in the United States, a BLA must be submitted to the FDA that provides data establishing to the FDA's satisfaction the safety, purity and potency of the investigational biological product for the proposed indication. The application includes all data available from nonclinical studies and clinical trials, including negative or ambiguous results as well as positive findings, together with detailed information relating to the product's manufacture and composition, and proposed labeling, among other things. The testing and approval processes require substantial time and effort, and there can be no assurance that the FDA will accept the BLA for filing and, even if filed, that any approval will be granted on a timely basis, if at all.

Under the Prescription Drug User Fee Act (PDUFA), each BLA must be accompanied by a significant user fee and after approval, an approved biologic will also be subject to a program fee. The FDA adjusts the PDUFA user fees on an annual basis. According to the FDA's fee schedule, the user fee for an application requiring clinical data, such as a BLA, will be $2.4 million for 2018. Fee waivers or reductions are available in certain circumstances, including a waiver of the application fee for the first application filed by a small business. Additionally, no user fees are assessed on BLAs for products designated as orphan drugs, unless the product also includes a non-orphan indication.

The FDA has 60 days from its receipt of a BLA to determine whether the application will be accepted for filing based on the FDA's threshold determination that the application is sufficiently complete to permit substantive review. The FDA may refuse to file any BLA that it deems incomplete or not properly reviewable at the time of submission and may request additional information. In this event, the BLA must be resubmitted with the additional information. The resubmitted application also is subject to review before the FDA accepts it for filing. After the BLA is accepted for filing, the FDA reviews the BLA to determine, among other things, whether the proposed product is safe and potent, or effective, for its intended use, and has an acceptable purity profile, and whether the product is being manufactured in accordance with GMPs to assure and preserve the product's identity, safety, strength, quality, potency, and purity, and biological product standards. The FDA may refer applications for novel biological products or biological products that present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved and, if so, under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Before approving a BLA, the FDA will inspect the facilities at which the product is manufactured. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with GMP requirements and adequate to assure consistent production of the product within required specifications. For a human cellular or tissue product, the FDA also will not approve the product if the manufacturer is not in compliance with the GTP. These are FDA regulations that govern the methods used in, and the facilities and controls used for, the manufacture of HCT/Ps, which are human cells or tissue intended for implantation, transplant, infusion, or transfer into a human recipient. The primary intent of the GTP requirements is to ensure that cell and tissue based products are manufactured in a manner designed to prevent the introduction, transmission and spread of communicable disease. FDA regulations also require tissue establishments to register and list their HCT/Ps with the FDA and, when applicable, to evaluate donors through screening and testing. Additionally, before approving a BLA, the FDA may inspect one or more clinical sites to assure that the clinical trials were conducted in compliance with IND study requirements and GCP. To assure GMP, GTP and GCP compliance, an applicant must incur significant expenditure of time, money and effort. If the FDA determines the manufacturing process or manufacturing facilities are not acceptable, it typically will outline the deficiencies and often will require the facility to take corrective action and provide documentation evidencing the implementation of such corrective action. This may significantly delay further review of the application. If the FDA finds that a clinical site did not conduct the clinical trial in accordance with GCP, the FDA may determine the data generated by the clinical site should be excluded from the primary efficacy analyses provided in the BLA and request additional testing or data. Additionally, notwithstanding the submission of any requested additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

The FDA also has authority to require a Risk Evaluation and Mitigation Strategy (REMS) from manufacturers to ensure that the benefits of a biological product outweigh its risks. A sponsor may also voluntarily propose a REMS as part of the BLA. The need for a REMS is determined as part of the review of the BLA. Based on statutory standards, elements of a REMS may include "dear doctor letters," a medication guide, more elaborate targeted educational programs, and in some cases restrictions on distribution. These elements are negotiated as part of the BLA approval, and in some cases may delay the approval date. Once adopted, REMS are subject to periodic assessment and modification.

After the FDA completes its initial review of a BLA, it will communicate to the sponsor that the biological product will either be approved, or it will issue a complete response letter to communicate that the BLA will not be approved in its current form. The complete response letter usually describes all of the specific deficiencies in the BLA identified by the FDA. The deficiencies identified may be minor, for example, requiring labeling changes, or major, for example, requiring additional clinical trials. Additionally, the complete response letter may include recommended actions that the applicant might take to place the applicant in a condition for approval. If a complete response letter is issued, the applicant may either resubmit the BLA, addressing all of the deficiencies identified in the letter, or withdraw the application.

The FDA may not grant approval on a timely basis, or at all. We may encounter difficulties or unanticipated costs in our efforts to secure necessary governmental approvals, which could delay or preclude us from marketing our products. The testing and approval process for a biological product usually takes several years to complete.

One of the performance goals agreed to by the FDA under PDUFA is to review 90% of standard BLAs within ten months of the 60-day filing date and 90% of priority BLAs within six months of the 60-day filing date, whereupon a review decision is to be made. The FDA does not always meet its PDUFA goal dates for standard and priority BLAs and its review goals are subject to change from time to time. The review process and the PDUFA goal data may be extended by three months if the FDA requests or the BLA applicant otherwise provides additional information or clarification regarding information already provided in the submission within the last three months before the PDUFA goal date.

Even if a product candidate receives regulatory approval, the approval may be limited to specific disease states, patient populations and dosages, or the indications for use may otherwise be limited, which could restrict the commercial value of the product. Further, the FDA may require that certain contraindications, warnings, or precautions be included in the product labeling. The FDA may impose restrictions and conditions on product distribution, prescribing or dispensing in the form of a risk management plan, or otherwise limit the scope of any approval. In addition, the FDA may require Phase 4 post-marketing clinical trials, designed to further assess a biological product's safety and effectiveness, and testing and surveillance programs to monitor the safety of approved products that have been commercialized. Further, even after regulatory approval is obtained, later discovery of previously unknown problems with a product may result in the imposition of new restrictions on the product or even complete withdrawal of the product from the market. Delay in obtaining, or failure to obtain and maintain, regulatory approval for NeoCart, or obtaining approval but for significantly limited use, would harm our business.

FDA Post-Approval Requirements

Maintaining substantial compliance with applicable federal, state, local and foreign statutes and regulations requires the expenditure of substantial time and financial resources. Rigorous and extensive FDA regulation of biological products continues after approval, particularly with respect to GMP. We may rely, in the future, on third parties for the production of clinical and commercial quantities of any future products that we may commercialize. Manufacturers of our products are required to comply with applicable requirements in the GMP regulations, including quality control and quality assurance and maintenance of records and documentation. We cannot be certain that we or our present or future suppliers will be able to comply with the GMP and other FDA regulatory requirements. Other post-approval requirements applicable to biological products include reporting of GMP deviations that may affect the identity, potency, purity and overall safety of a distributed product, record-keeping requirements, reporting of adverse effects, reporting updated safety and efficacy information and complying with electronic record and signature requirements. After a BLA is approved, the product also may be subject to official lot release. As part of the manufacturing process, the manufacturer is required to perform certain tests on each lot of the product before it is released for distribution. If the product is subject to official release by the FDA, the manufacturer submits samples of each lot of product to the FDA together with a release protocol showing a summary of the history of manufacture of the lot and the results of all of the manufacturer's tests performed on the lot. The FDA also may perform certain confirmatory tests on lots of some products, such as viral vaccines, before releasing the lots for distribution by the manufacturer. In addition, the FDA conducts laboratory research related to the regulatory standards on the safety, purity, potency and effectiveness of biological products.

Discovery of previously unknown problems or the failure to comply with the applicable regulatory requirements, by us or our suppliers, may result in restrictions on the marketing of a product or withdrawal of the product from the

market as well as possible civil or criminal sanctions and adverse publicity. FDA sanctions could include refusal to approve pending applications, suspension or revocation of an approval, clinical hold, warning or untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, mandated corrective advertising or communications with doctors, debarment, restitution, disgorgement of profits or civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on us.

Biological product manufacturers and other entities involved in the manufacture and distribution of approved biological products are required to register their facilities with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with GMPs and other laws. In addition, changes to the manufacturing process or facility generally require prior FDA approval before being implemented and other types of changes to the approved product, such as adding new indications and additional labeling claims, are also subject to further FDA review and approval.

Labeling, Marketing and Promotion

The FDA closely regulates the labeling, marketing and promotion of biological products, including direct-to-consumer advertising, promotional activities involving the internet, and industry-sponsored scientific and educational activities. While doctors are free to prescribe any product approved by the FDA for any use, a company can only make claims relating to safety and efficacy of a biological product that are consistent with FDA approval, and the company is allowed to market a biological product only for the particular use and treatment approved by the FDA. In addition, any claims we make for our products in advertising or promotion must be appropriately balanced with important safety and risk information and otherwise be adequately substantiated. Failure to comply with these requirements can result in adverse publicity, warning letters, corrective advertising, injunctions, seizures, potential civil and criminal penalties and exclusion from government healthcare programs.

Anti-Kickback and False Claims Laws

In the United States, the research, manufacture, distribution, sale and promotion of biological products are potentially subject to regulation by various federal, state and local authorities in addition to the FDA, including the Centers for Medicare & Medicaid Services, other divisions of the U.S. Department of Health and Human Services (for example, the Office of Inspector General), the U.S. Department of Justice, state Attorneys General, and other federal, state and local government agencies. For example, sales, marketing and scientific/educational grant programs must comply with the Anti-Kickback Statute, the False Claims Act, the privacy regulations promulgated under the Health Insurance Portability and Accountability Act and similar state laws. Pricing and rebate programs must comply with the Medicaid Drug Rebate Program requirements of the Omnibus Budget Reconciliation Act, and the Veterans Health Care Act. If products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. All of these activities are also potentially subject to federal and state consumer protection and unfair competition laws.

As noted above, in the United States, we are subject to complex laws and regulations pertaining to healthcare “fraud and abuse,” including the Anti-Kickback Statute, the False Claims Act and other state and federal laws and regulations. The Anti-Kickback Statute makes it illegal for any person, including a biological product manufacturer (or a party acting on its behalf), to knowingly and willfully solicit, receive, offer, or pay any remuneration that is intended to induce the referral of business, including the purchase or order of an item for which payment may be made under a federal healthcare program, such as Medicare or Medicaid. Violations of this law are punishable by up to five years in prison, criminal fines, administrative civil money penalties and exclusion from participation in federal healthcare programs. In addition, many states have adopted laws similar to the Anti-Kickback Statute. Some of these state prohibitions apply to the referral of patients for healthcare services reimbursed by any insurer, not just federal healthcare programs such as Medicare and Medicaid. Due to the breadth of these federal and state anti-kickback laws and the potential for additional legal or regulatory change in this area, it is possible that our future sales and marketing practices or our future relationships with physicians might be challenged under anti-kickback laws, which could harm us. Because we intend to commercialize products that could be reimbursed under a federal healthcare program and other governmental healthcare programs, we plan to develop a comprehensive compliance program that establishes internal controls to facilitate adherence to the rules and program requirements to which we will or may become subject.

The False Claims Act prohibits anyone from, among other things, knowingly presenting, or causing to be presented, for payment to federal programs (including Medicare and Medicaid) claims for items or services, including biological products, that are false or fraudulent. Although we likely would not submit claims directly to payers, manufacturers can be held liable under these laws if they are deemed to "cause" the submission of false or fraudulent claims by, for example, providing inaccurate billing or coding information to customers or promoting a product off-label. In addition, our future activities relating to the reporting of wholesaler or estimated retail prices for our products, the reporting of prices used to calculate Medicaid rebate information and other information affecting federal, state and third-party coverage and reimbursement for our products and the sale and marketing of our products, are subject to scrutiny under this law. For example, pharmaceutical companies have been prosecuted under the False Claims Act in connection with their off-label promotion of drugs. Penalties for a False Claims Act violation include three times the actual damages sustained by the government, plus mandatory civil penalties of between $5,500 and $11,000 for each separate false claim, the potential for exclusion from participation in federal healthcare programs, and, although the federal False Claims Act is a civil statute, conduct that results in a False Claims Act violation may also implicate various federal criminal statutes. If the government were to allege that we were, or convict us of, violating these false claims laws, we could be subject to a substantial fine and may suffer a decline in our stock price. In addition, private individuals have the ability to bring actions under the False Claims Act and certain states have enacted laws modeled after the False Claims Act.

There are also an increasing number of state laws that require manufacturers to make reports to states on pricing and marketing information. Many of these laws contain ambiguities as to what is required to comply with the laws. In addition, beginning in August 2013, a similar federal requirement requires manufacturers to track and report to the federal government certain payments made to physicians and teaching hospitals made in the previous calendar year. These laws may affect our sales, marketing, and other promotional activities by imposing administrative and compliance burdens on us. In addition, given the lack of clarity with respect to these laws and their implementation, our reporting actions could be subject to the penalty provisions of the pertinent state, and soon federal, authorities.

Other Regulations

We are also subject to numerous federal, state and local laws relating to such matters as safe working conditions, manufacturing practices, environmental protection, fire hazard control and disposal of hazardous or potentially hazardous substances. We may incur significant costs to comply with such laws and regulations now or in the future.

EU and EEA

Marketing authorization in the EU for products containing viable human tissues or cells such as NeoCart is governed by Regulation 1394/2007/EC on advanced therapy medicinal products, read in combination with Directive 2001/83/EC of the European parliament and of the Council, commonly known as the Community code on medicinal products. Regulation 1394/2007/EC establishes specific rules concerning the authorization, supervision and pharmacovigilance of gene therapy medicinal products, somatic cell therapy medicinal products and tissue engineered products. Manufacturers of advanced therapy medicinal products must demonstrate the quality, safety and efficacy of their products to the EMA which is required to provide an opinion regarding the application for marketing authorization. The European Commission grants or refuses marketing authorization in light of the opinion delivered by the EMA.

Applicants for marketing authorizations for medicinal products in the EEA are required to submit applications for marketing authorization in a form that is based on the ICH Common Technical Document, and must demonstrate the safety, quality and efficacy of the medicinal product for which the marketing authorization is sought. The application must include the results of pre-clinical tests and clinical trials conducted with the medicinal product.

The conduct of clinical trials in the EEA is governed by Directive 2001/20/EC which imposes obligations and procedures that are similar to those provided in applicable U.S. laws. The EU Good Clinical Practice rules and EU Good Laboratory Practice obligations must also be respected during conduct of the trials. Clinical trials must be approved by the competent regulatory authorities and the competent Ethics Committees in the EU Member States in which the clinical trials take place.

Moreover, applicants are required to provide evidence that studies have been conducted with the medicinal product in the pediatric population as provided by a Pediatric Investigation Plan approved by the Pediatric Committee of the

EMA. Alternatively, confirmation that the applicant has obtained a waiver or deferral for the conduct of these studies must be provided. Cell-based products must also comply with Directive 2004/23/EC of the European Parliament and of the Council of March 31, 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells (Tissues and Cells Directive). This Directive describes the conditions and quality requirements which must be applied when sourcing the cells intended for manufacturing of the cell-based medicinal product. The EU Member States have transposed the Tissues and Cells Directive into their national laws.

Locally different interpretations of the Tissue and Cells Directive have occurred during adoption of the national legal implementations by individual EU Member States. This has led to some inconsistency of approach leading to additional complexity in complying with the all-over requirements in this already difficult regulatory field.

Given the specific nature of cell-based products, the clinical development paths are less standardized than for classic pharmaceutical or biological products. Phase 1 studies are often not relevant, in particular for autologous cell-based products, since cells often need to be directly implanted into a tissue defect only present in patients. As cellular therapy Phase 3 studies are very complex to organize, often limited numbers of patients can be enrolled and follow up times can be very long, so that the design and execution of these large confirmatory trials might not always be possible to the classical extent. Upfront discussions and agreement with the regulatory authorities are an important criterion to success. It is also expected that new regulatory guidance will become available in the near future, more clearly describing the regulatory expectations.

Employees

As of December 31, 2018, we employed 49 full-time employees, including four in research and development, seven in clinical development and regulatory, 29 in manufacturing and quality control and assurance, and nine in executive, general and administrative. In January 2019 and March 2019, we implemented restructuring plans approved by our Board involving reductions in headcount to reduce operating costs and conserve cash, along with other cash conservation measures. The positions eliminated together represented all but one member of our workforce, including our Chief Executive Officer, Chief Operating Officer, Chief Medical Officer and Chief Business Officer. We intend to engage, Mr. Adam Gridley, our Chief Executive Officer, Mr. Stephen Kennedy, our Chief Operating Officer, along with up to four additional employees as consultants to assist with our continuing evaluation of strategic alternatives. Mr. Gridley will retain his statutory titles of president, treasurer and secretary of the Company while he continues to provide consulting services to us, and will remain a director of the Company. We have never had a work stoppage, and none of our employees is represented by a labor organization or under any collective bargaining arrangements.

Corporate Information

We were originally incorporated as a Massachusetts corporation in 2000. In 2006, we underwent a corporate reorganization pursuant to which we were incorporated as a Delaware corporation. Our principal offices are located at 830 Winter Street, 3rd Floor, Waltham, Massachusetts 02451, and our telephone number is (781) 547-7900. Our website address is www.histogenics.com. Our website and the information contained on, or that can be accessed through, our website shall not be deemed to be incorporated by reference in, and are not considered part of, this annual report. You should not rely on any such information in making your decision whether to purchase our common stock.

Available Information

We file annual, quarterly, and current reports, proxy statements, and other documents with the Securities and Exchange Commission (SEC) under the Securities Exchange Act of 1934, as amended (the Exchange Act). The SEC maintains an Internet website, www.sec.gov, that contains reports, proxy and information statements, and other information regarding issuers, including us, that file electronically with the SEC.

Copies of each of our filings with the SEC on Form 10-K, Form 10-Q and Form 8-K and all amendments to those reports, can be viewed and downloaded free of charge at our website, www.histogenics.com as soon as reasonably practicable after the reports and amendments are electronically filed with or furnished to the SEC.

Our code of ethics, other corporate policies and procedures, and the charters of our Audit Committee, Compensation Committee and Nominating/Corporate Governance Committee are available through our website at www.histogenics.com.

ITEM 1A. *RISK FACTORS*

Investing in our common stock involves risk. You should carefully consider the risks described below as well as all the other information in this report, including the consolidated financial statements and the related notes appearing at the end of this annual report on Form 10-K, before making an investment decision. The risks and uncertainties described below are not the only risks and uncertainties we face. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operations. If any of the following risks actually occur, our business, results of operations and financial condition could suffer. In that event the trading price of our common stock could decline, and you may lose all or part of your investment. The risks discussed below also include forward-looking statements and our actual results may differ substantially from those discussed in these forward-looking statements.

Risks Relating to Our Evaluation of Strategic Alternatives

Our exploration and pursuit of strategic alternatives may not be successful.

Based on the results of our Phase 3 clinical study of NeoCart and feedback from the U.S. Food and Drug Administration (the FDA) regarding a potential Biologics License Application (BLA) submission, we determined to cease all further development of NeoCart and implemented operating cost reductions and organizational restructurings, including recent reductions in our workforce, to preserve our cash resources and better align our organization with our current operating plan. Our strategic focus has shifted to the identification and evaluation of a range of potential strategic alternatives designed to maximize stockholder value. We have retained Canaccord Genuity LLC to advise and assist us in this review, along with legal advisors. Potential strategic alternatives that may be explored or evaluated as part of this process include the potential for an acquisition, merger, business combination, licensing and/or other strategic transaction involving Histogenics. Despite devoting significant efforts to identify and evaluate potential strategic transactions, the process may not result in 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 execution or approval of a definitive agreement. Even if we enter into a definitive agreement, we may not be successful in completing a transaction or, if we complete such a transaction, it may not enhance stockholder value or deliver expected benefits.

If we do not successfully consummate a strategic transaction, our Board of Directors may decide to pursue a liquidation and dissolution 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 liquidation as well as the amount of cash that will need to be reserved for commitments and contingent liabilities.

There can be no assurance that the process to identify a strategic transaction will result in a successfully consummated transaction. If a transaction is not completed, our Board of Directors (the Board) may decide to pursue a dissolution and liquidation of our company, which may be done under the protection of the bankruptcy laws or under Delaware state dissolution laws. In such an event, the amount of cash available for distribution to our stockholders will depend heavily on the timing of such decision and, ultimately, such liquidation, since the amount of cash available for distribution continues to decrease as we fund our operations while we evaluate our strategic alternatives. In addition, if our Board 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 provisions for contingent and unknown obligations, prior to making any distributions in liquidation to our stockholders. Our commitments and contingent liabilities may include: (i) regulatory and clinical obligations remaining under our Phase 3 clinical trial for NeoCart; (ii) payment of our lease obligations in the normal course of business or negotiated one-time termination fees in the event we determine that a wind-up of operations is in the best interests of the Company and our stockholders; (iii) obligations under our employment and related agreements with certain employees that provide for severance and other payments following a termination of employment occurring for various reasons, including a change in control of our Company; (iv) payments made related to potential investigations or litigation against us, and other various claims and legal actions arising in the ordinary course of business; and (v) payment of liabilities generated from our business operations. As a result of this requirement, a portion of our assets may need to be reserved pending the resolution of such obligations. In addition, we may be subject to litigation or other claims related to a liquidation and dissolution of our Company. If a liquidation and dissolution were pursued, our Board, in consultation with its legal and financial advisors, would need to evaluate these matters and make a determination about a reasonable amount to

reserve. Accordingly, holders of our common stock and other securities could lose all or a significant portion of their investment in the event of a liquidation, dissolution or winding up of our company.

If we are successful in completing a strategic transaction, we may be exposed to other operational and financial risks.

Although there can be no assurance that a strategic transaction will result from the process we have undertaken to identify and evaluate strategic alternatives, the negotiation and consummation of any such transaction will require significant time on the part of our management, and the diversion of management's attention may disrupt our business. The negotiation and consummation of any such transaction may also require more time or greater cash resources than we anticipate and expose us to other operational and financial risks, including:

- increased near-term and long-term expenditures;
- exposure to unknown liabilities;
- higher than expected transaction or integration costs;
- incurrence of substantial debt or dilutive issuances of equity securities to fund future operations;
- write-downs of assets or goodwill or incurrence of non-recurring, impairment or other charges;
- additional severance costs and retention payments;
- difficulty and cost in combining the operations and personnel of any acquired business with our operations and personnel;
- impairment of relationships with key suppliers or customers of any acquired business due to changes in management and ownership; or
- inability to retain key employees of our company or any acquired business.

Any of the foregoing risks could have a material adverse effect on our business, financial condition and prospects.

Following our recent reductions in force, we may not have resources or the required expertise to enable a potential strategic partner to develop NeoCart, which may impair its value.

Because of the specialized scientific nature of our business and the unique properties of NeoCart, our ability to preserve the option to resume NeoCart development is highly dependent upon our ability to attract and retain qualified scientific and technical personnel, consultants and advisors. Some of the potential strategic partners with whom we are evaluating a transaction place a high value on the NeoCart development program overall and the ability to resume NeoCart development activities. However, our ongoing restructuring efforts resulted in the elimination of all of our research and development, clinical operations and manufacturing staff. The loss of their services will significantly delay or prevent any resumption of the research and development of NeoCart should a strategic partner choose to resume those activities in the future.

Should a partner need to recruit additional personnel in order to resume research and development activities, such partner would need to hire additional qualified scientific personnel to perform research and development, as well as personnel with expertise in clinical testing, government regulation, manufacturing, marketing and sales, which may place a strain on its managerial, operational, regulatory compliance, financial and other resources. Historically, we have also relied on consultants and advisors to assist in formulating our research and development strategy and adhering to complex regulatory requirements and a potential strategic partner may need to re-engage some of those consultants and advisors should such partner want to resume the development of NeoCart. There is significant competition for qualified individuals from numerous pharmaceutical and biotechnology companies, universities and other research institutions. There can be no assurance that a strategic partner will be able to attract and retain such individuals in the future, on acceptable terms, if at all. The failure to attract and retain qualified personnel, consultants and advisors could delay or prevent a partner's ability to commercialize NeoCart, which would have a material adverse effect on our ability to consummate a transaction with such partner.

We may experience difficulties, delays or unexpected costs and not achieve anticipated benefits and savings from our recently announced corporate restructuring plans, and our restructuring activities may adversely affect our ability to consummate a strategic transaction that enhances stockholder value.

In order to better align our resources with our operational needs going forward and based on the results of our Phase 3 clinical study of NeoCart and feedback from the FDA regarding a potential BLA submission, we reduced our workforce in January 2019 and again in March 2019 leaving one remaining employee as of the end of March 2019. As part of this corporate restructuring and our focus on the identification and evaluation of strategic alternatives, we also discontinued our research activities and focused on the completion and close-out of any ongoing clinical trial activities. While we intend to engage our Chief Executive Officer, our Chief Operating Officer and up to four additional employees as consultants to assist with our continuing evaluation of strategic alternatives, these reductions in force resulted in the loss of numerous long-term employees, the loss of institutional knowledge and expertise, and the reallocation of certain job responsibilities, all of which could negatively affect operational efficiencies and increase our operating expenses such that we may not fully realize anticipated savings from the restructuring, and could significantly impair our ability to successfully complete a potential strategic transaction on terms that are favorable to our stockholders, or at all.

We are substantially dependent on our remaining employee and consultants to facilitate the consummation of a strategic transaction.

In connection with our restructuring in January 2019 and a further restructuring in March of 2019, we terminated all but one employee. 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 Chief Executive Officer, Jonathan Lieber, our Interim Chief Financial Officer, and Stephen Kennedy, our Executive Vice President and Chief Operating 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 evaluate and pursue strategic alternatives, as well as fulfill our reporting obligations as a public company.

We may not realize any additional value in a strategic transaction for our intellectual property.

The market capitalization of our company is or may be below the value of our cash, cash equivalents and marketable securities. Although our most advanced product candidate, NeoCart, failed to meet its primary endpoint, we believe that data from preclinical and clinical studies of NeoCart support potential further investigation and development of NeoCart and our underlying proprietary intellectual property relating to scaffolds and CT3. However, potential counterparties in a strategic transaction involving our Company may place minimal or no value on these assets, given the limited data regarding their potential application. Further, the development and any potential commercialization of NeoCart will require substantial additional funding associated with conducting the necessary clinical testing and obtaining regulatory approval. Consequently, any potential counterparty in a strategic transaction involving our company may choose not to spend additional resources and continue development of NeoCart and may attribute little or no value, in such a transaction, to NeoCart or our other intellectual property.

We may become involved in securities class action litigation that could divert management's attention and harm the company's business, and insurance coverage may not be sufficient to cover all costs and damages.

In the past, securities class action litigation has often followed certain significant business transactions, such as the sale of a company or announcement of any other strategic transaction, or the announcement of negative events, such as negative results from clinical trials. These events may also result in investigations by the Securities and Exchange Commission. We may be exposed to such litigation or investigation even if no wrongdoing occurred. Litigation and investigations are usually expensive and divert management's attention and resources, which could adversely affect our business and cash resources and our ability to consummate a potential strategic transaction or the ultimate value our stockholders receive in any such transaction.

Although we have ceased all further development of NeoCart and our other potential product candidates, if we were to resume research and development activities, we would require substantial additional funding. Raising additional capital may cause dilution to our existing stockholders, restrict our operations or require us to relinquish rights to our technologies or to a product candidate.

We currently do not have any external source of funds and do not expect to generate any revenue. We believe that our existing cash, cash equivalents and marketable securities and interest thereon will be sufficient to fund our projected operating requirements under our current operating plan, which is to seek a strategic alternative to maximize stockholder value, and into the middle of 2019. We have based our estimates on assumptions that may prove to be wrong, and we may use our available capital resources sooner than we currently expect if our operating plans change. If our current operating plans change and we determine to pursue further research and development activities, we will require substantial additional funding to operate, and would expect to finance these cash needs through a combination of equity offerings, debt financings, government or other third-party funding and licensing or collaboration arrangements.

To the extent that we raise additional capital through the sale of equity or convertible debt, the ownership interests of our stockholders will be diluted. In addition, the terms of any equity or convertible debt we agree to issue may include liquidation or other preferences that adversely affect the rights of our stockholders. Convertible debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, and declaring dividends, and may impose 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.

Additional funds may not be available when we need them on terms that are acceptable to us, or at all. If adequate funds are not available to us on a timely basis, we may be required to further curtail or cease our operations or we may have to relinquish valuable rights to our technologies, any future revenue streams, research programs or product candidates, or grant licenses on terms that may not be favorable to us.

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 evaluating strategic alternatives, as described elsewhere in these Risk Factors.

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 December 31, 2018 we had an accumulated deficit of $216.8 million. We anticipate that our existing cash, cash equivalents and marketable securities will be sufficient to fund our operations into the the middle 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.

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 a 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 a 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 a 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 a 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 a 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 certain of the strategic alternatives currently under evaluation by our Board.

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 a 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 a 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 consummate a transaction.

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 a 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 a 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 a 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 a 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 a 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

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

On October 17, 2018, we received a deficiency letter from the Staff notifying us that, for the 30 consecutive business days prior to October 17, 2018, the closing bid price for our common stock had closed below a minimum $1.00 per share required for continued listing on The Nasdaq Capital Market pursuant to Nasdaq Listing Rule 5550(a)(2) (Rule 5550(a)(2)). The Nasdaq deficiency letter has no immediate effect on the listing of our common stock, and our common stock will continue to trade on The Nasdaq Capital Market under the symbol “HSGX” at this time.

In accordance with Nasdaq Listing Rule 5810(c)(3)(A), we have been given 180 calendar days, or until April 15, 2019 to regain compliance with Rule 5550(a)(2). If we choose to implement a reverse stock split, we must complete the split no later than ten business days prior to April 15, 2019 to regain compliance. If at any time before April 15, 2019, the bid price of our common stock closes at $1.00 per share or more for a minimum of 10 consecutive

business days (an Automatic Compliance Event), the Staff will provide written confirmation that we have achieved compliance with Rule 5550(a)(2).

If we do not regain compliance with Rule 5550(a)(2) by April 15, 2019, we may be afforded a second 180 calendar day period to regain compliance. To qualify, we would be required to meet the continued listing requirement for market value of publicly held shares and all other initial listing standards for The Nasdaq Capital Market, except for the minimum bid price requirement. In addition, we would be required to notify Nasdaq of our intent to cure the deficiency during the second compliance period, which may include, if necessary, implementing a reverse stock split.

If we do not regain compliance with Rule 5550(a)(2) by April 15, 2019, and we are not eligible for an additional compliance period at that time, the Staff will provide notice to us that our securities will be subject to delisting. At that time, we may appeal the Staff's delisting determination to a Nasdaq Listing Qualifications Panel (Panel). We would remain listed pending the Panel's decision.

Further, on December 19, 2018, we received a deficiency letter from the Staff notifying us that for the last 30 consecutive business days prior to December 18, 2018, the market value of our 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 has provided us with 180 calendar days, or until June 17, 2019, to regain compliance with Rule 5550(b)(2). If we regain compliance with Rule 5550(b)(2), Nasdaq will provide written confirmation to us and close the matter. If we do not regain compliance with this requirement by June 17, 2019, we will receive written notification from the Staff that our securities are subject to delisting. At that time, we may appeal the delisting determination to a Hearing Panel.

The December 2018 deficiency letter did not result in the delisting of our common stock from The Nasdaq Capital Market. To regain compliance with Rule 5550(b)(2), the market value of our listed securities must meet or exceed $35 million for a minimum of ten consecutive business days during the 180-day grace period ending on or before June 17, 2019 (Nasdaq has the discretion to monitor compliance for as long as 20 consecutive business days before deeming us in compliance). We could also regain compliance with Nasdaq's alternative continued listing requirements by having stockholders' equity of $2.5 million or more, or net income from continuing operations of $500,000 in the most recently completed fiscal year.

A delisting would also 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.

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 limit our strategic alternatives and ability to consummate a potential transaction.

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 execute on a 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 warrants issued in our 2018 public offering;

- 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 1B. ***UNRESOLVED STAFF COMMENTS***

Not applicable.

ITEM 2. ***PROPERTIES***

Our corporate headquarters are currently located in Waltham, Massachusetts, for which we have a lease until December 2024, renewable for one five-year term. We lease approximately 25,472 square feet of office, manufacturing and laboratory space, including 5,700 square feet of cGMP clean room space that is outfitted for NeoCart manufacturing. This facility also houses our quality staff, including quality control testing, necessary to support any NeoCart manufacturing.

Additionally, we lease approximately 16,601 square feet of laboratory and manufacturing space, along with related office space, in Lexington, Massachusetts. The term of the Lexington lease expires on October 1, 2022 and can be extended for one five-year period thereafter. This facility includes clean room space that can be utilized for production of our CT3 adhesive components, our collagen scaffold and the collagen raw material used to produce the scaffold and components of the CT3 adhesive. This facility also includes necessary space for quality operations, including necessary quality control testing.

ITEM 3. ***LEGAL PROCEEDINGS***

From time to time, we may become subject to legal proceedings, claims and litigation arising in the ordinary course of business. We currently are not a party to any threatened or pending litigation and do not have contingency reserves established for any litigation liabilities. However, third parties might allege that we are infringing their patent rights or that we are otherwise violating their intellectual property rights, including trade names and trademarks. Such third parties may resort to litigation. We accrue contingent liabilities when it is probable that future expenditures will be made and such expenditures can be reasonably estimated. Regardless of the outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

ITEM 4. ***MINE SAFETY DISCLOSURES***

Not applicable.

PART II

ITEM 5. *MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED SHAREHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES*

Our common stock has been trading on The Nasdaq Capital Market or The Nasdaq Global Market under the symbol "HSGX" since our initial public offering in December 2014. Prior to that time, there was no established public trading market for our common stock. The following table sets forth, for the periods indicated, the range of high and low sale prices of our common stock as reported by

Year ending December 31, 2017	**High**	**Low**
First Quarter:	$ 2.24	$ 1.45
Second Quarter:	1.89	1.59
Third Quarter:	2.19	1.60
Fourth Quarter:	2.37	1.72
Year ending December 31, 2018	**High**	**Low**
First Quarter:	$ 3.04	$ 2.07
Second Quarter:	2.97	2.07
Third Quarter:	2.92	0.53
Fourth Quarter:	1.00	0.09

Holders

As of March 18, 2019, there were 11 holders of record of our common stock. The number of holders of record of our common stock does not reflect the number of beneficial holders whose shares are held by depositors, brokers or other nominees.

Dividends

We have not declared or paid any cash dividends on our common stock since our inception. We do not plan to pay dividends in the foreseeable future. We currently intend to retain earnings, if any, to finance our operations. Consequently, stockholders will need to sell shares of our common stock to realize a return on their investment, if any.

Securities Authorized for Issuance under Equity Incentive Plans

Information regarding securities authorized for issuance under equity incentive plans will be contained in our Proxy Statement for the 2018 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of the fiscal year ended December 31, 2018, under the captions "Equity Compensation Plan Information" and "Security Ownership of Certain Beneficial Owners and Management" and is incorporated herein by reference pursuant to General Instruction G(3) to Form 10-K.

ITEM 6. *SELECTED CONSOLIDATED FINANCIAL DATA*

As a smaller reporting company, we are not required to provide this information.

ITEM 7. *MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS*

The following discussion and analysis should be read in conjunction with our audited annual consolidated financial statements and the related notes that appear elsewhere in this annual report on Form 10-K. This discussion contains forward-looking statements reflecting our current expectations that involve risks and uncertainties. Actual results may differ materially from those discussed in these forward-looking statements due to a number of factors, including those set forth in the section entitled "Risk Factors" and elsewhere in this annual report on Form 10-K. For further information regarding forward-looking statements, please refer to the "Special Note Regarding Forward-Looking Statements" at the beginning of Part I of this annual report on Form 10-K.

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.

As a result of the FDA feedback, we initiated a process to evaluate strategic alternatives to maximize value for all of our stakeholders. The process is being conducted with the assistance of financial and legal advisors and is evaluating the full range of potential strategic alternatives, including but not limited to, acquisitions, business combinations, joint ventures, public and private capital raises and recapitalization and sale transaction options, including a sale of assets or intellectual property. Since these efforts may not be successful and given our limited cash reserves, we are also considering other possible alternatives, including a wind-down of operations, or Chapter 11 bankruptcy protection to complete or execute a restructuring transaction or liquidation. There is no guarantee that any cash (or other securities representing any value) will be returned to stockholders and there is the possibility that the Company's common stock will be worthless in a bankruptcy, wind-down or other liquidation scenario. 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 intend to engage, Mr. Adam Gridley, our Chief Executive Officer, Mr. Stephen Kennedy, our Chief Operating Officer, along with up to four additional employees as consultants to assist with our continuing evaluation of strategic alternatives.

We have 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 $216.8 million as of December 31, 2018. 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 do not expect to generate any future revenue from product sales until we successfully complete development and obtain regulatory approval for NeoCart. If we seek and obtain regulatory approval for NeoCart, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution. Accordingly, we will seek to fund our operations through public or private equity or debt financings or other sources. 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.

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.

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.

Revenue

We did not generate any revenue in 2018 or 2017 and do not expect to generate any revenue from product sales in the future unless we successfully complete the development of NeoCart and receive approval from the FDA to market NeoCart. As of December 31, 2018, we have recorded $10 million in deferred revenue relating to the upfront payment from MEDINET.

Research and Development Expenses

Research and development expenses consist of development costs associated with our RCT platform and development programs. These costs are expensed as incurred and include:

- compensation and employee-related costs including stock-based compensation;
- costs incurred under clinical trial agreements with investigative sites;

- costs to acquire, develop and manufacture preclinical study and clinical trial materials;
- costs associated with conducting our preclinical, clinical and regulatory activities, including fees paid to third-party professional consultants and service providers;
- costs for laboratory supplies and laboratory equipment;
- charges associated with the achievement of certain preclinical and financial milestones pursuant to our licenses for our bioadhesive, and our tissue engineering processor; and
- facilities, depreciation and other expenses including allocated expenses for rent and maintenance of facilities.

We expect our research and development expenses to decline in the future due to our decision to suspend the development of NeoCart and the restructuring plans we implemented in January 2019 and March 2019.

We cannot determine with certainty the timing and costs of initiation, the duration and the completion of current or future preclinical studies and clinical trials of our product candidates. Clinical and preclinical development timelines, the probability of success and related development costs can differ materially from expectations. In addition, we cannot forecast when future collaboration arrangements will be secured, if at all, and to what degree such arrangements would affect our development plans and capital requirements.

We do not track research and development expenses by product. We do not allocate general equipment and supply costs, facilities, depreciation and other miscellaneous expenses to specific projects.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and employee-related costs, including stock-based compensation and travel expenses for our employees in the executive, finance, sales and marketing, and human resource functions. Other general and administrative expenses include facility-related costs, professional fees for accounting, legal services and directors, consulting expenses and expenses associated with obtaining and maintaining patents.

Total Other Income (Expense), Net

Total other income (expense), net consists primarily of changes in liabilities that are held at fair value; interest income earned on cash, cash equivalents and marketable securities; interest expense on our equipment loan that matured and was fully repaid in the second quarter of 2018; and the extinguishment of liability related to Intrexon Corporation.

Critical Accounting Policies and Significant Judgments and Estimates

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 and the fair value of the warrants issued in connection with our 2016 Private Placement and 2018 underwritten public offering. 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.

While our significant accounting policies are described in more detail in the notes to our consolidated financial statements appearing elsewhere in this annual report on Form 10-K, we believe the following accounting policies to be most critical to the significant judgments and estimates used in the preparation of our consolidated financial statements.

Revenue Recognition

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

Revenue is recognized when, or as, performance obligations are satisfied, which occurs when control of the promised products or services is transferred to customers. Revenue is measured as the amount of consideration we expect to receive in exchange for transferring products or services to a customer (transaction price). To the extent that the transaction price includes variable consideration, we estimate 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 our 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 our 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. Our revenues are generated primarily through collaborative research, development and commercialization agreements. The terms of these agreements may contain multiple promises which may include: (i) licenses to our technology; (ii) services related to the transfer and update of know-how; and (iii) manufacturing supply services. Payments to the us under these arrangements typically include one or more of the following: non-refundable upfront license fees; milestone payments; royalties on future product sale; and fees for manufacturing supply services. None of our contracts as of December 31, 2018 contained a significant financing component.

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

Collaboration Revenue

No revenue has been recognized as of December 31, 2018. The collaboration and license agreements are within the scope of Accounting Standards Codification (ASC) 606 Revenue from Contracts with Customers.

In determining the appropriate amount of revenue to be recognized as we fulfill our obligations under the agreements, we perform 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) we satisfy each performance obligation. As part of the accounting for the arrangement, we must develop assumptions that require judgment to determine the stand-alone selling price for each performance obligation identified in the contract. We use 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 our intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, we recognize 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, we utilize 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. We evaluate the measure of progress each reporting period and, if necessary, adjust the measure of performance and related revenue recognition.

Manufacturing Supply Services: If the promise to supply products for clinical and/or commercial development are determined to be distinct from the other performance obligations identified in the arrangement, we recognize 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, we utilize 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. We evaluate the measure of progress each reporting period and, if necessary, adjust the measure of performance and related revenue recognition.

Milestone Payments: At the inception of each arrangement that includes developmental and regulatory milestone payments, we evaluate whether the achievement of each milestone specifically relates to our effort to satisfy a performance obligation or transfer a distinct good or service within a performance obligation. If the achievement of a milestone is considered a direct result of our 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 our effort to satisfy a performance obligation or transfer a distinct good or service, we evaluate the milestone to determine whether the milestone is considered probable of being reached and estimate the amount to be included in the transaction price using either the most likely amount or the expected value method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price to be allocated. At the end of each subsequent reporting period, we re-evaluate the probability of achievement of such development milestones and any related constraint, and if necessary, adjust our 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, we will recognize revenue at the later of: (i) when the related sales occur; or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied).

Income Taxes

We utilize the asset and liability method of accounting for income taxes. Under this method, deferred tax assets and liabilities are determined based on the difference between the financial statement carrying amounts and tax basis of assets and liabilities using enacted tax rates in effect for years in which temporary differences are expected to reverse. We provide a valuation allowance when it is more likely than not that deferred tax assets will not be realized. We recognize the benefit of an uncertain tax position that has been taken or we expect to take on income tax returns if such tax position is more likely than not to be sustained.

We follow the authoritative guidance regarding accounting for uncertainty in income taxes, which prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. These unrecognized tax benefits relate primarily to issues related to the timing of certain income and deductions for federal income tax purposes. We apply a variety of methodologies in making these estimates which include advice and studies performed by independent subject matter experts, evaluation of public actions taken by the U.S. Internal Revenue Service and other taxing authorities, as well as our own industry experience. We provide estimates for unrecognized tax benefits which may be subject to material adjustments until matters are resolved with taxing authorities or statutes expire. If our estimates are not representative of actual outcomes, our results of operations could be materially impacted.

We continue to maintain a valuation allowance against our deferred tax assets due to our assessment that their realization is not certain. We periodically evaluate the likelihood of the realization of deferred tax assets and reduce the carrying amounts of these deferred tax assets by a valuation allowance to the extent we believe a portion will not be realized. We consider many factors when assessing the likelihood of future realization of deferred tax assets, including our recent cumulative earnings experience by taxing jurisdiction, expectations of future taxable income, carryforward periods available to us for tax reporting purposes, various income tax strategies and other relevant factors. Significant judgment is required in making this assessment and, to the extent future expectations change, we would assess the recoverability of our deferred tax assets at that time. If we determine that the deferred tax assets become realizable in a future period, we would record material adjustments to income tax expense that period.

TAX REFORM

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

The staff of the Securities and Exchange Commission issued Staff Accounting Bulletin No. 118 to address the application of U.S. GAAP in situations when a registrant does not have the necessary information available, prepared or analyzed (including computations) in reasonable detail to complete the accounting for certain income tax effects of the TCJA. In connection with the initial analysis of the impact of the TCJA, the Company remeasured its deferred tax assets and liabilities based on the rates at which they are expected to reverse in the future, which is generally 21%. The remeasurement of our deferred tax assets and liabilities was offset by a corresponding change in the valuation allowance for the year ended December 31, 2017. As a result, there was no impact to our consolidated statements of operations and comprehensive loss as a result of the reduction in tax rates. The other provisions of the TCJA did not have a material impact on the Company's consolidated financial statements. Our final determination of the TCJA impact and the remeasurement of its deferred assets and liabilities was completed prior to the deadline of one year from the enactment of the TCJA. For the year ended December 31, 2018, there were no material changes to the analysis originally performed as of December 31, 2017

Uncertain Income Tax Positions

We record uncertain tax positions on the basis of a two-step process whereby (1) we determine whether it is more likely than not that the tax positions will be sustained on the basis of the technical merits of the positions and (2) for those tax positions that meet the more-likely-than-not recognition threshold, we recognize the largest amount of tax benefit that is more than 50% likely to be realized upon ultimate settlement with the related tax authority. We recognize interest and penalties related to unrecognized tax benefits within income tax expense. Any accrued interest and penalties are included within the related tax liability. A reconciliation of the beginning and ending pre-tax amounts of uncertain tax positions is as follows:

	Tax Positions
	(in thousands)
Balance at December 31, 2016	$ (562)
Reductions based on tax positions related to the period	123
Federal rate revision	136
Balance at December 31, 2017	(303)
Reductions based on tax positions related to the period	—
Federal rate revision	—
Balance at December 31, 2018	$ (303)

The uncertain tax positions giving rise to the unrecognized tax benefits of $0.3 million at December 31, 2018 relate to the timing of certain income and deductions for federal income tax purposes. The reversal of unrecognized tax benefits would not have any impact on the effective tax rate in future periods and are not expected to create cash tax liability upon settlement due to our ability to utilize both pre-change and post-change NOLs to offset their impact.

Accrued Expenses

As part of the process of preparing our consolidated financial statements, we are required to estimate our accrued expenses. This process involves reviewing open contracts and purchase orders, communicating with our personnel to identify services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of the actual cost. The majority of our service providers invoice us monthly in arrears for services performed or when contractual milestones are met. We make estimates of our accrued expenses as of each balance sheet date in our consolidated financial statements based on facts and circumstances known to us at that time. We periodically confirm the accuracy of our estimates with the service providers and make adjustments if necessary. Examples of estimated accrued research and development expenses include fees payable to:

- clinical research organizations and investigative sites in connection with clinical trials;
- vendors in connection with preclinical development activities;
- vendors related to product manufacturing, development, and distribution of clinical materials; and
- professional service fees for consulting and related services.

We base our expense accruals related to clinical trials on our estimates of the services received and efforts expended pursuant to our contract arrangements. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows and expense recognition. Payments under some of these contracts depend on factors such as the successful enrollment of patients and the completion of clinical trial milestones. In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from our estimate, we adjust the accrual or prepaid accordingly. Our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in our reporting changes in estimates in any particular period.

Although we do not expect our estimates to be materially different from amounts actually incurred, if our estimates of the status and timing of services performed differs from the actual status and timing of services performed, we may report amounts that are too high or too low in any particular period. To date, there have been no material differences from our estimates to the amount actually incurred.

Impairment of Long-Lived Assets

Long-lived assets consist primarily of property and equipment. We test long-lived assets for impairment at year end or whenever events or circumstances present an indication of impairment. If the sum of expected future cash flows (undiscounted and without interest charges) of the long-lived assets is less than the carrying amount of such assets, the assets would be written down to their estimated fair value based on the present value of expected future cash flows and an impairment loss would be recognized in earnings. Based on the triggering event that occurred in December 2018, we deemed the value of our fixed assets to be impaired and wrote-off $4.3 million in net book value of such assets.

Impairment of Intangible Assets

We test intangible assets for impairment at year end or whenever events or circumstances present an indication of impairment. If the sum of expected future cash flows (undiscounted and without interest charges) of the intangible assets is less than the carrying amount of such assets, an impairment loss would be recognized in earnings in "impairment of goodwill and intangible assets." The intangible assets would be written down to the estimated fair value, calculated based on the present value of expected future cash flows. Our intangible assets consisted of in-process research and development (IPR&D) obtained through the acquisition of ProChon and the AT Grade license and are fully impaired.

Financial Instruments Indexed to and Potentially Settled in the Our Common Stock

We evaluate all financial instruments issued in connection with its equity offerings when determining the proper accounting treatment for such instruments in our financial statements. We consider a number of generally accepted accounting principles under U.S. GAAP to determine such treatment and evaluates the features of the instrument to determine the appropriate accounting treatment. We utilize the Probability Weighted Expected Return Method (PWERM), Option Pricing Model (OM) or other appropriate methods to determine the fair value of its derivative financial instruments such as the warrant liability. For financial instruments indexed to and potentially settled in our common stock that are determined to be classified as liabilities on the consolidated balance sheet, changes in fair value are recorded as a gain or loss in our consolidated statement of operations with the corresponding amount recorded as an adjustment to the liability on its consolidated balance sheet.

Stock-Based Compensation

We account for grants of stock options and restricted stock based on their grant date fair value and recognize compensation expense over their vesting period. We estimate the fair value of stock options as of the date of grant using the Black-Scholes option pricing model and, if issued, restricted stock based on the fair value of the underlying common stock as determined by management or the value of the services provided, whichever is more readily determinable.

Stock-based compensation expense represents the cost of the grant date fair value of employee stock option grants recognized over the requisite service period of the awards (usually the vesting period) on a straight-line basis, net of estimated forfeitures. The expense is adjusted for actual forfeitures at year end. Stock-based compensation expense recognized in the financial statements is based on awards that are ultimately expected to vest.

The Black-Scholes option pricing model requires us to make certain assumptions and estimates concerning our stock price volatility, the rate of return of risk-free investments, the expected term of the awards, and our anticipated dividends. We utilize the volatility from an analysis of peer group companies used in the Black-Scholes model, as we do not believe we have sufficient historical data to support the assumption of utilizing only our stock price volatility.

We account for stock options and restricted stock awards to non-employees using the fair value approach. Stock options and restricted stock awards granted to non-employees are subject to periodic revaluation over their vesting terms.

On October 1, 2018, the Compensation Committee of the Board of Directors approved a repricing (the Repricing) of 3,807,779 stock options (the Options) granted prior to September 1, 2018 pursuant to our 2013 Equity Incentive Plan and our 2012 Equity Incentive Plan to executive officers, employees and consultants of the Company. The Options had exercise prices between $0.75628 and $9.97 per share, which were reduced to $0.568 per share (the closing price of the Company's common stock on The Nasdaq Capital Market on October 1, 2018). The number of shares, vesting schedules and expiration period of the Options were not altered. Options to purchase the Company's common stock held by non-employee members of the Board were not subject to the Repricing and remain unchanged. The impact to the Company's financial statements in 2018 was immaterial.

Other Company Information

JOBS Act

On April 5, 2012, the Jumpstart Our Business Startups Act (JOBS Act) was enacted. Section 107 of the JOBS Act permits an "emerging growth company" to delay the adoption of new or revised accounting standards until those standards would otherwise apply to private companies. 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," 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, (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.

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 to assess whether an ownership change has occurred or whether there have been multiple ownership changes since our formation. 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 $52.9 million of NOLs that as a result of the 2017 ownership change will expire unused.

As of December 31, 2018, and 2017, we had U.S. federal NOL carryforwards of $67 million and $44 million respectively, which may be available to offset future income tax liabilities and expire at various dates through 2037. As of December 31, 2018, and 2017, we also had U.S. state NOL carryforwards of $67 million and $43.7 million, respectively, which may be available to offset future income tax liabilities and expire at various dates through 2037. At December 31, 2018 and 2017, we also had $26.4 million and $26.3 million, respectively, of foreign NOL carryforwards which may be available to offset future income tax liabilities, which carryforwards do not expire.

As of December 31, 2018, we have provided a full valuation allowance for net deferred tax assets.

Recent Accounting Pronouncements

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

In July 2017, the FASB issued ASU No. 2017-11, Earnings Per Share (Topic 260): Distinguishing Liabilities from Equity (Topic 480); Derivatives and Hedging (Topic 815): (PART I) Accounting for certain financial instruments with down round features. This update addresses the complexity of accounting for certain financial instruments with down round features. The guidance is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2018. The Company has concluded that this guidance has no material impact on the presentation of its results of operations, financial position and disclosures.

In May 2017, the FASB issued ASU No. 2017-09, Compensation-Stock Compensation (Topic 718): Scope of Modification Accounting. This standard provides guidance on changes to the terms or conditions of a share-based payment award that requires an entity to apply modification accounting. The guidance is effective prospectively for annual periods beginning after December 15, 2017, and for interim periods and annual periods thereafter. The Company has concluded that this guidance has no material impact on the presentation of its results of operations, financial position and disclosuresIn November 2016, the FASB issued ASU 2016-18, Statement of Cash Flows: Restricted Cash (ASU 2016-18). The amendments in this update require that amounts generally described as restricted cash and restricted cash equivalents be included within cash and cash equivalents when reconciling the beginning-of-period and end-of-period total amounts shown on the statement of cash flows. ASU 2016-18 was effective January 1, 2018. As a result of adopting ASU 2016-18, the Company includes its restricted cash balance in the cash and cash equivalents reconciliation of operating, investing and financing activities. The following table provides a reconciliation of cash, cash equivalents, and restricted cash within the statement of financial position that sum to the total of the same such amounts shown in the statement of cash flows.

	As of December 31,	
	2018	2017
	(in thousands)	
Cash and cash equivalents	$ 15,542	$ 7,081
Restricted cash	137	137
Total cash, cash equivalents, and restricted cash shown in the statement of cash flows	$ 15,679	$ 7,218

In February 2016, the FASB issued ASU No. 2016-02- Leases (Topic 842). This standard requires companies to recognize on the balance sheet the assets and liabilities for the rights and obligations created by leased assets. ASU 2016-02 will be effective for the Company in the first quarter of 2019, with early adoption permitted. The Company estimates that it will recognize approximately $8 million to $10 million of right-of-use assets and corresponding lease liabilities on the balance sheet upon adoption. However, the population of contracts subject to balance sheet recognition and their initial measurement remains under evaluation; and the final impact on the balance sheet will depend on the lease portfolio at the time of adoption. The Company does not expect that adoption will have a material impact on its results of operations or statement of cash flows.

In May 2014, the FASB issued ASU No. 2014-09, Revenue from Contracts with Customers (Topic 606), which requires an entity to recognize the amount of revenue to which it expects to be entitled for the transfer of promised goods or services to customers. In the fourth quarter of 2017, the Company early adopted ASC 606 and this standard applies to all contracts with customers, except for contracts that are within the scope of other standards, such as leases, insurance, collaboration arrangements and financial instruments. The Company had only one revenue arrangement as of the adoption date. Topic 606 requires an entity to recognize the amount of revenue to which it expects to be entitled for the transfer of promised goods or services to customers. Topic 606 provides a five-step model for determining revenue recognition for arrangements that are within the scope of the standard: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation. The Company only applies the five-step model to contracts when it is probable that the entity will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer. At contract inception, once the contract is determined to be within the scope of Topic 606, the Company assesses the goods or services promised within each contract and determines those that are performance obligations, and assesses whether each promised good or service is distinct. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied. For a complete discussion of accounting for revenues, see Note 2, Revenue Recognition.

Results of Operations

Years Ended December 31, 2018 and 2017

The following table summarizes the results of our operations for the years ended December 31, 2018 and 2017:

	December 31,		Change	
	2018	2017	$	%
	(in thousands)			
Research and development expenses	$ 15,634	$ 15,566	$ 68	0 %
General and administrative expenses	10,204	9,384	820	9
Loss due to asset impairment	4,270	—	4,270	100
Other income (expense), net	21,465	(1,464)	22,929	(1,566)

Revenue. We did not record any revenue for the years ended December 31, 2018 and 2017. We do not expect to generate any product sales revenue in the future unless we successfully complete the development of NeoCart and receive approval from the FDA to market NeoCart. As of December 31, 2018, we have recorded $10 million in deferred revenue relating to the upfront payment from MEDINET.

Research and Development Expenses. Research and development expenses were $15.6 million for the year ended December 31, 2018 as compared to $15.5 million for the year ended December 31, 2017. The increase in research and development expenses of $0.1 million was primarily due to an increase in consulting expense of $1.6 million, an increase in materials costs of $0.9 million and an increase in repairs and maintenance expense of $0.3 million which were partially offset by a $1.8 million decline in clinical trial costs, a $0.6 million decline in depreciation expense and a $0.5 million decline in salaries and benefits. We expect our research and development expenses to decline in 2019 in connection with our decision to suspend the development of NeoCart and our related restructuring plans that we implemented in January 2019 and March 2019.

General and Administrative Expenses. General and administrative expenses were $10.2 million for the year ended December 31, 2018 as compared to $9.4 million for the year ended December 31, 2017. The increase in expense of $0.8 million was primarily due to an increase in professional fees of $0.6 million, an increase in facility-related expenses of $0.6 million and an increase in public relations expense of $0.1 million which were partially offset by a decrease in depreciation expense of $0.5 million. We expect our general and administrative expenses to decline in 2019 due to the restructuring plans that we implemented in January 2019 and March 2019.

Loss due to Asset Impairment. The loss due to asset impairment of $4.3 million for the year ended December 31, 2018 was in connection with the impairment of long-term assets.

Other Income (Expense), Net. Other income (expense), net was $21.5 million for the year ended December 31, 2018 as compared to ($1.5) million for the year ended December 31, 2017. The $22.9 million increase was primarily due to the reduction of the fair value of warrant liability of $20.6 million and a $1.5 million gain on extinguishment of liability which were partially offset by warrant expense of $0.8 million related to our underwritten equity offering in October 2018.

Liquidity and Capital Resources

As of December 31, 2018, we had an accumulated deficit of $216.8 million. We have historically funded our consolidated operations primarily through the proceeds from the sale of common stock, the private placement of preferred stock and convertible notes and commercial bank debt. As of December 31, 2018, we had cash, cash equivalents and marketable securities of $15.5 million. We believe our existing cash and cash equivalents will be sufficient to fund our projected cash needs into the middle of 2019.

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

	December 31,		Change	
	2018	2017	$	%
	(in thousands)			
Net cash used in operating activities	$ (15,777)	$ (23,020)	$ 7,243	(31) %
Net cash used in investing activities	(1,113)	(1,230)	117	(10)
Net cash provided by (used in) financing activities	25,351	(577)	25,928	(4,494)
Net increase (decrease) in cash and cash equivalents	$ 8,461	$ (24,827)	$ 33,288	(134) %

Operating Capital Requirements

We anticipate that we will continue to incur losses for the next several years. We are subject to all risks incident to the development of new therapeutic products, and we may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. We anticipate that we will need substantial additional funding in the future if we continue our operations.

We believe our existing cash and cash equivalents will be sufficient to fund our projected cash needs into the middle of 2019. Until we can generate a sufficient amount of revenue from the sale or licensing of our products, if ever, we expect to finance future cash needs through public or private equity or debt offerings. Additional capital may not be available on reasonable terms, if at all. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to further scale back or discontinue our operations. 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. If we cannot expand our operations or otherwise capitalize on our business opportunities because we lack sufficient capital, our business, financial condition and results of operations could be materially adversely affected.

Operating Activities

Cash used in operating activities decreased $7.2 million to $15.8 million for the year ended December 31, 2018 from $23.0 million for the year ended December 31, 2017. During the year ended December 31, 2018, the net cash used in operating activities of $15.8 million consisted primarily of our net loss of $8.6 million adjusted for non-cash items, including a decrease in fair value of warrants of $20.6 million, an increase in deferred revenue of $10.0 million, a decrease in operating assets and liabilities of $2.8 million, a $4.3 million loss from the impairment of long term assets, a $1.5 million gain on extinguishment of liability, $1.6 million in stock-based compensation expense, a $0.7 million decrease in deferred rent and lease incentive, $0.7 million in warrant expense and $0.5 million in depreciation expense. During the year ended December 31, 2017, the net cash used for operating activities of $23.0 million consisted primarily of our net loss of $26.4 million adjusted for non-cash items, including the increase in fair value of warrants of $1.5 million, $1.5 million in depreciation expense, $1.6 million in stock-based compensation expense, a $0.7 million decrease in operating assets and liabilities and a $0.5 million decrease in deferred rent and lease incentive.

Investing Activities

Cash used in investing activities decreased $0.1 million to $1.1 million for the year ended December 31, 2018 from $1.2 million for the year ended December 31, 2017. The difference was primarily related to purchases of property and equipment of $2.0 million partially offset by maturities of marketable securities of $0.9 million.

Financing Activities

Cash provided by financing activities increased $26.0 million to $25.4 million for the year ended December 31, 2018 due to the issuance of common stock of $25.5 million.

Loan and Security Agreements

Equipment Loan

In July 2014, we entered into a loan and security agreement with Silicon Valley Bank, which provides for a line of credit to finance certain equipment purchases up to an aggregate of $1.75 million through March 31, 2015. The line has been fully drawn and is payable in 36 monthly installments of principal and interest commencing six months following the date of the draw with an annual interest rate of 2.75% plus the greater of 3.25% and the prime rate in effect at the time of each draw, as published in the Wall Street Journal. The outstanding balance was fully paid as of May 2018.

In accordance with the terms of the equipment line of credit, we issued a warrant to Silicon Valley Bank in July 2014 to purchase 6,566 shares of our common stock at an exercise price per share of $7.99.

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 7A. QUALITATIVE AND QUANTITATIVE DISCLOSURES ABOUT MARKET RISK

Not applicable.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The consolidated financial statements and related consolidated financial statement schedules required to be filed are indexed on page 97 and are incorporated herein.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

Not applicable.

ITEM 9A. CONTROLS AND PROCEDURES

Conclusion Regarding the Effectiveness of Disclosure Controls and Procedures

Our management is responsible for establishing and maintaining disclosure controls and procedures (as defined in Rules 13a-15(e) or 15d-15(e)) under the Securities Exchange Act of 1934, as amended(the "Exchange Act"), that are designed to ensure that information we are required to disclose in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include controls and procedures designed to ensure that information required to be disclosed by us in the reports we file or submit under the Exchange Act is accumulated and communicated to our management, including our principal executive officer and principal financial officer, to allow timely decisions regarding required disclosure.

Under the supervision and with the participation of management, including our principal executive officer and principal financial officer, we carried out an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures pursuant to paragraph (b) of Exchange Act Rules 13a-15 or 15d-15 as of December 31, 2018. 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 December 31, 2018 as a result of the material weakness described below.

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. Our principal executive officer and principal financial officer believe that the remediation activities we have put in place will remediate the material weakness in the future.

Management's Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate "internal control over financial reporting" for the Company, as that term is defined in Rule 13a-15(f) and Rule 15d-15(f) under the Exchange Act. Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of our consolidated financial statements for external purposes in accordance

with U.S. generally accepted accounting principles. Internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with U.S. generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the company's assets that could have a material effect on the financial statements. Because of its inherent limitations, a system of internal control over financial reporting can provide only reasonable assurances and may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with policies and procedures may deteriorate.

Under the supervision of our Audit Committee and with the participation of management, including our principal executive officer and principal financial officer, we evaluated the effectiveness, as of December 31, 2018, of our internal control over financial reporting. In making this assessment, management used the criteria set forth in the "Internal Control-Integrated Framework" (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO Framework). Based on its evaluation under the COSO Framework, our management has concluded that our internal control over financial reporting was not effective as of December 31, 2018 as a consequence of the material weaknesses described above.

As a result, we 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 intend 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, 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

Except as described above, there have been no changes in our internal control over financial reporting identified in connection with the evaluation required by paragraph (d) of Exchange Act Rule 13a-15 or 15d-15 that occurred during our most recently completed fiscal quarter that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Limitations on the Effectiveness of Controls

Control systems, no matter how well conceived and operated, are designed to provide a reasonable, but not an absolute, level of assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, have been detected. Because of the inherent limitations in any control system, misstatements due to error or fraud may occur and not be detected.

ITEM 9B. ***OTHER INFORMATION***

None.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

EXECUTIVE OFFICERS AND DIRECTORS

Executive Officers

The following table sets forth the name, age and position of each of our executive officers as of the date of this Annual Report on Form 10-K. Information as of the date of this Annual Report on Form 10-K about the number of shares of common stock beneficially owned by each of the individuals designated as an executive officer as of the date of this Annual Report on Form 10-K, whether held directly or indirectly, appears below under the heading "*Equity Security Ownership of Certain Beneficial Owners and Management*."

Name	Age	Current Positions
Adam Gridley	46	President, Chief Executive Officer, Treasurer and Director(2)
Steven Kennedy	62	Executive Vice President and Chief Operating Officer(2)
Jonathan Lieber	49	Interim Chief Financial Officer

(1) Pursuant to a reduction in force approved by the Board in March 2019, Mr. Gridley's employment with us will terminate effective March 22, 2019. Mr. Gridley will retain his statutory titles of president, treasurer and secretary of the Company while he continues to provide consulting services to us, and will remain a director of the Company. In connection with the execution of the separation entered into with Mr. Gridley in connection with his termination, we and Mr. Gridley also intend to enter into a consulting agreement pursuant to which Mr. Gridley will provide consulting services to us through at least June 30, 2019 for an hourly fee of $250.

(2) Pursuant to a reduction in force approved by the Board in March 2019, Mr. Kennedy's employment with us will terminate effective March 22, 2019. In connection with the execution of the separation entered into with Mr. Kennedy in connection with his termination, we and Mr. Kennedy also intend to enter into a consulting agreement pursuant to which Mr. Kennedy will provide consulting services to us through at least June 30, 2019 for an hourly fee of $220.

Directors

The following table includes the name, age position, class and term expiration year for each of our directors and is current as of the date of this Annual Report on Form 10-K. Information about the number of shares of common stock beneficially owned by each director, whether held directly or indirectly, as of the date of this Annual Report on Form 10-K, appears below under the heading "*Equity Security Ownership of Certain Beneficial Owners and Management*."

Name	Age	Position	Class	Term Expiration Year
Joshua Baltzell	49	Chairman of the Board	Class I	2021
David Gill	64	Director	Class III	2020
Adam Gridley	46	President, Chief Executive Officer, Treasurer and Director(1)	Class II	2019
Michael Lewis	60	Director	Class II	2019
Kevin Rakin	58	Director	Class I	2021
Susan B. Washer	57	Director	Class II	2019

(1) Pursuant to a reduction in force approved by the Board in March 2019, Mr. Gridley's employment with us will terminate effective March 22, 2019. Mr. Gridley will retain his statutory titles of president, treasurer and secretary of the Company while he continues to provide consulting services to us, and will remain a director of the Company. Mr. Gridley will not be eligible to receive compensation under the Company's non-employee director compensation program.

The following paragraphs provide information, as of the date of this Annual Report on Form 10-K, about our current executive officers and directors:

Biographical Information – Executive Officers

Adam Gridley has served as our Chief Executive Officer and President since May 2014. Pursuant to a reduction in force approved by the Board in March 2019, Mr. Gridley's employment with us will terminate effective March 22, 2019. Mr. Gridley will retain his statutory titles of president, treasurer and secretary of the Company while he continues to provide consulting services to us, and will remain a director of the Company. In connection with the execution of the separation entered into with Mr. Gridley in connection with his termination, we and Mr. Gridley also intend to enter into a consulting agreement pursuant to which Mr. Gridley will provide consulting services to us through at least June 30, 2019. Mr. Gridley previously served from October 2012 until May 2014 as Senior Vice President of Technical Operations at Merz North America, Inc., the North American business unit of Merz, Inc., a privately held pharmaceuticals company. From September 2011 to October 2012, he was Senior Vice President, Operations & Product Development responsible for global research and development and manufacturing for Merz Aesthetics, Inc., a global business unit of Merz, Inc., and from July 2010 to September 2011, Mr. Gridley held the position of Senior Vice President, Product Development at Merz. From September 2008 to July 2010, Mr. Gridley was Senior Vice President, Corporate Development for BioForm Medical, Inc., a publicly traded company acquired by Merz, Inc. Mr. Gridley holds a B.S. and an M.B.A. from the University of Denver. We believe that Mr. Gridley's qualifications to serve as a director of the Company include his extensive experience as an executive in the biotechnology industry and his prior service as a senior-level executive in both early stage and mature biotechnology companies.

Stephen Kennedy has served as our Executive Vice President and Chief Operating Officer since October 2017 and previously served as our Chief Technology Officer from July 2015 to October 2017 and our Senior Vice President of Technical Operations from August 2013 to July 2015. Pursuant to a reduction in force approved by the Board in March 2019, Mr. Kennedy's employment with us will terminate effective March 22, 2019. In connection with the execution of the separation entered into with Mr. Kennedy in connection with his termination, we and Mr. Kennedy also intend to enter into a consulting agreement pursuant to which Mr. Kennedy will provide consulting services to us through at least June 30, 2019. From May 2011 to August 2013, Mr. Kennedy served as the Executive Vice President, Research and Development, at Mascoma Corporation, a biofuel company. Mr. Kennedy served as Executive Director of the Novartis/MIT Center for Continuous Manufacturing at the Massachusetts Institute of Technology from October 2010 to May 2011. Mr. Kennedy also served as Senior Vice President of Biologics Operations at Genzyme Corporation from 2008 to October 2010, after having held a variety of technical operations positions with the company beginning in 1992. Prior to this, Mr. Kennedy managed process development at Genencor International in Helsinki, Finland from 1989 to 1992. Mr. Kennedy has a B.S. from the University of Michigan, an M.S. from the University of Rochester and an M.B.A. from Boston University.

Jonathan Lieber has served as our Interim Chief Financial Officer since December 2018 and previously served as our Chief Financial Officer from July 2015 to December 2018. Prior to joining us, Mr. Lieber was Senior Vice President and Chief Financial Officer of Metamark Genetics, Inc., a privately held, urology-focused, molecular diagnostics company, from January 2014 to June 2015. From September 2012 to September 2013, Mr. Lieber served as the Chief Financial Officer and Treasurer of Repligen Corporation, a manufacturer and supplier of high-value consumables to the life sciences industry. From June 2009 to May 2012, Mr. Lieber served as Chief Financial Officer and Treasurer of Xcellerex, Inc., a privately held company engaged in the manufacture and sale of capital equipment and related consumables to the biopharmaceutical industry. Mr. Lieber received an M.B.A. in finance from the Stern School of Business of New York University and a B.S. in business administration from Boston University.

Biographical Information – Directors

Joshua Baltzell has served as a member of the Board since July 2012. Mr. Baltzell is a Venture Partner at Split Rock Partners, and also serves as a Venture Partner at SightLine Partners. He has been with Split Rock since 2004 and with SightLine since 2014. Mr. Baltzell has over 20 years of experience in the healthcare industry. Prior to his tenure in the venture capital industry, Mr. Baltzell held roles as an investment banker at Piper Jaffray Companies from 2000 to 2002, where he focused primarily on mergers and acquisitions in the medical device sector, as well as

various marketing and business development positions with SCIMED and Boston Scientific. Mr. Baltzell currently serves on the boards of Magnolia Medical, ViewPoint Medical and Colorescience. Mr. Baltzell holds a B.A. in economics from St. Olaf College and an M.B.A. from the University of Minnesota's Carlson School of Management. We believe that Mr. Baltzell's qualifications to serve as a director of the Company include his extensive experience in the venture capital industry, his investment banking experience in the healthcare and medical device industries with both publicly and privately held companies and his significant prior board experience.

David Gill has served as a member of the Board since February 2015. Mr. Gill served as the President and Chief Financial Officer of EndoChoice, Inc., a medical device company focused on gastrointestinal disease, from April 2016 through the sale of the company to Boston Scientific in November 2016 and as Chief Financial Officer from August 2014 to April 2016. Previously, he served as the Chief Financial Officer of INC Research (now known as Syneos Health), a clinical research organization, from February 2011 to August 2013 after having served as a board member and its audit committee chairman from 2007 to 2010. Mr. Gill also currently serves on the boards of Melinta Therapeutics, Inc. (f/k/a Cempra, Inc.), Evolus, Inc., Strata Skin Sciencess, Inc. and YmAbs Therapeutics, Inc. Earlier in his career, Mr. Gill served in a variety of senior executive leadership roles for several publicly-traded companies, including NxStage Medical, CTI Molecular Imaging, Inc., Interland Inc. and Novoste Corporation. Mr. Gill holds a B.S. degree, cum laude, in accounting from Wake Forest University and an M.B.A. degree, with honors, from Emory University, and was formerly a certified public accountant. We believe that Mr. Gill's qualifications to serve as a director of the Company include his extensive experience as an executive in the life sciences industry and his extensive prior service as a director of other public and private mature life sciences companies.

Michael Lewis has served as a member of the Board since May 2011. Mr. Lewis has more than 25 years of experience in the investment management and retail industries. Mr. Lewis is currently Chairman of Oceana Investment Corporation Limited, a private U.K. investment company. Mr. Lewis currently serves as Chairman of Strandbags Holdings Pty Limited, an Australian retail company comprising some 300 stores, and Chairman and Non-Executive Director of The Foschini Group Limited, a South African retail company with some 4,000 stores. Mr. Lewis serves on the board of United Trust Bank Limited, a U.K.-based bank, and served on the Supervisory Board of Axel Springer AG in Germany from 2007 to September 2012. Mr. Lewis previously worked for Ivory and Sime, a money manager based in Scotland, and Lombard Odier, a money manager based in England. He has an undergraduate degree and a postgraduate degree from the University of Cape Town. We believe Mr. Lewis' qualifications to serve as a director of the Company include his extensive experience in money management and as an investor and director of biomedical and other companies.

Kevin Rakin has served as a member of the Board since October 2012. Mr. Rakin is a co-founder and Partner at HighCape Partners, a growth equity life sciences fund where he has served since November 2013. From June 2011 to November 2012, Mr. Rakin was the President of Regenerative Medicine at Shire plc, a leading specialty biopharmaceutical company. Mr. Rakin currently serves on a number of boards, including Oramed Pharmaceuticals, Inc., Cheetah Medical Inc. and TELA Bio, Inc. Mr. Rakin holds an M.B.A. from Columbia University and received his graduate and undergraduate degrees in Commerce from the University of Cape Town, South Africa. We believe that Mr. Rakin's qualifications to serve as a director of the Company include his extensive experience as an executive in the biotechnology industry as well as his service in positions in various companies as a chief executive officer, chief financial officer and president and his involvement in public and private financings and mergers and acquisitions in the biotechnology industry.

Susan B. Washer has served as a member of the Board since April 2018. Ms. Washer is the President and Chief Executive Officer of Applied Genetic Technologies Corporation (AGTC), where she has served in such capacity since March 2002 and as a member of its board of directors since November 2003. Ms. Washer was also AGTC's chief operating officer from October 2001 to March 2002. From June 1994 to October 2001, Ms. Washer led two entrepreneurial firms including serving as president and chief executive officer of Scenic Productions and as the Founding Executive Director and then Business Advisor for the North Florida Technology Innovation Center, a public-private organization financing and providing services to entrepreneurial companies licensing STEM based technology from Florida universities. Ms. Washer currently serves on the board of directors of Biotechnology Innovation Organization (BIO) and the Alliance for Regenerative Medicine. Previously, Ms. Washer served as chairman of the BioFlorida board and the Southeast BIO board and continues her involvement with both organizations as a member of their respective boards. From October 1983 to June 1994, Ms. Washer served in various research and pharmaceutical management positions with Abbott Laboratories and Eli Lilly and Company. Ms. Washer received a B.S. in biochemistry from Michigan State University and an M.B.A. from the University of Florida. We believe that Ms. Washer's qualifications to serve as a director of the Company include her education

and professional background in science and business management, her years of experience in the pharmaceutical and biotechnology industries and her service as a senior executive of early and late stage biotechnology companies.

CORPORATE GOVERNANCE

Independence of the Board of Directors

As required under Nasdaq listing standards, a majority of the members of a listed company's board of directors must qualify as "independent," as affirmatively determined by the board of directors. Consistent with these regulations, after review of all relevant transactions or relationships between each director, or any of his family members, and the Company, its senior management and its independent registered public accounting firm, the Board has determined that all of our directors are independent directors within the meaning of applicable Nasdaq listing standards, except for Mr. Gridley, our Chief Executive Officer.

Information Regarding the Board of Directors and its Committees

As required under Nasdaq listing standards, our independent directors meet in regularly scheduled executive sessions at which only independent directors are present. Mr. Baltzell, Chairman of the Board, presides over these executive sessions. Dr. Kong resigned from the Board effective February 22, 2019. Mr. Baltzell was appointed as the Chairman of the Board effective February 22, 2019.

The Board has an Audit Committee (the Audit Committee), a Compensation Committee (the Compensation Committee), a Nominating/Corporate Governance Committee (the Nominating/Corporate Governance Committee) and a Special Committee (the Special Committee). The following table provides membership and meeting information for each of the Board's committees during 2018:

Committee	Chairman	Members	Number of Committee Meetings in 2018
Audit Committee	David Gill	John H. Johnson(1) and Kevin Rakin	6
Compensation Committee	John H. Johnson(2)	Joshua Baltzell, Kevin Rakin and Susan Washer(3)	7
Nominating/Corporate Governance Committee	Garheng Kong, M.D., Ph.D.(4)	Joshua Baltzell and Michael Lewis	3
Special Committee	Garheng Kong, M.D., Ph.D.(5)	Joshua Baltzell, David Gill and John H. Johnson	4

(1) Mr. Johnson resigned from the Board effective February 27, 2019. Ms. Washer was appointed to the Audit Committee effective February 27, 2019.

(2) Mr. Johnson resigned from the Board effective February 27, 2019. Mr. Baltzell was appointed as the chairman of the Compensation Committee effective February 27, 2019.

(3) Ms. Washer was appointed to the Compensation Committee effective February 27, 2019.

(4) Dr. Kong resigned from the Board effective February 22, 2019. Mr. Baltzell was appointed as the Chairman of the Board and Chairman of the Nominating/Corporate Governance Committee effective February 22, 2019.

(5) Dr. Kong resigned from the Board effective February 22, 2019. Mr. Baltzell was appointed as the Chairman of the Special Committee effective February 22, 2019.

Below is a description of each committee of the Board. The Board has determined that each member of the Audit Committee, Compensation Committee, Nominating/Corporate Governance Committee and Special Committee meets applicable rules and regulations regarding "independence," and that each such member is free of any relationship that would interfere with his individual exercise of independent judgment with regard to the Company.

Audit Committee

The Audit Committee of the Board oversees the quality and integrity of the Company's financial statements and other financial information provided to the Company's stockholders, the retention and performance of the Company's independent accountants, the effectiveness of the Company's internal controls and disclosure controls and the Company's compliance with ethics policies and SEC and related regulatory requirements. Pursuant to the Audit Committee charter, the functions of the Audit Committee include, among other things: (1) appointing, approving the compensation of and assessing the independence of our registered public accounting firm; (2) overseeing the work of our registered public accounting firm, including through the receipt and consideration of reports from such firm; (3) reviewing and discussing with management and the registered public accounting firm our annual and quarterly financial statements and related disclosures; (4) monitoring our internal control over financial reporting and our disclosure controls and procedures; (5) meeting independently with our registered public accounting firm and management; (6) furnishing the audit committee report required by SEC rules; (7) reviewing and approving or ratifying any related person transactions; and (8) overseeing our risk assessment and risk management policies. Our Audit Committee charter is available on the "Investors" section of our corporate website located at http://ir.histogenics.com. Three directors comprised the Audit Committee as of December 31, 2018: Mr. Gill (the Chairman of the Audit Committee), Mr. Johnson and Mr. Rakin. Mr. Johnson resigned from the Board effective February 27, 2019. Ms. Washer was appointed to the Audit Committee effective February 27, 2019. The Audit Committee met six times during 2018. In addition, the members of the Audit Committee met informally in conjunction with each regularly scheduled quarterly Board meeting and at other times throughout the year to discuss a variety of matters.

All members of our Audit Committee meet the requirements for financial literacy under the applicable rules and regulations of the SEC and Nasdaq. The Board has determined that Messrs. Gill and Rakin are "audit committee financial experts" as defined by applicable SEC rules and have the requisite financial sophistication as defined under the applicable Nasdaq rules and regulations.

The Board annually reviews the Nasdaq listing standards definition of independence for Audit Committee members and has determined that all members of our Audit Committee are independent (as independence is currently defined in applicable Nasdaq listing standards and Rule 10A-3 promulgated under the Exchange Act).

Compensation Committee

The Compensation Committee of the Board reviews and approves the design of, assesses the effectiveness of and administers compensation programs for officers and employees, including our equity incentive plans. Pursuant to the Compensation Committee charter, the functions of the Compensation Committee include: (1) evaluating the performance of our chief executive officer and determining the chief executive officer's salary and contingent compensation based on his or her performance and other relevant criteria; (2) identifying the corporate and individual objectives governing the chief executive officer's compensation; (3) approving the compensation of our other executive officers; (4) making recommendations to the Board with respect to director compensation; (5) reviewing and approving the terms of material agreements between us and our executive officers; (6) overseeing and administering our equity incentive plans and employee benefit plans; (7) reviewing and approving policies and procedures relating to the perquisites and expense accounts of our executive officers; (8) preparing the annual Compensation Committee report required by SEC rules; and (9) conducting a review of executive officer succession planning, as necessary, reporting its findings and recommendations to the Board and working with the Board in evaluating potential successors to executive officer positions. In accordance with Nasdaq listing standards and our amended and restated Compensation Committee charter, the Board has granted our Compensation Committee the authority and responsibility to retain or obtain the advice of compensation consultants, legal counsel and other compensation advisers, the authority to fund such advisers, and the responsibility to consider the independence factors specified under applicable law and any additional factors the Compensation Committee deems relevant. Our Compensation Committee charter is available on the "Investors" section of our corporate website located at http://ir.histogenics.com.

In addition, the Compensation Committee has adopted additional internal policies and procedures relating to administration of the Company's equity incentive plans, including the following:

- Members of the Compensation Committee receive initial and periodic training from an independent consultant with expertise in compensation management matters concerning the Company's operative

equity incentive plans and compensation procedures as well as general best practices for compensation committees.

- With the assistance of legal counsel, the Compensation Committee conducts reviews of the Compensation Committee's charter, the Company's equity incentive plans and the Compensation Committee's current practices, procedures and controls and has developed equity compensation compliance procedures and a checklist of key plan provisions to be reviewed prior to the issuance and delivery of equity awards. Among other things, the checklist addresses: (1) the expiration date of the applicable equity incentive plan or any portion thereof; (2) the overall shares available under the applicable plan; (3) any annual limitations on awards as set forth in the applicable equity incentive plan; (4) prior grants made to proposed recipients during any relevant period; and (5) the proper recording of the equity grants in accordance with the terms of the applicable equity incentive plan. The Compensation Committee has designated the Company's Chief Financial Officer and Vice President of Finance to monitor compliance with the foregoing compliance procedures and checklists (the Compliance Monitor).
- In advance of the Compensation Committee's first meeting each year, the Compliance Monitor provides the Compensation Committee information on the following: (1) the aggregate number of shares available for issuance under each equity incentive plan still in effect; (2) the expiration date for each such equity incentive plan; (3) the annual limit on equity grants to any one individual under each equity incentive plan; and (4) the number of shares covered by awards already granted to each of the Company's executive officers under the Company's equity incentive plans. The Compensation Committee reviews this information prior to making any equity compensation award to any executive officer.
- Prior to the dissemination of the Company's annual proxy statement released in conjunction with the annual meeting of stockholders, the Board (or an appropriate committee thereof), with the assistance of legal counsel, verifies that all awards made under, amendments or proposed amendments of, and summaries or descriptions of, the Company's equity compensation plans have been disclosed accurately and properly in such proxy statement.
- With the assistance of legal counsel, the Compensation Committee formally reviews and approves all disclosures in the Company's SEC filings concerning executive officer and director compensation matters before the documents are publicly filed.
- In the event of a proposed or contemplated stock split, reverse stock split or any other change to the Company's capitalization, the Board will receive guidance from outside legal counsel on the effect of such capitalization change on the Company's equity incentive plans, if any, including but not limited to the aggregate and annual limitations of those equity incentive plans.
- The Board will seek stockholder approval of any amendment made to the Company's equity incentive plans in the Company's next annual meeting of stockholders following the amendment if such approval is required by the terms of such equity incentive plan, applicable Delaware law, SEC regulations or Nasdaq governance rules and listing standards.
- The Board receives periodic reports on the Company's compliance with its procedures, policies and guidelines for issuing equity awards. These reports are prepared and made with the input of the Compliance Monitor, the Compensation Committee and outside legal counsel.

Four directors comprised the Compensation Committee of the Board as of December 31, 2018: Mr. Johnson (the Chairman of the Compensation Committee), Mr. Baltzell, Mr. Rakin and Ms. Washer. Mr. Johnson resigned from the Board effective February 27, 2019. Mr. Baltzell was appointed as Chairman of the Compensation Committee effective February 27, 2019. The Compensation Committee met seven times during 2018 and acted twice by written consent. In addition, the members of the Compensation Committee met informally in conjunction with each regularly scheduled quarterly Board meeting and at other times throughout the year to discuss a variety of matters.

The Board has determined that all members of the Compensation Committee are independent (as independence is currently defined in the Nasdaq listing standards). In addition, each of our directors serving on our Compensation Committee satisfies the heightened independence standards for members of a compensation committee under Nasdaq listing standards. Each member of this committee is also a non-employee director, as defined pursuant to

Rule 16b-3 promulgated under the Exchange Act, and an outside director, as defined pursuant to Section 162(m) of the Internal Revenue Code of 1986, as amended (the Code).

Our Chief Executive Officer and our Interim Chief Financial Officer often participate in the Compensation Committee's meetings. Neither of them participates in the determination of their own respective compensation or the compensation of directors. However, Mr. Gridley does make recommendations to the Compensation Committee regarding the amount and form of the compensation of the other executive officers and key employees, and he often participates in the Compensation Committee's deliberations about their compensation. No other executive officers participate in the determination of the amount or form of the compensation of executive officers or directors.

The Compensation Committee has retained Radford, an independent compensation consulting firm, since January 2015. In February 2018, Radford presented a summary executive compensation report to the Compensation Committee. Radford previously provided the Compensation Committee with data about the compensation paid by our peer group of companies and other employers who compete with the Company for executives, updated the Compensation Committee on new developments in areas that fall within the Compensation Committee's jurisdiction and was available to advise the Compensation Committee regarding all of its responsibilities. The consultant serves at the pleasure of the Compensation Committee, rather than the Company, and the consultant's fees are approved by the Compensation Committee. In February 2018, our Compensation Committee assessed the independence of Radford pursuant to applicable SEC rules and Nasdaq listing standards and concluded that the work of Radford has not raised any conflict of interest.

Compensation Committee Interlocks and Insider Participation

None of the members of the Compensation Committee is or has ever been an officer or employee of the Company. No executive officer of the Company serves as a member of the Board or compensation committee of any other entity that has one or more executive officers serving as a member of the Board or our Compensation Committee.

Nominating/Corporate Governance Committee

Our Nominating/Corporate Governance Committee identifies, evaluates and recommends nominees to the Board and committees of the Board, conducts searches for appropriate directors and evaluates the performance of the Board and of individual directors. Pursuant to the Nominating/Corporate Governance Committee charter, the functions of the Nominating/Corporate Governance Committee include, among other things: (1) identifying, evaluating and making recommendations to the Board and our stockholders concerning nominees for election to the Board, to each of the Board's committees and as committee chairs; (2) annually reviewing the performance and effectiveness of the Board and developing and overseeing a performance evaluation process; (3) annually evaluating the performance of management, the Board and each Board committee against their duties and responsibilities relating to corporate governance; (4) annually evaluating adequacy of our corporate governance structure, policies and procedures; and (5) providing reports to the Board regarding the Committee's nominations for election to the Board and its committees. Our Nominating/Corporate Governance Committee charter is available on the "Investors" section of our corporate website located at http://ir.histogenics.com. Three directors comprised the Nominating/Corporate Governance Committee as of December 31, 2018: Dr. Kong (the Chairman of the Nominating/Corporate Governance Committee), Mr. Baltzell and Mr. Lewis. Dr. Kong resigned from the Board effective February 22, 2019. Mr. Baltzell was appointed as the Chairman of the Nominating/Corporate Governance Committee effective February 22, 2019. The Nominating/Corporate Governance Committee met three times during 2018. In addition, the members of the Nominating/Corporate Governance Committee met informally in conjunction with each regularly scheduled quarterly Board meeting and at other times throughout the year to discuss a variety of matters.

The Nominating/Corporate Governance Committee believes that candidates for director should have certain minimum qualifications, including being able to read and understand basic financial statements and having a general understanding of the Company's industry and market. The Nominating/Corporate Governance Committee also considers other factors it deems appropriate, including, but not limited to:

- the candidate's relevant expertise and experience upon which to offer advice and guidance to management;
- the candidate having sufficient time to devote to the affairs of the Company;
- the candidate having a proven track record in his or her field;
- the candidate's ability to exercise sound business judgment;
- the candidate's commitment to vigorously represent the long-term interests of our stockholders;
- whether or not a conflict of interest exists between the candidate and our business;
- whether the candidate would be considered independent under applicable Nasdaq and SEC standards;
- the current composition of the Board; and
- the operating requirements of the Company.

In conducting this assessment, the Nominating/Corporate Governance Committee considers diversity, gender, age, skills and such other factors as it deems appropriate given the then-current needs of the Board and the Company, to maintain a balance of knowledge, experience and capability. While diversity and variety of experiences and viewpoints represented on the Board should always be considered, the Nominating/Corporate Governance Committee believes that a director nominee should not be chosen nor excluded solely or largely because of race, color, gender, national origin or sexual orientation or identity.

In the case of incumbent directors whose terms of office are set to expire, the Nominating/Corporate Governance Committee reviews such directors' overall service to the Company during their term, including the number of meetings attended, level of participation, quality of performance and any other relationships and transactions that might impair such directors' independence.

When there is a vacancy on the Board, the Nominating/Corporate Governance Committee uses its network of contacts to compile a list of potential candidates, but may also engage, if it deems it appropriate, a professional search firm. The Nominating/Corporate Governance Committee conducts any appropriate and necessary inquiries into the backgrounds and qualifications of possible candidates after considering the function and needs of the Board. The Nominating/Corporate Governance Committee meets to discuss and consider such candidates' qualifications and then selects a nominee for recommendation to the Board by majority vote.

The Nominating/Corporate Governance Committee will consider director candidates recommended by stockholders and evaluate them using the same criteria as candidates identified by the Board or the Nominating/Corporate Governance Committee for consideration. If a stockholder of the Company wishes to recommend a director candidate for consideration by the Nominating/Corporate Governance Committee, the stockholder recommendation should be delivered to the Corporate Secretary of the Company at the principal executive offices of the Company pursuant to the terms and conditions of the Bylaws. The stockholder recommendation must, among other things, set forth:

- for each person whom the stockholder proposes to nominate for election or reelection as a director, all information relating to such person as would be required to be disclosed in solicitations of proxies for the election of such nominees as directors pursuant to Regulation 14A promulgated under the Exchange Act and such person's written consent to serve as a director if elected;
- as to the stockholder giving the notice and the beneficial owner, if any, on whose behalf the nomination or proposal is made: (1) the name and address of such stockholder, as they appear on the Company's books, and of such beneficial owner; (2) the class and number of shares of the Company that are owned beneficially and of record by such stockholder and such beneficial owner and a representation that the stockholder will notify the Company in writing of the class and number of such shares owned

beneficially and of record as of March 1, 2019 for the meeting promptly following the later of March 1, 2019 or the date notice of March 1, 2019 is first publicly disclosed; (3) whether either such stockholder or beneficial owner intends to deliver a proxy statement and form of proxy to holders of, in the case of a proposal, at least the percentage of the Company's voting shares required under applicable law to carry the proposal or, in the case of a nomination or nominations, a sufficient number of holders of the Company's voting shares to elect such nominee or nominees; and (4) whether and the extent to which any derivative instrument, swap, option, warrant, short interest, hedge or profit interest or other transaction has been entered into by or on behalf of such stockholder with respect to stock of the Company and whether any other agreement, arrangement or understanding (including any short position or any borrowing or lending of shares of stock) has been made by or on behalf of such stockholder, the effect or intent of any of the foregoing being to mitigate loss to, or to manage risk of stock price changes for, such stockholder or to increase or decrease the voting power or pecuniary or economic interest of such stockholder with respect to stock of the Company;

- any option, warrant, convertible security, stock appreciation right, or similar right with an exercise or conversion privilege or a settlement payment or mechanism at a price related to any class or series of shares of the Company or with a value derived in whole or in part from the value of any class or series of shares of the Company, whether or not such instrument or right shall be subject to settlement in the underlying class or series of capital stock of the Company or otherwise (a Derivative Instrument) directly or indirectly owned beneficially by such stockholder and any other direct or indirect opportunity to profit or share in any profit derived from any increase or decrease in the value of shares of the Company and a representation that the stockholder will notify the Company in writing of any such Derivative Instrument in effect as of March 1, 2019 for the meeting promptly following the later of March 1, 2019 or the date notice of March 1, 2019 is first publicly disclosed;
- a description of any agreement, arrangement or understanding with respect to the proposal of business between or among such stockholder and the beneficial owner, if any, on whose behalf the proposal is made, any of their respective affiliates or associates, and any others acting in concert with any of the foregoing and a representation that the stockholder will notify the Company in writing of any such agreements, arrangements or understandings in effect as of March 1, 2019 for the meeting promptly following the later of March 1, 2019 or the date notice of March 1, 2019 is first publicly disclosed;
- a representation that the stockholder is a holder of record of stock of the Company entitled to vote at such meeting and intends to appear in person or by proxy at the meeting to propose such business; and
- any other information that is required to be provided by the stockholder pursuant to Section 14 of the Exchange Act and the rules and regulations promulgated thereunder in such stockholder's capacity as a proponent of a stockholder proposal.

In addition, the Bylaws require that the stockholder recommendation shall set forth as to each person whom the stockholder proposes to nominate for election or reelection as a director: (1) the name, age, business address and residence address of the person; (2) the principal occupation or employment of the person; (3) the class, series and number of shares of capital stock of the Company that are owned beneficially and of record by the person; (4) a statement as to the person's citizenship; (5) the completed and signed representation and agreement described above; (6) any other information relating to the person that is required to be disclosed in solicitations for proxies for election of directors pursuant to Section 14 of the Exchange Act; (7) such person's written consent to being named in the proxy statement as a nominee and to serving as a director if elected; and (8) whether and the extent to which any derivative instrument, swap, option, warrant, short interest, hedge or profit interest or other transaction has been entered into by or on behalf of such person with respect to stock of the Company and whether any other agreement, arrangement or understanding (including any short position or any borrowing or lending of shares of stock) has been made by or on behalf of such person, the effect or intent of any of the foregoing being to mitigate loss to, or to manage risk of stock price changes for, such person or to increase or decrease the voting power or pecuniary or economic interest of such person with respect to stock of the Company.

We believe that each of our directors and nominees brings a strong background and set of skills to the Board, giving the Board, as a whole, an appropriate balance of the knowledge, experience, attributes, skills and expertise. In addition, seven of our eight directors are independent under Nasdaq standards (Mr. Gridley, our Chief Executive Officer, being the only exception as he is a Company employee) and our Nominating/Corporate Governance

Committee believes that all eight directors are independent of the influence of any particular stockholder or group of stockholders whose interests may diverge from the interests of our stockholders as a whole. We believe that our directors have a broad range of personal characteristics including leadership, management, biotechnology, pharmaceutical, business, marketing and financial experience and abilities to act with integrity, with sound judgment and collegially, to consider strategic proposals, to assist with the development of our strategic plan and oversee its implementation, to oversee our risk management efforts and executive compensation and to provide leadership, to commit the requisite time for preparation and attendance at board and committee meetings and to provide required expertise on the Board committees. As described above, the Nominating/Corporate Governance Committee has recommended the members of the Board for their directorships. In evaluating such directors, our Nominating/Corporate Governance Committee has reviewed the experience, qualifications, attributes and skills of our directors and nominees, including those identified in the biographical information set forth above in the section entitled "*Biographical Information – Directors*." The Nominating/Corporate Governance Committee believes that the members of the Board offer insightful and creative views and solutions with respect to issues facing the Company. In addition, the Nominating/Corporate Governance Committee also believes that the members of the Board function well together as a group. The Nominating/Corporate Governance Committee believes that the above-mentioned attributes and qualifications, along with the leadership skills and other experiences of the members of the Board described in further detail above under the section entitled "*Biographical Information – Directors*," provide the Company with the perspectives and judgment necessary to guide the Company's strategies and monitor their execution.

Special Committee

The Special Committee was officially formed on September 5, 2018 as our Board considered various strategic alternatives for the Company, but had also met on an interim, ad hoc basis for several months prior such formation (though with no authority to review or approve specific transactions during such interim period). The Special Committee was delegated the exclusive power and authority (1) consider, evaluate and comprehensively review the Company's strategic options, including, but not limited to, potential strategic partnerships or transactions, cost reductions, reorganization, wind-down, liquidation or bankruptcy (collectively, without limitation, the Strategic Options); (2) take into consideration the Company's risk profile and the potential impact of any Special Committee recommendation on the Company's business model and strategic plan; (3) periodically report its recommendations relating to the Strategic Options to the full Board; and (4) perform such other duties as may be requested by the Board.

Four directors comprised the Special Committee as of December 31, 2018: Dr. Kong (the Chairman of the Special Committee), Mr. Baltzell, Mr. Gill and Mr. Johnson. Dr. Kong resigned from the Board effective February 22, 2019. Mr. Baltzell was appointed as the Chairman of the Special Committee effective February 22, 2019. The Special Committee met four times during 2018. In addition, the members of the Special Committee met informally more than a dozen times throughout the year (including prior to becoming a formal board committee) to discuss a variety of matters, including reviewing and assessing strategic alternatives for the Company in the fourth quarter of 2018 following the suspension of our NeoCart program .

Separation of CEO and Chairman of the Board Roles

The Board separates the positions of Chairman of the Board and Chief Executive Officer. Separating these positions allows our Chief Executive Officer to focus on our day-to-day business, while allowing the Chairman of the Board to lead the Board in its fundamental role of providing advice to and independent oversight of management. The Board recognizes the time, effort, and energy that the Chief Executive Officer is required to devote to his position in the current business environment, as well as the commitment required to serve as our Chairman of the Board, particularly as the Board's oversight responsibilities continue to grow. We believe that having separate positions and having an independent outside director serve as Chairman of the Board is the appropriate leadership structure for the Company at this time.

Meetings of the Board of Directors

The Board met nine times during 2018 and acted three times by written consent. Each director attended 75% or more of the aggregate of the meetings of the Board and of the committees on which he or she served, held during the

period for which he or she was a director or committee member, other than Mr. Rakin who attended 67% of the meetings of the Board (but attended 75% or more of the committees on which he served).

Director Attendance at Annual Meetings of Stockholders

Directors are encouraged, but not required, to attend our annual stockholder meetings. All of our directors attended our 2018 Annual Meeting of Stockholders.

Stockholder Communications with the Board of Directors

Stockholders may communicate with the Board, including the independent members of the Board, by sending a letter to Histogenics Corporation, 830 Winter Street, 3rd Floor, Waltham, MA 02451, Attention: Corporate Secretary. Each such communication should set forth (1) the name and address of such stockholder, as they appear on the Company's books and, if the shares of the Company's stock are held by a nominee, the name and address of the beneficial owner of such shares, and (2) the number of shares of the Company's stock that are owned of record by such record holder and beneficially by such beneficial owner. The Corporate Secretary will review all communications from stockholders, but may, in his sole discretion, disregard any communication that he believes is not related to the duties and responsibilities of the Board. If deemed an appropriate communication, the Corporate Secretary will submit a stockholder communication to a chairman of a committee of the Board, or a particular director, as appropriate.

The Board has also adopted internal policies and procedures, with the assistance of outside legal counsel, for responding to communications from the Company's stockholders, including litigation demand letters (a Litigation Demand), which provide that:

- any Litigation Demand is promptly forwarded to the independent Chairman of the Board and outside legal counsel;
- investigations of any Litigation Demand will be directed and supervised by one or more disinterested and independent (*i.e.*, non-management) members of the Board and such supervision will not be delegated to any member of the Company's management team (though in appropriate cases members of management may otherwise assist an investigation);
- the Board has standing authority to retain and be advised by disinterested and independent outside legal counsel and other advisers, as needed;
- the Board may authorize a special demand review committee to investigate a Litigation Demand, which committee would ensure the preparation of a written record of the resolution creating the demand review committee, its purpose, composition, structure, duties, responsibilities and scope of authority; and
- upon completion of its investigation, the Board will receive a recommendation from the independent and disinterested members of the Board who investigated the Litigation Demand and vote on whether to adopt that recommendation and inform the demanding stockholder accordingly.

The Board's Litigation Demand policy notes that every Litigation Demand situation is unique and that flexibility is required in responding thereto. Failure to adhere to any of the particular processes above is not deemed a breach of any Board member's fiduciary duties.

Code of Business Conduct

We have adopted a Code of Business Conduct that applies to each of our directors, officers and employees, including our principal executive officer, principal financial officer, principal accounting officer or controller and persons performing similar functions. The Code of Business Conduct addresses various topics, including: (1) compliance with applicable laws, rules and regulations; (2) conflicts of interest; (3) public disclosure of information; (4) insider trading; (5) corporate opportunities; (6) competition and fair dealing; (7) gifts; (8) discrimination, harassment and retaliation; (9) health and safety; (10) record-keeping; (11) confidentiality;

(12) protection and proper use of company assets; (13) payments to government personnel; and (14) the reporting of illegal and unethical behavior.

The Code of Business Conduct is available on the "Investors" section of our corporate website located at http://ir.histogenics.com. Any waiver of the Code of Business Conduct for an executive officer or director may be granted only by the Board or a committee thereof and must be timely disclosed as required by applicable law. We intend to disclose future amendments to certain provisions of our Code of Business Conduct, or waivers of those provisions, applicable to any principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions on our website, www.histogenics.com.

We have implemented whistleblower procedures that establish formal protocols for receiving and handling complaints from employees. Any concerns regarding accounting or audit matters reported under these procedures will be communicated promptly to the Audit Committee.

Risk Oversight

The Board has responsibility for the oversight of the company's risk management processes and, either as a whole or through its committees, regularly discusses with management our major risk exposures, their potential impact on our business and the steps we take to manage them. The risk oversight process includes the Board receiving regular reports from Board committees and members of senior management to enable the Board to understand the Company's risk identification, risk management and risk mitigation strategies with respect to areas of potential material risk, including operations, finance, legal, regulatory, strategic, cybersecurity and reputational risk.

The Audit Committee reviews information regarding liquidity and operations, and oversees our management of financial risks. Periodically, the Audit Committee reviews our policies with respect to risk assessment, risk management, loss prevention and regulatory compliance. Oversight by the Audit Committee includes direct communication with our external independent auditors and discussions with management regarding significant risk exposures and the actions management has taken to limit, monitor or control such exposures. The Compensation Committee is responsible for assessing whether any of our compensation policies or programs has the potential to encourage excessive risk-taking. The Nominating/Corporate Governance Committee manages risks associated with the independence of the Board, corporate disclosure practices and potential conflicts of interest. While each committee is responsible for evaluating certain risks and overseeing the management of such risks, the entire Board is regularly informed through committee reports about such risks. Matters of significant strategic risk are considered by the Board as a whole.

The oversight of risk within the Company is an evolving process requiring the Company to continually look for opportunities to further embed systematic enterprise risk management into ongoing business processes within the Company. The Board encourages management to continue to drive this evolution.

Employee Compensation Risks

As part of its oversight of the Company's executive compensation program, the Compensation Committee considers the impact of the Company's executive compensation program, and the incentives created by the compensation awards that it administers, on the Company's risk profile. In addition, the Compensation Committee reviews the compensation policies and procedures for all employees, including the incentives that they create and factors that may reduce the likelihood of excessive risk taking, to determine whether they present a significant risk to the Company. The Compensation Committee has determined that, for all employees, our Company's compensation programs are not reasonably likely to have a material adverse effect on the Company.

Director Compensation

The Board adopted a non-employee director policy effective as of the date of our initial public offering and subsequently amended and restated such policy in June 2015 and June 2017. The table below sets forth the provisions of the Amended and Restated Compensation Program for Non-Employee Directors.

Term	Compensation
Annual Cash Retainer(1)	$ 40,000
Chairman of Board(1)	Additional annual retainer of $20,000
Chair of Audit Committee(1)	Additional annual retainer of $10,000
Chair of Compensation Committee(1)	Additional annual retainer of $7,500
Chair of Nominating/Corporate Governance Committee(1)	Additional annual retainer of $7,500
Chair of Special Committee(1)	Additional monthly retainer of $3,000
Non-Chair Member of Audit Committee(1)	Additional annual retainer of $5,000
Non-Chair Member of Compensation Committee(1)	Additional annual retainer of $3,750
Non-Chair Member of Nominating/Corporate Governance Committee(1)	Additional annual retainer of $3,750
Non-Chair Member of Special Committee(1)	Additional monthly retainer of $2,500
Initial Option Grant	Option to purchase up to 25,000 shares of our common stock(2)
Annual Option Grant	Option to purchase 25,000 shares of our common stock following each annual meeting of stockholders(3)

(1) All annual cash retainer fees are paid in four quarterly payments.
(2) Option vests and becomes exercisable with respect to 8.33% of the option shares for each three-month period after the date of grant, except that in the event of a change in control or a director's death or disability, the option will accelerate and become immediately exercisable.
(3) Option vests and becomes exercisable with respect to 8.33% of the option shares for each one-month period following the date of grant, except that in the event of a change in control or a director's death or disability, the option will accelerate and become immediately exercisable.

All stock option grants to non-employee directors will have an exercise price per share equal to the fair market value of one share of our common stock on the date of grant and will be subject to the terms of our 2013 Equity Incentive Plan. Each option granted under our Amended and Restated Compensation Program for Non-Employee Directors that is not fully vested will become fully vested upon a change in control of our Company or if the non-employee director's service terminates due to death.

We currently have a policy to reimburse our non-employee directors for travel, lodging and other reasonable expenses incurred in connection with their attendance at board and committee meetings.

Director Compensation Table for Year Ended December 31, 2018

The following table sets forth information regarding compensation earned by each of our non-employee directors during the fiscal year ended December 31, 2018.

Name (1)	Fees Earned or Paid in Cash ($)	Option Awards ($)	Total ($)
Garheng Kong, M.D., Ph.D.(2)	$ 70,000	$ 54,677	$ 124,677
Josh Baltzell	49,583	54,677	104,260
David Gill	52,083	54,677	106,760
John Johnson(3)	54,583	54,677	109,260
Michael Lewis	40,469	54,677	95,146
Kevin Rakin	48,750	54,677	103,427
Susan Washer (4)	20,052	52,282	72,334

(1) Mr. Gridley was not eligible in 2018 to receive any compensation from us for his service as a director pursuant to our Amended and Restated Compensation Program for Non-Employee Directors because Mr. Gridley is a Company employee.

(2) Dr. Kong resigned from the Board effective February 22, 2019.

(3) Mr. Johnson resigned from the Board effective February 27, 2019.

(4) Ms. Washer was appointed to the Board on April 16, 2018.

The following table sets forth information regarding outstanding option awards held by each of our non-employee directors as of December 31, 2018.

	Option Awards			
Name	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price ($)	Option Expiration Date
Garheng Kong, M.D., Ph.D.(5)	20,000	—	6.86	June 24, 2025(1)
	10,000	—	1.58	December 16, 2026(1)
	25,000	—	1.72	June 13, 2027(1)
	12,500	12,500	2.97	June 15, 2028(1)
Josh Baltzell	20,000	—	6.86	June 24, 2025(1)
	10,000	—	1.58	December 16, 2026(1)
	25,000	—	1.72	June 13, 2027(1)
	12,500	12,500	2.97	June 15, 2028(1)
David Gill	13,200	—	8.30	February 1, 2025(2)
	6,800	—	6.86	June 24, 2025(1)
	10,000	—	1.58	December 16, 2026(1)
	25,000	—	1.72	June 13, 2027(1)
	12,500	12,500	2.97	June 15, 2028(1)
John Johnson(6)	9,255	—	7.13	December 10, 2023(3)
	20,475	—	6.86	June 24, 2025(1)
	10,000	—	1.58	December 16, 2026(1)
	25,000	—	1.72	June 13, 2027(1)
	12,500	12,500	2.97	June 15, 2028(1)
Michael Lewis	20,000	—	6.86	June 24, 2025(1)
	10,000	—	1.58	December 16, 2026(1)
	25,000	—	1.72	June 13, 2027(1)
	12,500	12,500	2.97	June 15, 2027(1)
Kevin Rakin	20,000	—	6.86	June 24, 2025(1)
	10,000	—	1.58	December 16, 2026(1)
	25,000	—	1.72	June 13, 2027(1)
	12,500	12,500	2.97	June 15, 2028(1)
Susan Washer(7)	25,000	—	2.84	April 16, 2028(4)

(1) This option vests in twelve equal monthly installments commencing on the date of grant.

(2) As of December 31, 2017, this option was exercisable with respect to 50% of the shares when the optionee completes each twelve-month period of continuous service after February 2, 2015, and the balance of the shares become exercisable in equal quarterly instalments over the 36 months thereafter. This was the vesting schedule applicable to all initial grants to directors under the Company's initial Compensation Program for Non-Employee Directors. In June 2015 and June 2017, the Board amended and restated the initial Compensation Program for Non-Employee Directors. Under the Amended and Restated Compensation Program for Non-Employee Directors, initial grants for new directors become exercisable with respect to 8.33% of the shares after each three-month period of continuous service as a director after the date of grant. On February 26, 2016, the Compensation Committee amended the vesting schedule of the option to reflect the Amended and Restated Compensation Program for Non-Employee Directors such that the shares subject to this option are now exercisable with respect to 8.33% of the shares after each three-month period of continuous service as a director after the date of grant. The table above reflects the modified vesting schedule.

(3) Exercisable with respect to 25% of the shares when the optionee completes each twelve-month period of continuous service after November 13, 2013. If we are subject to a change in control before the optionee's service terminates, then the option shall vest in full.

(4) This option vests in twelve equal quarterly installments commencing on the date of grant.
(5) Dr. Kong resigned from the Board effective February 22, 2019.
(6) Mr. Johnson resigned from the Board effective February 27, 2019.
(7) Ms. Washer was appointed to the Board on April 16, 2018.

SECTION 16(a) BENEFICIAL OWNERSHIP REPORTING COMPLIANCE

Section 16(a) of the Exchange Act requires our directors, executive officers and certain holders of more than 10% of our common stock to file reports regarding their ownership and changes in ownership of our securities with the SEC and to furnish us with copies of all Section 16(a) reports that they file.

Based solely upon a review of Forms 3 and 4 and amendments thereto furnished to us and written representations provided to us by all of our directors and executive officers and certain of our greater than 10% stockholders, we believe that during the year ended December 31, 2018, our directors, executive officers and greater than 10% stockholders complied with all applicable Section 16(a) filing requirements.

ITEM 11. EXECUTIVE COMPENSATION

2018 Summary Compensation Table

The following table provides information concerning the compensation paid to Adam Gridley, our President and Chief Executive Officer, and our next two most highly compensated executive officers during the year ended December 31, 2018, who are Stephen Kennedy, our Executive Vice President and Chief Operating Officer, and Donald Haut, Ph.D. We refer to these individuals as our named executive officers.

Name and Principal Position	Year	Salary ($)	Bonus ($)	Option Awards ($)(4)	All Other Compensation ($)	Total ($)
Adam Gridley(1)	2018	478,065	—	186,056	—	664,121
Director, President and Chief Executive Officer	2017	435,000	382,725	182,548	—	1,000,273
Stephen Kennedy(2)	2018	391,875	—	74,156	—	466,031
Executive Vice President and Chief Operating Officer	2017	352,914 (2)	240,438	138,729	—	732,081
Donald Haut, Ph.D.(3)	2018	377,415	—	40,436	—	417,851
Former Chief Business Officer	2017	213,546	94,343	184,974	—	492,863

(1) Pursuant to a reduction in force approved by the Board in March 2019, Mr. Gridley's employment with us will terminate effective March 22, 2019. Mr. Gridley will retain his statutory titles of president, treasurer and secretary of the Company while he continues to provide consulting services to us, and will remain a director of the Company. In connection with the execution of the separation entered into with Mr. Gridley in connection with his termination, we and Mr. Gridley also intend to enter into a consulting agreement pursuant to which Mr. Gridley will provide consulting services to us through at least June 30, 2019 for an hourly fee of $250.
(2) Pursuant to a reduction in force approved by the Board in March 2019, Mr. Kennedy's employment with us will terminate effective March 22, 2019. In connection with the execution of the separation entered into with Mr. Kennedy in connection with his termination, we and Mr. Kennedy also intend to enter into a consulting agreement pursuant to which Mr. Kennedy will provide consulting services to us through at least June 30, 2019 for an hourly fee of $220.
(3) Dr. Haut's service with the Company terminated on January 23, 2019 in connection with a reduction in force.
(4) Represents the aggregate grant date fair value of option awards, computed in accordance with FASB ASC Topic 718. See Note 11 to our consolidated financial statements included in this Annual Report on Form 10-K for a discussion of the assumptions made by us in determining the fair value of our equity awards.

Narrative Explanation of Certain Aspects of the Summary Compensation Table

The compensation paid to our named executive officers consists of the following components:

- base salary;
- performance-based cash bonuses; and
- long-term incentive compensation in the form of stock options.

Base Salaries

For the year ended December 31, 2018, the annual base salaries for our named executive officers were as follows: Mr. Gridley—$478,065; Mr. Kennedy—$391,875; and Dr. Haut—$377,415. In addition to actions taken with respect to hiring new, or promoting existing, executive officers, the Compensation Committee of the Board approved the annual base salaries for our named executive officers for the twelve-month period ended December 31, 2018, and approved option grants under the Company's 2013 Equity Incentive Plan to certain of our named officers, as listed below in the section entitled "*Outstanding Equity Awards at 2018 Fiscal Year-End*." Due to the discontinuation of the NeoCart program, the base salaries of our named executive officers were not increased for the year ending December 31, 2019.

Performance-Based Bonuses

Pursuant to employment agreements with Messrs. Gridley and Kennedy and Dr. Haut, each named executive officer is to earn an annual bonus equal to a specified percentage of his base salary (60% with respect to Mr. Gridley, 40% with respect to Mr. Kennedy and 35% with respect to Dr. Haut). The actual amount of bonus earned is determined by the Board based on our performance and the officer's achievement of objectives and goals determined by our chief executive officer (or, with respect to Mr. Gridley, the Board). Due to the discontinuation of the NeoCart program, no performance-based bonuses were awarded to our named executive officers for the year ended December 31, 2018 and no changes were made to the specified percentage of base salary potentially available as a performance-based bonus for our named executive officers for the year ending December 31, 2019.

Long-Term Incentive Compensation

We offer stock options to our employees, including our named executive officers, as the long-term incentive component of our compensation program. Our stock options allow our employees to purchase shares of our common stock at a price equal to the fair market value of our common stock on the date of grant. Our stock options granted to newly hired employees generally vest as to 25% of the total number of option shares on the first anniversary of the award and in equal monthly installments over the following 36 months.

For information regarding the vesting acceleration provisions applicable to the options held by our named executive officers, please see "*Severance Benefits*" and "*Change in Control Benefits*" below.

Outstanding Equity Awards at 2018 Fiscal Year-End

The following table sets forth information regarding each unexercised option held by each of our named executive officers as of December 31, 2018.

	Option Awards			
Name	Number of Securities Underlying Unexercised Options Exercisable(#)	Number of Securities Underlying Unexercised Options Unexercisable(#)	Option Exercise Price ($)	Option Expiration Date
Adam Gridley(8)	197,435	— (1)	7.99	April 29, 2024
	38,220	— (1)	8.97	July 16, 2024
	99,666	4,334 (2)	9.96	February 26, 2025
	123,958	51,042 (3)	1.58	December 15, 2026
	80,208	94,792 (2)	1.72	February 13, 2027
	—	300,000 (2)	2.63	February 15, 2028
Stephen Kennedy(9)	27,767	— (4)	7.13	December 10, 2023
	47,054	2,046 (2)	9.96	February 26, 2025
	42,708	7,292 (5)	6.11	July 29, 2025
	17,708	7,292 (2)	2.56	February 25, 2026
	34,375	40,625 (2)	1.72	February 13, 2027
	14,583	35,417 (6)	2.12	October 9, 2027
	—	115,000 (2)	2.63	February 15, 2028
Donald Haut, Ph.D.(10)	73,125	121,875 (7)	6.37	July 1, 2025
	—	105,000 (2)	2.63	February 15, 2028

(1) Option vests over four years of service following May 12, 2014, with 25% vesting upon completion of twelve months of service and in 36 equal monthly installments thereafter.

(2) Option vests over four years of service commencing on the date of grant, with 25% vesting upon completion of twelve months of service and in 36 equal monthly installments thereafter.

(3) Option vests over four years of service following February 26, 2016, with 25% vesting upon completion of twelve months of service and in 36 equal monthly installments thereafter.

(4) Option vests over four years of service following August 19, 2013, with 25% vesting upon completion of twelve months of service and in 36 equal monthly installments thereafter.

(5) Option vests over four years of service following July 29, 2015, with 25% vesting upon completion of twelve months of service and in 36 equal monthly installments thereafter.

(6) Option vests over four years of service following October 10, 2017, with 25% vesting upon completion of twelve months of service and in 36 equal monthly installments thereafter.

(7) Option vests over four years of service following June 5, 2017, with 25% vesting upon completion of twelve months of service and in 36 equal monthly installments thereafter.

(8) Pursuant to a reduction in force approved by the Board in March 2019, Mr. Gridley's employment with us will terminate effective March 22, 2019. Mr. Gridley will retain his statutory titles of president, treasurer and secretary of the Company while he continues to provide consulting services to us, and will remain a director of the Company. In connection with the execution of the separation entered into with Mr. Gridley in connection with his termination, we and Mr. Gridley also intend to enter into a consulting agreement pursuant to which Mr. Gridley will provide consulting services to us through at least June 30, 2019.

(9) Pursuant to a reduction in force approved by the Board in March 2019, Mr. Kennedy's employment with us will terminate effective March 22, 2019. In connection with the execution of the separation entered into with Mr. Kennedy in connection with his termination, we and Mr. Kennedy also intend to enter into a consulting agreement pursuant to which Mr. Kennedy will provide consulting services to us through at least June 30, 2019.

(10) Dr. Haut's service with the Company terminated on January 23, 2019 in connection with a reduction in force.

For information regarding the vesting acceleration provisions applicable to the options held by our named executive officers, please see "*Change in Control Benefits*" below.

Due to the suspension of the NeoCart program, no equity awards were made to our named executive officers for the year ended December 31, 2018.

Employment Agreements

Adam Gridley

In April 2014, we entered into a letter agreement with Adam Gridley, under which Mr. Gridley agreed to become our president and chief executive officer, effective as of May 12, 2014. Under this agreement, Mr. Gridley's base salary for 2018 was $478,065 per year. Mr. Gridley was eligible to receive an annual cash bonus with a target equal to 60% of his base salary, subject to satisfaction of objective or subjective criteria established by the Board. Pursuant to a reduction in force approved by the Board in March 2019, Mr. Gridley's employment with us will terminate effective March 22, 2019. Mr. Gridley will retain his statutory titles of president, treasurer and secretary of the Company while he continues to provide consulting services to us, and will remain a director of the Company. In connection with the execution of the separation entered into with Mr. Gridley in connection with his termination, we and Mr. Gridley also intend to enter into a consulting agreement pursuant to which Mr. Gridley will provide consulting services to us through at least June 30, 2019 for an hourly fee of $250. For a period of twelve months after the termination of his employment, Mr. Gridley will be subject to certain restrictions on competing with us and prohibiting the solicitation of our employees and customers. Mr. Gridley has an at-will employment relationship with us.

Pursuant to his letter agreement, Mr. Gridley received an option to purchase up to 197,435 shares of our common stock. In addition, upon the final closing for the sale of shares of our Series A-1 Preferred Stock in May 2014, Mr. Gridley was granted an additional option to purchase up to 38,220 shares such that, together with the original option, Mr. Gridley's options represented 4% of our common stock, including shares issuable upon conversion of option and warrants, outstanding on the date of such final closing. The shares subject to such options vest 25% after the first twelve months of Mr. Gridley's continuous service, with the remainder vesting in equal monthly installments over the next three years of his continuous service. In addition, for information regarding the vesting acceleration provisions applicable to Mr. Gridley's options, please see "*Change in Control Benefits*" below.

In connection with the commencement of his employment, we paid Mr. Gridley $48,446 to assist with temporary housing and related expenses.

Stephen Kennedy

In October 2017, Stephen Kennedy was promoted to Chief Operating Officer. In connection with this promotion, we entered into an amended and restated employment agreement with Mr. Kennedy. Under this amended agreement, Mr. Kennedy's base salary for 2018 was $391,875. Mr. Kennedy was eligible to receive an annual cash bonus equal to 40% of his base salary, subject to satisfaction of objective or subjective criteria established by the Board. Pursuant to a reduction in force approved by the Board in March 2019, Mr. Kennedy's employment with us will terminate effective March 22, 2019. In connection with the execution of the separation entered into with Mr. Kennedy in connection with his termination, we and Mr. Kennedy also intend to enter into a consulting agreement pursuant to which Mr. Kennedy will provide consulting services to us through at least June 30, 2019 for an hourly fee of $220. For a period of twelve months after the termination of his employment, Mr. Kennedy will be subject to certain restrictions on competing with us and prohibiting the solicitation of our employees and customers. Mr. Kennedy has an at-will employment relationship with us.

Pursuant to his amended and restated employment agreement, Mr. Kennedy received an option to purchase up to 50,000 shares of our common stock, as described in more detail above under "*Outstanding Equity Awards at 2018 Fiscal Year-End*." The shares subject to the option will vest 25% after the first twelve months of Mr. Kennedy's continuous service after October 10, 2017 with the remainder vesting in equal monthly installments over the next three years of his continuous service. In addition, for information regarding the vesting acceleration provisions applicable to Mr. Kennedy's option, please see "*Change in Control Benefits*" below.

Donald Haut, Ph.D.

In June 2017, we entered into an employment agreement with Donald Haut, Ph.D. in connection with his appointment as our Chief Business Officer. Under this agreement, Dr. Haut's base salary for 2018 was $377,415. Dr. Haut was eligible to receive an annual cash bonus with a target amount equal to 35% of his base salary, subject to satisfaction of objective or subjective criteria established by the Board. Dr. Haut had an at-will employment relationship with us. Dr. Haut was terminated without cause in connection with a reduction in force implemented in January 2019. For a period of twelve months after the termination of his employment, Dr. Haut will be subject to certain restrictions on competing with us and prohibiting the solicitation of our employees and customers.

Pursuant to his employment agreement, Dr. Haut received an option to purchase up to 195,000 shares of our common stock, as described in more detail above under "Outstanding Equity Awards at 2018 Fiscal Year-End." The options vested 25% after the first twelve months of Dr. Haut's continuous service, with the remainder vesting in equal monthly installments over the next three years of his continuous service. In connection with his separation from service and pursuant to his employment agreement, Dr. Haut also received an additional nine months of vesting for all outstanding options at the time of separation. For further information regarding the vesting acceleration provisions applicable to Dr. Haut's option, please see "*Change in Control Benefits*" below.

Severance Benefits

Adam Gridley

As described above, in April 2014, we entered into a letter agreement with Adam Gridley under which Mr. Gridley agreed to become our president and chief executive officer, effective May 12, 2014. Pursuant to a reduction in force approved by the Board in March 2019, Mr. Gridley's employment with us will terminate effective March 22, 2019. Under this agreement, if we terminated Mr. Gridley's employment without cause or Mr. Gridley had resigned for good reason, we would have been, and are obligated to continue to pay Mr. Gridley his base salary, and he will be entitled to health benefits, for a period of twelve months following the termination of his employment. Such benefits are subject to Mr. Gridley's execution of a general release of all claims he may have against us and certain related parties. As part of the separation agreement entered into with Mr. Gridley, we have agreed with Mr. Gridley to pay his severance benefit of salary continuation for 12 months in one lump sum.

For purposes of Mr. Gridley's letter agreement, cause meant Mr. Gridley's unauthorized use or disclosure of our confidential information or trade secrets which would have caused material harm to us; material breach of any agreement with us; material failure to comply with our written policies or rules after receiving written notification of such failure; sale, possession or use of illegal drugs or habitual intoxication on our premises or the premises of a customer or business partner while conducting our business; conviction of, or plea of guilty or no contest to, a felony; gross negligence or willful misconduct in the course of service to us that results in material harm to us; continuing and willful failure to perform reasonably assigned duties after receiving written notification of such failure; or failure to cooperate in good faith with a governmental or internal investigation of us, if so requested.

For purposes of his letter agreement, good reason meant, without Mr. Gridley's consent, a material reduction in his base salary, a change in his title or position that materially reduces his level of authority or responsibility, relocation of his principal workplace by more than 40 miles or a material breach by us of the letter agreement.

Stephen Kennedy

If we terminated Mr. Kennedy's employment without cause or Mr. Kennedy had resigned for good reason, we will continue to pay Mr. Kennedy his base salary, and he will be entitled to health benefits, for a period of nine months following the termination of his employment. As part of the separation agreement entered into with Mr. Kennedy, we have agreed with Mr. Kenned to pay his severance benefit of salary continuation for nine months in one lump sum.

For purposes of his employment agreement, cause meant Mr. Kennedy's unauthorized use or disclosure of confidential information or trade secrets which would have caused material harm to the Company, a material breach of any agreement between Mr. Kennedy and the Company which is not remedied within 15 days after notice from the Company, a material failure to comply with the legal directives of the Board which is not remedied within 15 days after notice from the Board, the sale, possession or use of illegal drugs or habitual intoxication, conviction of, plea of "guilty" or "no contest" to any felony, gross negligence or willful misconduct in the course of performing

service to the Company, failure to perform reasonably assigned duties after receiving written notification of such failure from the Board or failure to cooperate in good faith with a governmental or internal investigation of the Company, if the Company has requested Mr. Kennedy's cooperation.

For purposes of the employment agreement, resignation for good reason meant a material reduction in Mr. Kennedy's base salary, a change in Mr. Kennedy's title or position with the Company that materially reduces his level of authority or responsibility, a relocation of principal workplace by more than 40 miles or a material breach by the Company of its obligations under the employment agreement.

Donald Haut, Ph.D.

If we terminated Dr. Haut's employment without cause or Dr. Haut resigned for good reason, we would have been, and are, obligated continue to pay Dr. Haut his base salary, and he will be entitled to health benefits, for a period of nine months following the termination of his employment. Dr. Haut's service with the Company was terminated on January 23, 2019 in connection with a reduction in force. As part of the separation agreement entered into with Dr. Haut, we agreed with Dr. Haut to pay his severance benefit of salary continuation for nine months in one lump sum.

For purposes of his employment agreement, cause meant Dr. Haut's unauthorized use or disclosure of confidential information or trade secrets which causes material harm to the Company, a material breach of any agreement between Dr. Haut and the Company, a material failure to comply with the legal directives of the Board, the sale, possession or use of illegal drugs or habitual intoxication, conviction of, plea of "guilty" or "no contest" to any felony, gross negligence or willful misconduct in the course of performing service to the Company, failure to perform reasonably assigned duties after receiving written notification of such failure from the Board, or failure to cooperate in good faith with a governmental or internal investigation of the Company, if the Company has requested Dr. Haut's cooperation.

For purposes of the employment agreement, resignation for good reason meant a material reduction in Dr. Haut's base salary, a change in Dr. Haut's title or position with the Company that materially reduces his level of authority or responsibility or a relocation of principal workplace by more than 40 miles.

Change in Control Benefits

In the event that we experience a change in control and within twelve months after such change in control, a named executive officer is terminated by us without cause or such individual resigns for good reason, then such individual's options will become fully vested and exercisable.

For purposes of the stock option agreements, change in control means an acquisition by any individual, entity or group of 50% or more of our voting stock, certain changes in the composition of the Board, our merger, consolidation, liquidation, dissolution or sale of all or substantially all of our assets.

For purposes of the stock option agreements, cause and good reason have substantially the same meanings as under each named executive officer's employment agreement, described above.

Executive Retention Bonus Plan

In September 2018, the Board adopted the Executive Officer Retention Bonus Plan (the Initial Retention Plan). The Initial Retention Plan provided for payment of a cash retention bonus to the executive officers of the Company, including the Company's named executive officers, who continued employment with the Company through April 30, 2019 (the Initial Retention Date). The Initial Retention Plan was intended to help ensure the Company's continued operations. The Compensation Committee of the Board administered the Initial Retention Plan.

Under the terms of the Initial Retention Plan, each executive officer who continued employment with the Company through the Initial Retention Date was eligible to receive a cash bonus payable in a lump sum within 15 days following the Initial Retention Date. Additionally, the retention bonus amount would be payable in the event the executive officer was terminated without cause or resigned for good reason.

The table below sets forth the retention bonus amount for each named executive officer under the Initial Retention Plan:

Executive Officer		Retention Bonus Amount
Adam Gridley	$	119,516
Stephen Kennedy	$	97,969
Donald Haut, Ph.D.	$	94,354

In connection with his separation from service without cause as part of the January 2019 reduction in force, Dr. Haut was paid his retention bonus under the Initial Retention Plan.

Effective January 25, 2019, the Board approved an amendment to Initial Retention Plan (the Retention Plan). The Retention Plan, as amended, provides for payment of a cash retention bonus to the executive officers of the Company, including the Company's named executive officers, who continue employment with the Company through June 30, 2019 (the Retention Date). The Retention Plan is intended to help ensure the Company's continued operations and strategic process. The Compensation Committee of the Board will continue to administer the Retention Plan.

Under the terms of the Retention Plan, each executive officer who continues employment with the Company through the Retention Date will be eligible to receive a cash bonus payable in a lump sum within 15 days following the Retention Date. Additionally, the retention bonus amount would be payable in the event the executive officer is terminated without cause or resigns for good reason.

The table below sets forth the retention bonus amount for each current executive officer under the Retention Plan assuming all terms and conditions are satisfied:

Executive Officer		Retention Bonus Amount
Adam Gridley	$	191,200
Stephen Kennedy	$	156,750

For the avoidance of doubt, the amounts set forth above are not in addition to the amounts provided for under the Initial Retention Plan, but are the only amounts payable under the Retention Plan, as amended. In connection with their separation from service without cause as part of the March 2019 reduction in force, Messrs. Gridley and Kennedy will be paid their respective retention bonus under the Retention Plan.

Retirement Benefits

We have established a 401(k) tax-deferred retirement savings plan, which permits participants, including our named executive officers, to make contributions by pre-tax salary deduction pursuant to Section 401(k) of the Code. We are responsible for administrative costs of the 401(k) plan. We may, at our discretion, make matching contributions to the 401(k) plan. No employer contributions have been made to date.

Employee Benefits and Perquisites

Our named executive officers are eligible to participate in our health and welfare plans to the same extent as all full-time employees. Although we generally do not provide our named executive officers with perquisites or other personal benefits, we offered temporary housing and related assistance to Mr. Gridley in connection with the commencement of his employment with us, as described in the Summary Compensation Table above.

Tax and Accounting Considerations

Section 162(m) of the Code generally denies a deduction to any publicly-held corporation for compensation paid in a taxable year to its named executive officers exceeding $1 million. As a result of changes made by the 2017 Tax

Cuts and Jobs Act, starting with compensation paid in 2018, Section 162(m) will limit the Company from deducting compensation, including performance-based compensation, in excess of $1 million paid to anyone who serves as our chief executive officer, chief financial officer or who is among the three most highly compensated executive officers for any year beginning after December 31, 2016. The only exception to this rule is for compensation that is paid pursuant to a binding contract in effect on November 2, 2017 that would have otherwise been deductible under the prior Section 162(m) rules. Prior to the enactment of the 2017 Tax Cuts and Jobs Act, Section 162(m) limited us from deducting compensation paid in years prior to 2018, excluding performance-based compensation, in excess of $1 million paid to anyone who served as the chief executive officer or who was one of the three most highly compensated executive officers for the applicable tax year, excluding the chief financial officer. Our Compensation Committee considers tax and accounting implications in determining all elements of our compensation plans, programs and arrangements. For pre-2018 years, the Compensation Committee retained the discretion to make awards of either bonuses or equity awards that did not satisfy Section 162(m) and, therefore, may not have been deductible. Base salaries, time-vested restricted stock, time-vested retention and transition payments and discretionary or subjectively determined bonus awards generally did not qualify as performance-based compensation under the pre-2018 rules. In September 2014, our stockholders approved our 2013 Equity Incentive Plan that permits us to satisfy the performance-based requirements under Section 162(m) with respect to the grant of stock options.

Equity Compensation Plan Information

The following table provides information as of December 31, 2018 with respect to the shares of our common stock that may be issued under our existing equity compensation plans.

Plan Category	Number of Securities to be Issued Upon Exercise of Outstanding Options, RSUs, Warrants and Rights		Weighted Average Exercise Price of Outstanding Options, Warrants and Rights	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans	
Equity compensation plans approved by stockholders	3,339,471	(1)	$ 1.03	361,973	(2)
Equity compensation plans not approved by stockholders	—		—	—	
Total	3,339,471			361,973	

(1) Of these shares, 22,330 were subject to options then outstanding under our 2012 Equity Incentive Plan and 3,317,141 were subject to options then outstanding under our 2013 Equity Incentive Plan (the 2013 Plan).

(2) Represents 361,973 shares of common stock available for issuance under the 2013 Plan and 361,973 shares of common stock available for issuance under our 2013 Employee Stock Purchase Plan (the ESPP). On January 1 of each year, (i) the number of shares reserved under the 2013 Plan is automatically increased by the smaller of 4.0% of the total number of shares of common stock that are outstanding on December 31 of the prior year or such lesser number as may be approved by the Board and (ii) the number of shares reserved under our ESPP is automatically increased by the least of 1% of the total number of shares of common stock that are outstanding on December 31 of the prior year 51,382 shares of common stock or such lesser number as may be approved by the Board. In December 2018, the Board determined that no shares would be added to the 2013 Plan or the ESPP.

Option Repricing

In addition, on October 1, 2018, the Compensation Committee approved the Repricing of the Options granted prior to September 1, 2018 pursuant to 2013 Plan and 2012 Equity Incentive Plan to executive officers, employees and consultants of the Company, including Options held by Adam Gridley, the Company's Chief Executive Officer, Jonathan Lieber, the Company's Chief Financial Officer, Stephen Kennedy, the Company's Chief Operating Officer, Donald Haut, Ph.D., the Company's then Chief Business Officer and Lynne Kelley, M.D., FACs, the Company's then Chief Medical Officer. The Options had exercise prices between $0.75628 and $9.97 per share, which were reduced to $0.568 per share (the closing price of the Company's common stock on The Nasdaq Capital Market on October 1, 2018). The number of shares, vesting schedules and expiration period of the Options were not altered. Options to purchase the Company's common stock held by non-employee members of the Board are not

subject to the Repricing and remain unchanged. In light of current market conditions that have affected the publicly traded stock price of the Company's common stock, the Committee effectuated the Repricing in order to provide the service providers holding the Options with incentives that were not being adequately achieved by the Options based on the exercise prices of the Options prior to the Repricing. The Options were repriced unilaterally, and the consent of holders was neither necessary nor obtained. The impact to the Company's financial statements in 2018 was immaterial.

Cancellation of Performance Options

In connection with the Repricing, on October 1, 2018, the Compensation Committee also approved the cancelation of certain options with performance-based vesting conditions (the Performance Options) previously issued to Messrs. Gridley, Lieber and Kennedy. Messrs. Gridley, Lieber and Kennedy were previously granted the Performance Options to purchase 60,000, 30,000 and 30,000 shares of the Company's common stock, respectively, which would vest in full if the Company's stock price was at or above $19.92 for any consecutive 60-day period within four years of the date of grant as long as the recipient provided continuous service during such consecutive 60-day period (the Performance Criteria). The Committee determined that the probability of achieving the Performance Criteria was unlikely based on the current trading price of the Company's common stock on the Nasdaq Capital Market and cancelled the Performance Options pursuant to the Committee's authority under the 2013 Plan.

AUDIT COMMITTEE REPORT

The Audit Committee has also reviewed and discussed with Grant Thornton the audited consolidated financial statements in this Annual Report on Form 10-K. In addition, the Audit Committee discussed with Grant Thornton those matters required to be discussed by Statement of Accounting Standards 114, as modified, as adopted by the Public Company Accounting Oversight Board (PCAOB) in Rule 3200T and by PCAOB Auditing Standard No. 1301, *Communications with Audit Committees*, as may be further modified or supplemented. Additionally, Grant Thornton provided to the Audit Committee the written disclosures and the letter required by PCAOB Rule 3526, *Communication with Audit Committees Concerning Independence*, as adopted by the PCAOB. The Audit Committee also discussed with Grant Thornton its independence from the Company.

Based upon the review and discussions described above, the Audit Committee recommended to the Board that the audited consolidated financial statements for the year ended December 31, 2018 be included in this Annual Report on Form 10-Kfor filing with the SEC.

Submitted by the following members of the Audit Committee:

David Gill, Chairman
Susan Washer
Kevin Rakin

The material in this Audit Committee Report is not "soliciting material," is not deemed "filed" with the SEC and is not to be incorporated by reference in any filing of Histogenics under the Securities Act of 1933, as amended (the Securities Act), or the Exchange Act, whether made before or after the date hereof and irrespective of any general incorporation language in any such filing.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The following table sets forth certain information known to us regarding beneficial ownership of our common stock as of March 1, 2019 by:

- each person, or group of affiliated persons, who is known by us to beneficially own more than five percent of our outstanding common stock;
- each of our named executive officers;
- each of our directors; and
- all of our current directors and executive officers as a group.

Applicable percentage ownership is based on 94,599,601 shares of common stock outstanding at March 1, 2019.

The table below is based upon information supplied by executive officers, directors and principal stockholders and Schedule 13Gs and 13Ds filed with the SEC through March 1, 2019.

In computing the number of shares of common stock beneficially owned by a person and the percentage ownership of that person, we deemed to be outstanding all shares of common stock subject to options or warrants held by that person or entity that are currently exercisable or that will become exercisable within 60 days of March 1, 2019. We did not deem these shares outstanding, however, for the purpose of computing the percentage ownership of any other person. Unless otherwise indicated, the principal address of each of the stockholders below is c/o Histogenics Corporation, 830 Winter Street, 3rd Floor, Waltham, Massachusetts 02451.

Name and Address of Beneficial Owner	Number of Shares Beneficially Owned	Percentage of Shares Beneficially Owned
5% Stockholders		
Wilmslow Estates Limited(1) c/o Stonehage Group 2 The Forum, Grenville Street St Helier, Jersey, Channel Islands JE1 4HH	5,258,859	5.6%
Directors and Named Executive Officers		
Joshua Baltzell(2)	75,833	*
David Gill(3)	89,833	*
Michael Lewis(4)	5,334,692	*
Kevin Rakin(5)	534,797	*
Susan Washer(6)	8,333	*
Adam Gridley(7)	667,487	*
Stephen Kennedy(8)	236,449	*
Jonathan Lieber(9)	195,290	*
All current executive officers and directors as a group (8 persons)(10)	7,142,714	7.4%

* Less than one percent of the outstanding shares of common stock.

(1) Wilmslow's economic interest is ultimately owned by a family discretionary trust associated with Michael Lewis, who is referenced in footnote 4 below. Wilmslow has sole voting and investment power over the shares of capital stock owned.

(2) Shareholdings include 75,833 shares of common stock issuable upon exercise of options exercisable within 60 days of March 1, 2019.

(3) Shareholdings include 75,833 shares of common stock issuable upon exercise of options exercisable within 60 days of March 1, 2019.

(4) Shareholdings include 75,833 shares of common stock issuable upon exercise of options exercisable within 60 days of March 1, 2019. Mr. Lewis is the settlor of the trust which ultimately owns the economic interest in Wilmslow referenced in footnote 1 above. Mr. Lewis has no beneficial interest in the trust which ultimately owns the economic interest in Wilmslow, but other members of his family are discretionary beneficiaries in such trust. To the extent Mr. Lewis may be deemed to hold an indirect beneficial interest under applicable United States securities laws, Mr. Lewis disclaims such beneficial ownership.

(5) Shareholdings include (i) 75,833 shares of common stock issuable upon exercise of options exercisable within 60 days of March 1, 2019, (ii) 146,735 shares of common stock owned by the Kevin L. Rakin Irrevocable Trust, (iii) 33,333 shares of common stock owned by The Alison N Hoffman and Kevin L Rakin Irrevocable Trust For Sarah Hoffman Rakin and (iv) 33,333 shares of common stock owned by The Alison N Hoffman and Kevin L Rakin Irrevocable Trust For Julia Hoffman Rakin. Mr. Rakin is an affiliate of the Kevin L. Rakin Irrevocable Trust, The Alison N Hoffman and Kevin L Rakin Irrevocable Trust For Sarah Hoffman Rakin and The Alison N Hoffman and Kevin L Rakin Irrevocable Trust For Julia Hoffman Rakin. Mr. Rakin disclaims beneficial ownership in the shares owned by the foregoing affiliated trusts.

(6) Shareholdings include 8,333 shares of common stock issuable upon exercise of options exercisable within 60 days of March 1, 2019.

(7) Shareholdings include 660,487 shares of common stock issuable upon exercise of options exercisable within 60 days of March 1, 2019. Pursuant to a reduction in force approved by the Board in March 2019, Mr. Gridley's employment with us will terminate effective March 22, 2019.

(8) Shareholdings include 236,449 shares of common stock issuable upon exercise of options exercisable within 60 days of March 1, 2019. Pursuant to a reduction in force approved by the Board in March 2019, Mr. Kennedy's employment with us will terminate effective March 22, 2019.

(9) Shareholdings include 190,290 shares of common stock issuable upon exercise of options exercisable within 60 days of March 1, 2019. Mr. Lieber resigned as the Company's Chief Financial Officer effective December 21, 2018. Mr. Lieber was appointed as the Company's interim chief financial officer pursuant to a consulting agreement between the Company and Danforth Advisors, LLC (Danforth) on December 21, 2018.

(10) Includes 1,398,891 shares of common stock issuable upon exercise of options exercisable within 60 days of March 1, 2019 and the shareholdings attributable to Messrs. Lewis and Rakin in footnotes 4 and 5 above, respectively.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

In addition to the compensation arrangements with directors and executive officers described elsewhere in this Annual Report on Form 10-K, the following is a description of transactions since January 1, 2016 to which we have been a party, in which the amount involved exceeded or will exceed the lesser of $120,000 or one percent of the average of our total assets at year-end for the last two years, and in which any of our directors, executive officers or beneficial owners of more than five percent of our convertible preferred stock or common stock, or an affiliate or immediate family member thereof, had or will have a direct or indirect material interest, other than compensation, termination and change-in-control arrangements.

All of the transactions set forth below were approved by a majority of the Board, including a majority of the independent and disinterested members of the Board. We believe that we have executed all of the transactions set forth below on terms no less favorable to us than we could have obtained from unaffiliated third parties. It is our intention to ensure that all future transactions between us and our officers, directors and principal stockholders and their affiliates are approved by the Audit Committee and a majority of the members of the Board, including a majority of the independent and disinterested members of the Board, and are on terms no less favorable to us than those that we could obtain from unaffiliated third parties.

February 2019 Repricing and Exercise of Warrants

As described below, as part of the 2016 Private Placement (as defined below), we sold and issued warrants to purchase up to 13,333,334 shares of the Company's Common Stock (such warrants, along with warrants to purchase up to 133,333 shares of the Company's Common Stock issued to the placement agent for the transaction, the 2016 Warrants). The exercise price of the 2016 Warrants was $2.25 per share. Also as described below, as part of the October 2018 Offering (as defined below), we sold and issued warrants (the 2018 Warrants) to purchase up to 19,616,250 shares of the Company's Common Stock. The exercise price of the 2018 Warrants was $0.70 per share, subject to the Company's right pursuant to Section 2(e) of the 2018 Warrants to reduce the exercise price to any amount and for any period of time deemed appropriate by Board (the Voluntary Adjustment Right).

On February 8, 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 and provided a general release of claims of such Participating 2016 Holders against us with respect to the 2016 Warrants. We also agreed to modify the reference to "three (3) Trading Days" in the first sentence of Section 2(d)(i) of the 2016 Warrants held by the Participating 2016 Holders to say "two (2) Trading Days." The Participating 2016 Holders own, in the aggregate, 2016 Warrants to purchase a total of 12,957,953 shares of our Common Stock. After the full exercise of the 2016 Warrants held by the Participating 2016 Holders, 2016 Warrants to purchase approximately 508,714 shares of the Company's Common Stock remain outstanding.

On February 8, 2019, pursuant to the Voluntary Adjustment Right, we determined to reduce the exercise price of the 2018 Warrants from $0.70 to $0.01 per share (the 2018 Reduced Exercise Price) through the close of business on February 8, 2019. Additionally, on February 8, 2019, we and all of the holders of the 2018 Warrants (the Participating 2018 Holders and, together with the Participating 2016 Holders, the Holders) entered into a Warrant Exercise Agreement (the 2018 Exercise Agreement) pursuant to which in consideration for the 2018 Reduced Exercise Price, the Participating 2018 Holders agreed to exercise the 2018 Warrants held by such Participating 2018 Holders in full at the 2018 Reduced Exercise Price for cash and provided a general release of claims of such Participating 2018 Holders against us with respect to the 2018 Warrants. The Participating 2018 Holders own, in the aggregate, 2018 Warrants to purchase a total of 19,616,250 shares of the Company's Common Stock. After the full exercise of the 2018 Warrants held by the Participating 2018 Holders, no 2018 Warrants remain outstanding.

Wilmslow, which is a greater than 5% holder of our common stock and an affiliate of Michael Lewis, a member of the Board, exercised their outstanding 2016 Warrants and 2018 Warrants pursuant to a 2016 Exercise Agreement and 2018 Exercise Agreement, respectively. Kevin Rakin, a member of the Board, and certain of his affiliated trusts, exercised their outstanding 2016 Warrants and 2018 Warrants pursuant to a 2016 Exercise Agreement and 2018 Exercise Agreement, respectively.

October 2018 Public Offering

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

Wilmslow, which is a greater than 5% holder of our common stock and an affiliate of Michael Lewis, a member of the Board, purchased Securities in the October 2018 Offering. Kevin Rakin, a member of the Board, purchased Securities in the October 2018 Offering.

2016 Private Placement

In September 2016, we entered into a securities purchase agreement with certain institutional and accredited investors (the Securities Purchase Agreement) for the sale and issuance of 2,596,059 shares of our Common Stock (the Common Shares) and 24,158.8693 shares of our Series A Convertible Preferred Stock (the Preferred Shares), which Preferred Shares are convertible into an aggregate of 10,737,275 shares of our Common Stock, for total consideration of approximately $30,000,000 (the 2016 Private Placement). H.C. Wainwright & Co., LLC (HCW) served as the sole placement agent for the 2016 Private Placement. As part of the 2016 Private Placement, we provided each purchaser 100% warrant coverage based on an as-converted number of shares of our Common Stock issued and issuable upon conversion of the Preferred Shares plus the Common Shares and accordingly issued the investors warrants (the Purchaser Warrants) to purchase 13,333,334 shares of our Common Stock at an exercise price of $2.25 per share and exercisable for a period of five years following receipt of the stockholder approval required under the Securities Purchase Agreement. We also issued HCW a warrant (the HCW Warrant and, together with the Purchaser Warrants, the Common Stock Warrants) for the purchase of 133,333 shares of Common Stock at an exercise price of $2.25 per share and exercisable for a period of five years following receipt of the stockholder approval required under the Securities Purchase Agreement pursuant to the terms of our letter agreement with HCW.

The certificate of designation filed with the Secretary of State of the State of Delaware describing the rights, preference and privileges of the Series A Convertible Preferred Stock provides that, until stockholder approval was obtained, holders could not convert the Preferred Shares if such conversion would result in the purchasers under the Securities Purchase Agreement owning in the aggregate an amount of Common Stock issued in connection with the 2016 Private Placement in excess of 19.99% the number of shares of Common Stock outstanding immediately prior to the closing of the 2016 Private Placement. The Common Stock Warrants provide that until stockholder approval was obtained, holders could not exercise the Common Stock Warrants. We obtained stockholder approval of the 2016 Private Placement on November 22, 2016.

Wilmslow, which is a greater than 10% holder of our Common Stock and an affiliate of Michael Lewis, a member of the Board, purchased Common Shares, the Preferred Shares and the Common Stock Warrants in the 2016 Private Placement. The Rakin Trusts, which are each affiliates of Kevin Rakin, a member of the Board, purchased Common Shares, the Preferred Shares and the Common Stock Warrants in the 2016 Private Placement. Split Rock Partners II, LP, which is a greater than 10% holder of our Common Stock, purchased Common Shares, the Preferred Shares and the Common Stock Warrants in the 2016 Private Placement.

Former Intrexon Collaboration Agreement and Obligations

In September 2014, we entered into our ECC with Intrexon governing a “channel collaboration” arrangement. Pursuant to the ECC, we are responsible for the research and development costs incurred by Intrexon associated with the development of product candidates developed under our collaboration, the effect of which may increase the level of our overall research and development expenses. In December 2018, we and Intrexon entered into a mutual termination and release agreement (the “Mutual Termination Agreement”) pursuant to which we and Intrexon mutually agreed to terminate the ECC. Pursuant to the ECC, we were responsible for the research and development costs incurred by Intrexon associated with the development of product candidates under the ECC. As of September 30, 2018, we had accrued approximately $3.0 million of research and development expenses under the ECC (the Accrued Expenses). In connection with the Mutual Termination Agreement, in lieu of payment of the Accrued Expenses, we agreed and paid to Intrexon an aggregate of up to $1.5 million, with $0.375 million paid at the time of entering into the Mutual Termination Agreement and $1.125 million payable within one year following our submission of a BLA to the FDA for NeoCart.... We adjusted the accrued expenses to reflect a $1.125 million balance as of December 31, 2018 and the related gain on extinguishment of liability of $1.5 million.

Investors' Rights Agreement

On December 18, 2013, we entered into a second amended and restated investors' rights agreement (Investors' Rights Agreement) with the purchasers of our then-outstanding Preferred Stock (which was converted to common stock in connection with our initial public offering), including certain of our existing stockholders who were represented at the time by members of the Board, including Wilmslow, Sofinnova Venture Partners VIII, L.P. and Split Rock Partners II, LP. Under the Investors' Rights Agreement, we granted information and inspection rights which terminated upon the closing of our initial public offering. In addition, the holders of 4,479,418 shares of our common stock as of March 1, 2019, who are parties to the Investors' Rights Agreement, are provided rights to demand registration of shares of common stock and to participate in a registration of our common stock that we may decide to do, from time to time. These registration rights survived our initial public offering and may be exercised until their termination on December 3, 2019, unless earlier exercised. Certain of the shares subject to the Investors' Rights Agreement are held by affiliates of certain of our directors and by holders of five percent of our capital stock.

Indemnification Agreements

We have entered, or will enter, into indemnification agreements with our directors, executive officers and certain key employees. Under these agreements, we agree to indemnify our directors, executive officers and certain key employees against any and all expenses incurred by them in connection with proceedings because of their status as one of our directors, executive officers or key employees to the fullest extent permitted by Delaware law, subject to certain limitations. In addition, these indemnification agreements provide that, to the fullest extent permitted by Delaware law, we will pay for all expenses incurred by our directors, executive officers and certain key employees in connection with a legal proceeding arising out of their service to us.

In addition, as permitted by Section 145 of the Delaware General Corporation Law, our amended and restated bylaws provide that we are authorized to enter into indemnification agreements with our directors and executive officers and we are authorized to purchase directors' and officers' liability insurance, which we currently maintain to cover our directors and executive officers.

Policies and Procedures for Related Party Transactions

In November 2013, we adopted a related party transaction policy under which our directors, executive officers and any person who is known to be the beneficial owner of more than 5% of any class of our voting securities, including their immediate family members and affiliates, are not permitted to enter into a related party transaction with us without the prior consent of our Audit Committee or another independent committee of the Board where it is inappropriate for our Audit Committee to review such transaction due to a conflict of interest. Any request for us to enter into a transaction with an executive officer, director, or any of such persons' immediate family members or affiliates, in which the amount involved exceeds $120,000 must first be presented to our Audit Committee for review, consideration and approval. All of our directors and executive officers are required to report to our Audit Committee any such related party transaction. In approving or rejecting the proposed agreement, our Audit Committee shall consider the relevant facts and circumstances available and deemed relevant to the Audit Committee, including costs, and benefits to us, the terms of the transaction, the availability of other sources for comparable services or products and, if applicable, the impact on a director's independence. Our Audit Committee shall approve only those agreements that, in light of known circumstances, are not inconsistent with our best interests, as our Audit Committee determines in the good faith exercise of its discretion.

Stock Options

For information regarding stock options granted to our named executive officers and directors, see "*Corporate Governance – 2018 Director Compensation*" and "*Compensation of Executive Officers*."

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

Independent Registered Public Accounting Firm's Fees

The following table represents aggregate fees billed to Histogenics for the years ended December 31, 2018 and December 31, 2017, by Grant Thornton, our principal accountant.

	Year ended December 31,	
	2018	2017
Audit fees(1)	$ 420,548	$ 354,524
Audit-related fees	—	—
Tax fees	—	—
All other fees		4,900
Total fees	$ 420,548	$ 359,424

(1) The fees billed or incurred by Grant Thornton for professional services rendered in connection with the annual audit and quarterly review of our consolidated financial statements for the years ended December 31, 2018 and 2017, the consents issued for our registration statements, the statements included in our filings with the SEC regarding registered direct and public common stock and warrant offerings in 2018 and the use of Grant Thornton's online research tool.

All fees described above were pre-approved by the Audit Committee in accordance with applicable SEC requirements.

Pre-Approval Policies and Procedures

The Audit Committee's policy is to pre-approve all audit and permissible non-audit services rendered by Grant Thornton, our independent registered public accounting firm. The Audit Committee can pre-approve specified services in defined categories of audit services, audit-related services and tax services up to specified amounts, as part of the Audit Committee's approval of the scope of the engagement of Grant Thornton or on an individual case-by-case basis before Grant Thornton is engaged to provide a service. The Audit Committee has determined that the rendering of tax-related services by Grant Thornton is compatible with maintaining the principal accountant's independence for audit purposes. Grant Thornton has not been engaged to perform any non-audit services.

PART IV

ITEM 15. ***EXHIBITS AND FINANCIAL STATEMENTS SCHEDULES***

(a) The following documents are filed as part of, or incorporated by reference into, this annual report on Form 10-K:

1. *Financial Statements*. See Index to Consolidated Financial Statements under Item 8 of this annual report on Form 10-K.
2. *Financial Statement Schedules*. All schedules have been omitted because the information required to be presented in them is not applicable or is shown in the consolidated financial statements or related notes.
3. *Exhibits*. We have filed, or incorporated into this annual report on Form 10-K by reference, the exhibits listed on the accompanying Exhibit Index immediately following the consolidated financial statements of this annual report on Form 10-K.

(b) *Exhibits*. The following exhibits are filed as part of this annual report on Form 10-K or are incorporated herein by reference:

EXHIBIT INDEX

Exhibit	Description
3.1	Sixth Amended and Restated Certificate of Incorporation (filed as Exhibit 3.1 to the Company'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 3.4 to the Company's Registration Statement on Form S-1 (SEC File No. 333-199202), as filed on October 7,2014, and incorporated herein by reference)
3.3	Certificate of Designation of Preferences, Rights and Limitations of Series A Convertible Preferred Stock of Histogenics Corporation (filed as Exhibit 3.3 to the Company's Current Report on Form 8-K as filed on September 16, 2016, and incorporated herein by reference)
4.1	Specimen stock certificate evidencing the shares of common stock (filed as Exhibit 4.1 to Amendment No. 3 to the Company's Registration Statement on Form S-1 (SEC File No. 333-199202), as filed on November 26, 2014, and incorporated herein by reference)
4.2	Second Amended and Restated Investors' Rights Agreement dated as of December 18, 2013 (filed as Exhibit 4.2 to the Company's Registration Statement on Form S-1 (SEC File No. 333-199202), as filed on October 7, 2014, and incorporated herein by reference)
4.3	Second Amended and Restated Stockholders' Agreement dated as of December 18, 2013 (filed as Exhibit 4.3 to the Company's Registration Statement on Form S-1 (SEC File No. 333-199202), as filed on October 7, 2014, and incorporated herein by reference)
4.4	Warrant to Purchase Common Stock dated July 9, 2014 issued to Silicon Valley Bank (filed as Exhibit 4.4 to the Company's Registration Statement on Form S-1 (SEC File No. 333-199202), as filed on October 7, 2014, and incorporated herein by reference)
4.5	Amended and Restated Royalty Agreement dated as of October 14, 2014 (filed as Exhibit 4.5 to Amendment No. 1 to the Company's Registration Statement on Form S-1 (SEC File No. 333-199202), as filed on November 7, 2014, and incorporated herein by reference)
4.6	Registration Rights Agreement dated September 29, 2016 (filed as Exhibit 10.35 to the Company's Current Report on Form 8-K as filed on September 29, 2016, and incorporated herein by reference)
4.7	Form of Warrant to Purchase Common Stock (filed as Exhibit 4.6 to the Company's Current Report on Form 8-K as filed on September 29, 2016, and incorporated herein by reference)
4.8	Warrant to Purchase Common Stock of Histogenics Corporation issued to H.C. Wainwright & Co., LLC dated September 29, 2016 (filed as Exhibit 4.7 to the Company's Current Report on Form 8-K as filed on September 29, 2016, and incorporated herein by reference)
10.1	Form of Indemnity Agreement for directors and officers (filed as Exhibit 10.1 to the Company's Registration Statement on Form S-1 (SEC File No. 333-199202), as filed on October 7, 2014, and incorporated herein by reference)

Exhibit	Description
10.2+	2012 Equity Incentive Plan, as amended, and form of option agreement thereunder (filed as Exhibit 10.6 to the Company's Registration Statement on Form S-1 (SEC File No. 333-199202), as filed on October 7, 2014, and incorporated herein by reference)
10.3+	2013 Equity Incentive Plan (filed as Exhibit 10.3 to the Company's Current Report on Form 8-K as filed on May 4, 2016, and incorporated herein by reference)
10.3A+	Amendment No. 1 to 2013 Equity Incentive Plan (filed as Exhibit 10.3A to the Company's Registration Statement on Form S-8 (SEC File No. 333-212358), as filed on June 30, 2016, and incorporated herein by reference)
10.4+	2013 Employee Stock Purchase Plan (filed as Exhibit 10.4 to the Company's Current Report on Form 8-K as filed on May 4, 2016, and incorporated herein by reference)
10.5†	License Agreement dated as of May 12, 2005 among the Company and Angiotech Pharmaceuticals (US), Inc. and Angiodevice International GmbH (filed as Exhibit 10.10 to the Company's Registration Statement on Form S-1 (SEC File No. 333-199202), as filed on October 7, 2014, and incorporated herein by reference)
10.6†	Amendment to License Agreement dated as of August 31, 2007 among the Company and Angiotech Pharmaceuticals (US), Inc. and Angiodevice International GmbH (filed as Exhibit 10.11 to the Company's Registration Statement on Form S-1 (SEC File No. 333-199202), as filed on October 7, 2014, and incorporated herein by reference)
10.7†	Second Amendment to License Agreement dated as of January 1, 2008 among the Company and Angiotech Pharmaceuticals (US), Inc. and Angiodevice International GmbH (filed as Exhibit 10.12 to the Company's Registration Statement on Form S-1 (SEC File No. 333-199202), as filed on October 7, 2014, and incorporated herein by reference)
10.8†	Third Amendment to License Agreement dated as of April 15, 2008 among the Company and Angiotech Pharmaceuticals (US), Inc. and Angiodevice International GmbH (filed as Exhibit 10.13 to the Company's Registration Statement on Form S-1 (SEC File No. 333-199202), as filed on October 7, 2014, and incorporated herein by reference)
10.9†	Fourth Amendment to License Agreement dated as of November 1, 2008 among the Company and Angiotech Pharmaceuticals (US), Inc. and Angiodevice International GmbH (filed as Exhibit 10.14 to the Company's Registration Statement on Form S-1 (SEC File No. 333-199202), as filed on October 7, 2014, and incorporated herein by reference)
10.10†	Fifth Amendment to License Agreement dated as of August 6, 2010 among the Company and Angiotech Pharmaceuticals (US), Inc. and Angiodevice International GmbH (filed as Exhibit 10.15 to the Company's Registration Statement on Form S-1 (SEC File No. 333-199202), as filed on October 7, 2014, and incorporated herein by reference)
10.11†	Reinstatement Agreement and Sixth Amendment to License Agreement dated as of February 8, 2011 among the Company and Angiotech Pharmaceuticals (US), Inc. and Angiodevice International GmbH (filed as Exhibit 10.16 to the Company's Registration Statement on Form S-1 (SEC File No. 333-199202), as filed on October 7, 2014, and incorporated herein by reference)
10.12†	Seventh Amendment to License Agreement dated as of March 31, 2011 among the Company and Angiotech Pharmaceuticals (US), Inc. and Angiodevice International GmbH (filed as Exhibit 10.17 to the Company's Registration Statement on Form S-1 (SEC File No. 333-199202), as filed on October 7, 2014, and incorporated herein by reference)
10.13†	Eighth Amendment to License Agreement dated as of June 29, 2012 among the Company and Angiotech Pharmaceuticals (US), Inc. and Angiodevice International GmbH (filed as Exhibit 10.18 to the Company's Registration Statement on Form S-1 (SEC File No. 333-199202), as filed on October 7, 2014, and incorporated herein by reference)
10.14†	Paid-up License Agreement dated as of March 6, 2013 between the Company and Koken Co., Ltd. (filed as Exhibit 10.19 to the Company's Registration Statement on Form S-1 (SEC File No. 333-199202), as filed on October 7, 2014, and incorporated herein by reference)

Exhibit	Description
10.15†	Agreement dated as of June 22, 2012 between the Company and Purpose Co., Ltd. f/k/a Takagi Sangyo Co. Ltd. and f/k/a Takagi Industrial Co., Ltd. (filed as Exhibit 10.20 to the Company's Registration Statement on Form S-1 (SEC File No. 333-199202), as filed on October 7, 2014, and incorporated herein by reference)
10.16†	Exclusive Agreement dated as of April 15, 2001 between the Company and The Board of Trustees of The Leland Stanford Junior University (filed as Exhibit 10.21 to the Company's Registration Statement on Form S-1 (SEC File No. 333-199202), as filed on October 7, 2014, and incorporated herein by reference)
10.17	First Amendment to Exclusive Agreement dated as of October 26, 2005 between the Company and The Board of Trustees of The Leland Stanford Junior University (filed as Exhibit 10.22 to the Company's Registration Statement on Form S-1 (SEC File No. 333-199202), as filed on October 7, 2014, and incorporated herein by reference)
10.18†	Second Amendment to Exclusive Agreement dated as of January 15, 2006 between the Company and The Board of Trustees of The Leland Stanford Junior University (filed as Exhibit 10.23 to the Company's Registration Statement on Form S-1 (SEC File No. 333-199202), as filed on October 7, 2014, and incorporated herein by reference)
10.19†	Amendment No. 3 to the License Agreement Effective 4/15/2001 dated as of May 1, 2009 between the Company and The Board of Trustees of The Leland Stanford Junior University (filed as Exhibit 10.24 to the Company's Registration Statement on Form S-1 (SEC File No. 333-199202), as filed on October 7, 2014, and incorporated herein by reference)
10.20	Amendment No. 4 to the License Agreement Effective 4/15/2001 dated as of April 29, 2010 between the Company and The Board of Trustees of The Leland Stanford Junior University (filed as Exhibit 10.25 to the Company's Registration Statement on Form S-1 (SEC File No. 333-199202), as filed on October 7, 2014, and incorporated herein by reference)
10.21	Lease Agreement dated of June 9, 2006 between the Company and Intercontinental Fund III 830 Winter Street LLC (filed as Exhibit 10.28 to the Company's Registration Statement on Form S-1 (SEC File No. 333-199202), as filed on October 7, 2014, and incorporated herein by reference)
10.22	First Amendment to Lease dated as of October 1, 2009 between the Company and Intercontinental Fund III 830 Winter Street LLC (filed as Exhibit 10.29 to the Company's Registration Statement on Form S-1 (SEC File No. 333-199202), as filed on October 7, 2014, and incorporated herein by reference)
10.23†	Collagen Technology Transfer Agreement dated as of April 15, 2014 between the Company and Advanced BioMatrix, Inc. (filed as Exhibit 10.31 to the Company's Registration Statement on Form S-1 (SEC File No. 333-199202), as filed on October 7, 2014, and incorporated herein by reference)
10.24+	Employment Agreement dated April 26, 2014 between the Company and Adam Gridley (filed as Exhibit 10.32 to the Company's Registration Statement on Form S-1 (SEC File No. 333-199202), as filed on October 7, 2014, and incorporated herein by reference)
10.25	Lease Agreement dated as of June 2, 2014 between the Company and ARE-60 Westview, LLC (filed as Exhibit 10.33 to the Company's Registration Statement on Form S-1 (SEC File No. 333-199202), as filed on October 7, 2014, and incorporated herein by reference)
10.26†	Exclusive Channel Collaboration Agreement dated as of September 30, 2014 between the Company and Intrexon Corporation (filed as Exhibit 10.35 to the Company's Registration Statement on Form S-1 (SEC File No. 333-199202), as filed on October 7, 2014, and incorporated herein by reference)
10.27+	Amended and Restated Employment Agreement by and between Histogenics Corporation and Stephen Kennedy dated October 10, 2017 (filed as Exhibit 10.39 to the Company's Current Report on Form 8-K as filed on October 12, 2017, and incorporated herein by reference)
10.28†	First Amendment to License Agreement, dated May 9, 2016, between the Company and Purpose Co., Ltd., f/k/a Takagi Sangyo Co. Ltd. (filed as Exhibit 10.33 to the Company's Quarterly Report on Form 10-Q as filed on August 11, 2016, and incorporated herein by reference)

Exhibit	Description
10.29	Second Amendment to Lease dated as of April 28, 2017 between the Company and CRP/KING 830 Winter, L.L.C. (filed as Exhibit 10.33 to the Company's Quarterly Report on Form 10-Q as filed on August 10, 2017, and incorporated herein by reference)
10.30‡	License and Commercialization Agreement dated as of December 21, 2017 between the Company and MEDINET Co., Ltd. (filed as Exhibit 10.33 to the Company's Annual Report on Form 10-K as filed on March 15, 2018, and incorporated herein by reference)
10.31+	Consulting Agreement, effective December 21, 2018, between the Company and Danforth Advisors, LLC (filed as Exhibit 10.2 to the Company's Current Report on Form 8-K as filed on December 21, 2018, and incorporated herein by reference)
21.1	List of Subsidiaries (filed as Exhibit 21.1 to the Company's Annual Report on Form 10-K as filed on March 27, 2015, and incorporated herein by reference)
23.1*	Consent of Grant Thornton LLP, independent registered public accounting firm
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

+ Indicates management contract or compensatory plan.
† Confidential treatment has been granted with respect to certain portions of this document.

* Filed herewith.

(c) *Financial Statement Schedules*. See Item 15(a)(2) above.

ITEM 16. ***FORM 10-K SUMMARY***

Not applicable.

Signatures

Pursuant to the requirements of Section 13 and 15(d) of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this annual report on Form 10-K to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Waltham, Commonwealth of Massachusetts, on March 21, 2019.

HISTOGENICS CORPORATION

By: /s/ Adam Gridley
Adam Gridley,
President and Chief Executive Officer

Pursuant to the requirements of the Securities Act of 1934, this annual report on Form 10-K has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Adam Gridley **Adam Gridley**	Chief Executive Officer, President and Director (Principal Executive Officer)	March 21, 2019
/s/ Jonathan Lieber **Jonathan Lieber**	Interim Chief Financial Officer (Principal Financial and Accounting Officer)	March 21, 2019
/s/ Joshua Baltzell **Joshua Baltzell**	Chairman of the Board of Directors	March 21, 2019
/s/ David Gill **David Gill**	Director	March 21, 2019
/s/ Michael Lewis **Michael Lewis**	Director	March 21, 2019
/s/ Kevin Rakin **Kevin Rakin**	Director	March 21, 2019
/s/ Susan Washer **Susan Washer**	Director	March 21, 2019

Histogenics Corporation

Index to the Consolidated Financial Statements

Report of Independent Registered Public Accounting Firm

Board of Directors and Shareholders
Histogenics Corporation

Opinion on the financial statements

We have audited the accompanying consolidated balance sheets of Histogenics Corporation (a Delaware corporation) and subsidiaries (the "Company") as of December 31, 2018 and 2017, the related consolidated statements of operations, convertible preferred stock and stockholders' equity (deficit), and cash flows for each of the two years in the period ended December 31, 2018, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2018 and 2017, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2018, in conformity with accounting principles generally accepted in the United States of America.

Going concern

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company has incurred net losses from inception, including a net loss of approximately $8.6 million during the year ended December 31, 2018, and as of that date, its total liabilities exceeded its total assets by approximately $458,000. These conditions, along with other matters as set forth in Note 1, raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.
We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.
Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ GRANT THORNTON LLP

We have served as the Company's auditor since 2012

Hartford, Connecticut
March 21, 2019

Histogenics Corporation

Consolidated Balance Sheets
(In thousands, except share and per share data)

	December 31, 2018	December 31, 2017
ASSETS		
Current assets:		
Cash and cash equivalents	$ 15,542	$ 7,081
Marketable securities	—	900
Prepaid expenses and other current assets	858	194
Total current assets	16,400	8,175
Property and equipment, net	141	2,723
Other assets	750	—
Restricted cash	137	137
Total assets	$ 17,428	$ 11,035
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable	$ 1,590	$ 776
Accrued expenses	1,000	2,705
Current portion of deferred rent	45	35
Current portion of deferred lease incentive	238	111
Current portion of equipment loan	—	178
Total current liabilities	2,873	3,805
Accrued expenses due to Intrexon Corporation	1,125	3,040
Deferred revenue	10,000	—
Deferred rent	351	280
Deferred lease incentive	1,025	499
Warrant liability	2,512	14,679
Total liabilities	17,886	22,303
Commitments and contingencies (Note 7)		
Convertible preferred stock and stockholders' equity (deficit):		
Convertible preferred stock, $0.01 par value; 30,000 shares authorized, 400.4910 and 4,605.6533 shares issued and outstanding at December 31, 2018 and 2017, respectively	—	—
Common stock, $0.01 par value; 100,000,000 shares authorized, 62,025,398 and 24,571,029 shares issued and outstanding at December 31, 2018 and 2017, respectively	513	159
Additional paid-in capital	215,859	196,760
Accumulated deficit	(216,830)	(208,187)
Total stockholders' equity (deficit)	(458)	(11,268)
Total liabilities and stockholders' equity (deficit)	$ 17,428	$ 11,035

The accompanying notes are an integral part of these consolidated financial statements.

Histogenics Corporation

Consolidated Statements of Operations
(In thousands, except share and per share data)

	Year Ended December 31,	
	2018	2017
Revenue	$ —	$ —
Operating expenses:		
Research and development	15,634	15,566
General and administrative	10,204	9,384
Loss due to asset impairment	4,270	—
Total operating expenses	30,108	24,950
Loss from operations	(30,108)	(24,950)
Other income (expense):		
Interest income (expense), net	163	134
Other income (expense), net	(106)	(116)
Gain due to extinguishment of liability	1,540	—
Warrant expense	(733)	—
Change in fair value of warrant liability	20,601	(1,482)
Total other income (expense), net	21,465	(1,464)
Net loss	$ (8,643)	$ (26,414)
Loss attributable to common stockholders—basic	$ (8,522)	$ (22,499)
Loss attributable to common stockholders—diluted	$ (29,123)	$ (22,499)
Loss per common share—basic	$ (0.23)	$ (0.99)
Loss per common share—diluted	$ (0.79)	$ (0.99)
Weighted-average shares used to compute loss per common share—basic	36,398,450	22,669,819
Weighted-average shares used to compute loss per common share—diluted	37,090,197	22,669,819

The accompanying notes are an integral part of these consolidated financial statements.

Histogenics Corporation

Consolidated Statements of Convertible Preferred Stock and Stockholders' Equity (Deficit)
(In thousands, except share and per share data)

	Series A Convertible Preferred Stock $0.01 Par Value		Common Stock $0.01 Par Value		Restricted Stock $0.01 Par Value		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders Equity (Deficit)
	Shares	Amount	Shares	Amount	Shares	Amount			
Balance at December 31, 2016	13,416	$ -	20,645,723	$ 159	1,889	$ -	$195,181	$ (181,773)	$ 13,567
Stock-based compensation expense	-	-	-	-	-	-	1,573	-	1,573
Exercise of common stock options	-	-	7,497	-	-	-	6	-	6
Vesting of restricted stock	-	-	1,889	-	(1,889)	-	-	-	-
Conversion of Series A convertible preferred stock	(8,811)	-	3,915,920	-	-	-	-	-	-
Net loss	-	-	-	-	-	-	-	(26,414)	(26,414)
Balance at December 31, 2017	4,605	$ -	24,571,029	$ 159	-	$ -	$196,760	$ (208,187)	$ (11,268)
Stock-based compensation expense	-	-	-	-	-	-	1,625	-	1,625
Exercise of common stock options	-	-	919	-	-	-	2	-	2
Exercise of warrants	-	-	104,092	-	-	-	1	-	1
Issuance of common stock, net	-	-	35,480,397	354	-	-	17,471	-	17,825
Conversion of Series A convertible preferred stock	(4,205)	-	1,868,961	-	-	-	-	-	-
Net loss	-	-	-	-	-	-	-	(8,643)	(8,643)
Balance at December 31, 2018	400	$ -	62,025,398	$ 513	-	$ -	$215,859	$ (216,830)	$ (458)

The accompanying notes are an integral part of these consolidated financial statements.

Histogenics Corporation

Consolidated Statements of Cash Flows
(In thousands, except share and per share data)

	Year Ended December 31,	
	2018	2017
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (8,643)	$ (26,414)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	450	1,534
Amortization of discount of investments	—	54
Deferred revenue	10,000	—
Deferred rent and lease incentive	734	(543)
Stock-based compensation	1,625	1,573
Warrant expense	733	
Change in warrant liability	(20,601)	1,482
Loss due to asset impairment	4,270	—
Gain on extinguishment of liability due to Intrexon Corporation	(1,540)	—
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(664)	(21)
Other long term assets	(750)	—
Accounts payable	689	(849)
Accounts payable due to Intrexon Corporation	—	(360)
Accrued expenses due to Intrexon Corporation	(375)	—
Accrued expenses	(1,705)	524
Net cash used in operating activities	(15,777)	(23,020)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchases of property and equipment	(2,013)	(276)
Proceeds from maturities of marketable securities	900	7,050
Purchases of marketable securities	—	(8,004)
Net cash used in investing activities	(1,113)	(1,230)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of common stock, net of issuance costs	25,526	—
Repayments on equipment term loan	(178)	(583)
Proceeds from exercise of stock options and warrants	3	6
Net cash provided by (used in) financing activities	25,351	(577)
Net increase (decrease) in cash and cash equivalents	8,461	(24,827)
Cash and cash equivalents and restricted cash —Beginning of period	7,218	32,045
Cash and cash equivalents and restricted cash —End of period	$ 15,679	$ 7,218
Supplemental Disclosure of Non-Cash Items:		
Purchases of property and equipment in accounts payable	$ 125	$ —
Public offering costs in accounts payable	$ 99	$ —
Supplemental Disclosure of Cash Flow information:		
Cash paid for taxes	$ 105	$ 197
Cash paid for interest	$ 1	$ 30

The accompanying notes are an integral part of these consolidated financial statements.

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 addition, the Company initiated a process to evaluate strategic alternatives to maximize value for all of its stakeholders. The process is being conducted with the assistance of financial and legal advisors and is evaluating the full range of potential strategic alternatives, including but not limited to, acquisitions, business combinations, joint ventures, public and private capital raises and recapitalization and sale transaction options, including a sale of assets or intellectual property. Since these efforts may not be successful and given our limited cash reserves, we are also considering other possible alternatives, including a wind-down of operations, or Chapter 11 bankruptcy protection to complete or execute a restructuring transaction or liquidation.

On May 13, 2011, the Company completed the acquisition of ProChon Biotech Ltd. ("ProChon"), a privately-held biotechnology company focused on modulating the fibroblast growth factor system for consideration of $2.2 million to enable it to create more effective solutions for tissue regeneration. ProChon's products combine cell regeneration technologies with proprietary growth factors and biocompatible scaffolds to restore injured or chronically damaged tissues. The acquisition led to the initial recognition of goodwill, which was subsequently written off in 2011, and intangible assets including IPR&D and a licensing agreement which were fully impaired in 2016 as discussed in Note 2.

On September 29, 2016, the Company closed a private placement of common stock, preferred stock and warrants, contemplated by a securities purchase agreement dated September 15, 2016, with certain institutional and accredited investors. The net proceeds after deducting placement agent fees and other transaction-related expenses were $27.6 million. See Note 8, Capital Stock, for further discussion of the private placement.

In January 2018, the Company closed a registered direct offering where the Company issued 2,691,494 shares of common stock at a price of $2.35 per share. The underwriter option to purchase additional shares of 351,064 were fully exercised. The total net proceeds of the offering were approximately $5.9 million after deducting underwriting discounts and commissions.

In March 2018, the Company entered into an equity distribution agreement ("ATM Agreement") with Canaccord Genuity Inc. ("Canaccord"), pursuant to which the Company may, from time to time, sell shares of its common stock having an aggregate offering price of up to $10.0 million (the "Shares") through Canaccord, as sales agent. During the year ended December 31, 2018, the Company sold an aggregate of 6,633,903 shares of common stock and received $4.5 million after deducting commissions related to the ATM Agreement and other offering costs.

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

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

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

Liquidity

The consolidated financial statements have been prepared on a going-concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. As shown in the accompanying consolidated financial statements, the Company has incurred losses and cash flow deficits from operations since inception, resulting in an accumulated deficit at December 31, 2018 of $216.8 million. The Company has financed operations to date primarily through public and private placements of equity securities, and borrowings under debt agreements. The Company anticipates that it will continue to incur net losses for the foreseeable future. The Company believes that its existing cash, cash equivalents and marketable securities will only be sufficient to fund its projected cash needs into the middle of 2019. Accordingly, these factors, among others, raise substantial doubt about the Company's ability to continue as a going concern. To meet future capital needs, the Company would need to raise additional capital through debt or equity financing or other strategic transactions. However, any such financing may not be on favorable terms or available to the Company. The failure of the Company to obtain sufficient funds on commercially acceptable terms when needed will have a material adverse effect on the Company's business, results of operations and financial condition. The forecast of cash resources is forward-looking information that involves risks and uncertainties, and the actual amount of our expenses could vary materially and adversely as a result of a number of factors. The Company has based its estimates on assumptions that may prove to be wrong, and the Company's expenses could prove to be significantly higher than it currently anticipates.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Accounting

The consolidated financial statements are prepared in conformity with accounting principles generally accepted in the United States of America ("U.S. GAAP"). The consolidated financial statements include the accounts of Histogenics Corporation and its wholly-owned subsidiaries, ProChon and Histogenics Securities Corporation. All significant intercompany accounts and transactions are eliminated in consolidation.

Use of Estimates

The preparation of the Company's consolidated financial statements requires it to make estimates and assumptions that impact the reported amounts of assets, liabilities, revenues and expenses and the disclosure of contingent assets and liabilities in the Company's consolidated financial statements and accompanying notes. The most significant estimates in the Company's consolidated financial statements relate to the valuation of equity awards, warrant liability, recoverability of deferred tax assets, estimated useful lives of fixed assets. The Company bases estimates and assumptions on historical experience when available and on various factors that it believes to be reasonable under the circumstances. The Company evaluates its estimates and assumptions on an ongoing basis. The Company recorded in 2018 a loss on impairment of fixed assets. See Note 5 Property and Equipment. The Company's actual results may differ from these estimates under different assumptions or conditions.

Foreign Currency Translation

The Company's consolidated financial statements are prepared in U.S. dollars. The Company's foreign subsidiary uses the U.S. dollar as its functional and reporting currency, as management determined that the U.S. dollar is the primary currency of the economic environment in which the subsidiary operates. When transactions are required to be paid in the local currency of the foreign subsidiary, any resulting foreign currency transaction gain or loss is recorded as a component of "Other income (expense), net" in the consolidated statements of operations.

Segment and Geographic Information

Operating segments are defined as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision-maker ("CODM") or decision-making group in making decisions regarding resource allocation and assessing performance. The Company operates in two geographic regions: the United States (Massachusetts) and Israel (Tel Aviv) and views its operations as two operating segments: Histogenics Corporation (United States) and ProChon (Israel) as the CODM reviews separate discrete financial information in making decisions regarding resource allocations and assessing performance. Operating segments that have similar economic characteristics can be aggregated. As the nature of the products, customers, and methods to distribute products are the same and the nature of the regulatory environment, the production processes and historical and estimated future margins are similar, the two operating segments have been aggregated into one reporting segment as they have similar economic characteristics.

Fair Value Measurements

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

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

Fair value should be based on the assumptions that market participants would use when pricing an asset or liability and is based on a fair value hierarchy that prioritizes the information used to develop those assumptions. Fair value measurements should be disclosed separately by level within the fair value hierarchy. For assets and liabilities recorded at fair value, it is the Company's policy to maximize the use of observable inputs (quoted prices in active markets) and minimize the use of unobservable inputs (Company assumptions) when developing fair value measurements, in accordance with established fair value hierarchy.

Fair value measurements for assets and liabilities where there exists limited or no observable market data are based primarily upon estimates, and often are calculated based on the economic and competitive environment, the characteristics of the asset or liability and other factors. Therefore, the results cannot be determined with precision and may not be realized in an actual sale or immediate settlement of the asset or liability. Additionally, there may be inherent weaknesses in any valuation technique, and changes in the underlying assumptions used, including discount rates and estimates of future cash flows, could significantly affect the results of current or future values.

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

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

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

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

Level 3: Pricing inputs are unobservable for the assets, that is, inputs that reflect the reporting entity's own assumptions about the assumptions market participants would use in pricing the assets. Level 3 includes private investments that are supported by little or no market activity.

Level 3 valuations are for instruments that are not traded in active markets or are subject to transfer restrictions and may be adjusted to reflect illiquidity and/or non-transferability, with such adjustment generally based on available market evidence. In the absence of such evidence, management's best estimate is used.

An adjustment to the pricing method used within either Level 1 or Level 2 inputs could generate a fair value measurement that effectively falls in a lower level in the hierarchy. The Company had no assets or liabilities classified as Level 1 or Level 2 as of December 31, 2018 and 2017 other than the money market fund described in the "Cash and Cash Equivalents" section and the asset-backed securities in the "Marketable securities" section below. There were no material re-measurements of fair value with respect to financial assets and liabilities, during the periods presented, other than those assets and liabilities that are measured at fair value on a recurring basis. The Company's only assets or liabilities classified as level 3 are the warrants issued in connection with the September 2016 private placement and the October 2018 underwritten public offering. There were no transfers between Levels 1, 2 and 3 during the twelve months ended December 31, 2018 and 2017.

The fair value of the warrants issued in connection with the September 2016 private placement was determined using a Monte Carlo simulation model. This model incorporated several assumptions at each valuation date including: the price of the Company's common stock on the date of valuation, the historical volatility of the price of the Company's common stock, the remaining contractual term of the warrant and estimates of the probability of a fundamental transaction occurring. The fair value of the warrants issued in connection with the October 2018 underwritten public offering was determined using the Black Scholes model. See Note 8, Capital Stock, for further discussion of the private placement and underwritten public offering.

Description	Total	Quoted prices in active markets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
		(in thousands)		
December 31, 2018				
Assets:				
Cash Equivalents				
Money market funds	9,711	9,711	—	—
Liabilities:				
Warrant liability	2,512	—	—	2,512
December 31, 2017				
Assets:				
Cash Equivalents				
Money market funds	5,547	5,547	—	—
Marketable securities:				
Asset-backed securities	900	—	900	—
Liabilities:				
Warrant liability	14,679	—	—	14,679

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

	As of December 31, 2018
	(in thousands)
Beginning balance, January 1, 2018	$ 14,679
Issuance of warrants	8,434
Change in fair value of warrant liability	(20,601)
Ending balance	$ 2,512

Cash and Cash Equivalents

Cash and cash equivalents include cash in readily available checking and savings accounts and money market funds. The Company considers all highly liquid investments with an original maturity of three months or less from the date of purchase to be cash equivalents.

Marketable Securities

The Company classifies marketable securities with a remaining maturity when purchased of greater than three months as available for sale. The Company considers all available for sale securities, including those with maturity dates beyond 12 months, as available to support current operational liquidity needs and therefore classifies all securities including those with maturity dates beyond 90 days at the date of purchase as current assets within the consolidated balance sheets. Available for sale securities are maintained by the Company's investment managers and may consist of commercial paper, high-grade corporate notes, U.S. Treasury securities, U.S. government agency securities, and certificates of deposit. Available for sale securities are carried at fair value with the unrealized gains and losses included in other comprehensive income (loss) as a component of stockholders' equity (deficit) until realized. Any premium or discount arising at purchase is amortized and/or accreted to interest income and/or expense over the life of the instrument. Realized gains and losses are determined using the specific identification method and are included in other income (expense).

If any adjustment to fair value reflects a decline in value of the investment, the Company considers all available evidence to evaluate the extent to which the decline is "other-than-temporary" and, if so, marks the investment to market through a charge to the Company's consolidated statement of operations and comprehensive loss.

The Company did not hold any available for sale securities prior to the first quarter of 2017. The amortized cost of available for sale securities is adjusted for amortization of premiums and accretion of discounts to maturity. At December 31, 2018, the balance in the Company's accumulated other comprehensive loss was composed solely of activity related to the Company's available for sale marketable securities.

The aggregate fair value of available for sale securities held by the Company for less than twelve months as of December 31, 2017 was $0.9 million which matured in 2018. The Company did not hold any available for sale securities and there were no sales of such during the year ended December 31, 2018. The Company determined that there was no material change in the credit risk of any of its investments. As a result, the Company determined it did not hold any investments with any other-than-temporary impairment as of December 31, 2017. The weighted average maturity of the Company's portfolio was less than one month at December 31, 2017.

Concentration of Credit Risk

Financial instruments, which potentially subject the Company to significant concentration of credit risk, consist primarily of cash and cash equivalents. The Company maintains deposits in federally insured financial institutions in excess of federally insured limits. The Company has not experienced any losses in such accounts and management believes that the Company is not exposed to significant credit risk due to the financial position of the depository institutions in which those deposits are held. The Company has no financial instruments with off-balance sheet risk of loss.

Property and Equipment

Property and equipment are recorded at historical cost. Costs for capital assets not yet placed into service are capitalized as construction in progress, and are depreciated in accordance with the below guidelines once placed into service. Maintenance and repair costs are expensed as incurred. Costs which materially improve or extend the lives of existing assets are capitalized. The Company provides for depreciation and amortization using the straight-line method over the estimated useful lives of the assets, which are as follows:

Asset Category	Estimated Useful Lives
Office equipment	3 to 5 years
Laboratory equipment	3 to 5 years
Leasehold improvements	Shorter of the remaining lease term or useful life

Upon retirement or sale, the cost of assets disposed and the related accumulated depreciation are removed from the accounts and any resulting gain or loss is recorded in the consolidated statements of operations.

Impairment of Long-Lived Assets

Long-lived assets consist primarily of property and equipment and identifiable intangible assets. When impairment indicators exist, the Company's management evaluates long-lived assets for potential impairment. An impairment loss is recorded if and when events and circumstances indicate that assets might be impaired and the undiscounted cash flows estimated to be generated by those assets are less than the carrying amount of those assets. In 2018 a triggering event caused an impairment of the Company's property and equipment. The triggering event related to the Company's announcement that the NeoCart program was discontinued and the subsequent 73% reduction in stock price. An impairment loss of $4.3 million was recognized in earnings. See Note 5 Property and Equipment.

Restricted Cash

Restricted cash represents cash held in a depository account at a financial institution to collateralize a conditional stand-by letter of credit related to the Company's Lexington, Massachusetts facility lease agreement. Restricted cash is reported as non-current unless the restrictions are expected to be released in the next twelve months.

Deferred Rent

Deferred rent consists of the difference between cash payments and the recognition of rent expense on a straight-line basis for the facilities the Company occupies. The Company's leases for its Waltham, Massachusetts and Lexington, Massachusetts facilities provide for fixed increases in minimum annual rental payments. The total amount of rental payments due over each lease term is being charged to rent expense ratably over the life of each lease, respectively.

Financial Instruments Indexed to and Potentially Settled in the Company's Common Stock

The Company evaluates all financial instruments issued in connection with its equity offerings when determining the proper accounting treatment for such instruments in the Company's financial statements. The Company considers a number of generally accepted accounting principles under U.S. GAAP to determine such treatment and evaluates the features of the instrument to determine the appropriate accounting treatment. The Company utilizes the Probability Weighted Expected Return Method ("PWERM"), Option Pricing Model ("OM") or other appropriate methods to determine the fair value of its derivative financial instruments, such as the warrant liability. For financial instruments indexed to and potentially settled in the Company's common stock that are determined to be classified as liabilities on the consolidated balance sheet, changes in fair value are recorded as a gain or loss in the Company's consolidated statement of operations with the corresponding amount recorded as an adjustment to the liability on its consolidated balance sheet.

Revenue Recognition

In May 2014, the Financial Accounting Standards Board (the "FASB") issued a new standard related to revenue recognition, Accounting Standard Update ("ASU") No. 2014-09, Revenue from Contracts with Customers. This new

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

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

If the contract contains a single performance obligation, the entire transaction price is allocated to the single performance obligation. Contracts that contain multiple performance obligations require an allocation of the transaction price to each performance obligation based on a relative standalone selling price basis unless the transaction price is variable and meets the criteria to be allocated entirely to a performance obligation or to a distinct service that forms part of a single performance obligation. The Company's revenues are generated primarily through collaborative research, development and commercialization agreements. The terms of these agreements may contain multiple promises which may include: (i) licenses to the Company's technology; (ii) services related to the transfer and update of know-how; and (iii) manufacturing supply services. Payments to the Company under these arrangements typically include one or more of the following: non-refundable upfront license fees; milestone payments; royalties on future product sales; and fees for manufacturing supply services. None of the Company's contracts as of December 31, 2018 contained a significant financing component.

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

Collaboration Revenue

While no revenue has been recognized as of December 31, 2018, the Company has collaboration and license agreements with strategic partners for the development and commercialization of product candidates. The collaboration and license agreements are within the scope of Accounting Standards Codification (ASC 606) Revenue from Contracts with Customers.

In determining the appropriate amount of revenue to be recognized as it fulfills its obligations under the agreements, the Company performs the following steps: (i) identification of the promised goods or services in the contract; (ii) determination of whether the promised goods or services are performance obligations including whether they are distinct in the context of the contract; (iii) measurement of the transaction price, including the constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations; and (v) recognition of revenue when (or as) the Company satisfies each performance obligation. As part of the accounting for the arrangement, the Company must develop assumptions that require judgment to determine the stand-alone selling price for each performance obligation identified in the contract. The Company uses key assumptions to determine the stand-alone

selling price, which may include market conditions, reimbursement rates for personnel costs, development timelines and probabilities of regulatory success.

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

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

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

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

License and Collaboration Arrangements

MEDINET Co., Ltd.

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

In exchange for the license, MEDINET agreed to pay the Company an non-refundable upfront cash payment of $10.0 million which was received in January 2018. As of December 31, 2018, the contract with MEDINET was wholly unperformed. MEDINET also agreed to pay the Company tiered royalties, at percentages ranging from the

low single digits to low double digits, of net sales of MEDINET products governed by the License Agreement. The Company is eligible to receive up to ¥330 million ($3.0 million as of December 31, 2018) in development milestone payments, $1.0 million and ¥720 million ($6.5 million as of December 31, 2018) in regulatory payments and up to an aggregate of ¥7,100 million ($64.3 million as of December 31, 2018) for the achievement of certain commercial milestones related to the sales of MEDINET products governed by the License Agreement.

The Company assessed the promised goods and services to determine if they are distinct. Due to the unique nature of the clinical manufacturing services, there are no third-party vendors from which MEDINET can obtain such services from currently. The Company expects to be the only vendor capable of providing the commercial manufacturing services for a period of at least one to two years, which is approximately the estimated length of the clinical trial period in Japan. After this point, if the Company were to transfer to a third-party its technology and know-how related to the commercial manufacturing services that third-party vendor would be capable of providing the commercial manufacturing services, and therefore MEDINET would be able to choose whether to utilize the Company or another vendor for such services. The Company determined that the option to obtain to commercial manufacturing services does not represent a material right, as the fees charged to MEDINET by the Company are expected to approximate the fair market value for manufacturing services. As noted, with the assistance of the Company, third-party vendors could have the capability to perform such services by this time, and the Company expects the contract value to approximate the market price. Due to MEDINET's limitations in obtaining the clinical manufacturing services from a third-party, as well as MEDINET's limited ability to obtain the benefits of the licensed intellectual property without the clinical manufacturing services, the licensed intellectual property and clinical manufacturing services are determined to be a combined performance obligation. Based on this assessment, the Company determined that the promised goods and services do not have standalone value and are highly interrelated. Accordingly, the promised goods and services represent one performance obligation.

Based on the assessment of the combined performance obligation, the Company determined that the predominant promise in the arrangement is the transfer of the license and associated knowhow which are expected to occur over the length of the clinical trial. The Company determined that MEDINET will be simultaneously receiving and consuming the benefits of the Company's performance of the clinical trial. Therefore, the revenue associated with the combined performance obligation will be recognized over time.

In determining the correct measure of progress to use when recognizing revenue over time, the Company assessed whether an input or output based measure of progress would be appropriate. The Company determined that an output based measure of progress would be appropriate to use when recognizing revenue associated with the combined performance obligation. The Company will recognize revenue based on the clinical manufacturing services completed to date. At the outset of the clinical trial in Japan to be conducted by MEDINET, the Company will have quantifiable estimates of total clinical candidates, and therefore, of total estimated performance. The Company will recognize revenue based on performance completed to date, as evidenced by the estimated number of clinical trial enrollees. The Company expects to provide the clinical manufacturing services to MEDINET over an estimated period of two years. Therefore, the estimated two-year clinical manufacturing period is the appropriate timing of revenue recognition for the combined performance obligation. Revenue will be recognized using the output method, as the clinical manufacturing services are delivered, over the estimated two-year year proportional performance service period. Upon the conclusion of the clinical manufacturing period, the Company expects other third-party vendors to have the capabilities to provide similar services. At this point, the license would effectively become a distinct performance obligation, with no remaining undelivered obligations. Therefore, the Company determined that the up-front payment associated with the licensed intellectual property should be fully recognized by the conclusion of the clinical manufacturing service period. Upon conclusion of the clinical manufacturing service period, the Company will have no remaining performance obligations, and MEDINET will be able to obtain commercial manufacturing services from other vendors.

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

The upfront transaction price of $10.0 million will be recognized over a period of approximately two-years, commencing at the start of the clinical trial which, in management's judgement represents the Company's best estimate of the period of performance for satisfying the performance obligation of supply of clinical trial materials and transfer of license to MEDINET. Management has included $10.0 as non-current based on the feedback from the FDA and subsequent suspension of the NeoCart program. MEDINET relies on Company's NeoCart product to supply clinical trial patients. MEDINET has suspended development of its clinical trial. Management will reevaluate that estimate at each reporting period. Revenue is being recognized using the output method, as the clinical manufacturing services are delivered, over the estimated two year proportional performance clinical manufacturing period.

Transaction Price Allocated to Future Performance Obligations

Remaining performance obligations represents the transaction price of contracts for which work has not been performed (or has been partially performed) and excludes unexercised contract options. As of December 31, 2018, the aggregate amount of the transaction price allocated to the remaining performance obligations was $10.0 million. The contract with MEDINET is wholly unperformed, and the Company recognized no revenue associated with the agreement during the years ended December 31, 2018 and 2017, respectively.

Research and Development Costs

Research and development costs are charged to expense as incurred. These costs include, but are not limited to: license fees related to the acquisition of in-licensed products; employee-related expenses, including salaries, benefits and travel; expenses incurred under agreements with contract research organizations and investigative sites that conduct clinical trials and preclinical studies; the cost of acquiring, developing and manufacturing clinical trial materials; facilities, depreciation and other expenses, which include direct and allocated expenses for rent and maintenance of facilities; insurance and other supplies; and costs associated with preclinical activities and regulatory operations.

Costs for certain development activities, such as clinical trials, are recognized based on an evaluation of the progress to completion of specific tasks using data such as patient enrollment, clinical site activations, or information provided to the Company by its vendors with respect to their actual costs incurred. Payments for these activities are based on the terms of the individual arrangements, which may differ from the pattern of costs incurred, and are reflected in the consolidated financial statements as prepaid or accrued research and development expense.

Collaboration Arrangements

Costs reimbursed to a collaborator for work that it performs are recorded as research and development expenses. These reimbursements can include payments for work performed, or a milestone for which a payment is due, the reimbursements or development milestone achievement are recorded as research and development expense.

In September 2014, the Company entered into a collaboration agreement with Intrexon Corporation ("Intrexon") for the development and commercialization of allogeneic cell therapeutics for the treatment or repair of damaged articular hyaline cartilage in humans, utilizing Intrexon's proprietary technology (the "Collaboration Agreement"). Under the terms of the Collaboration Agreement, the Company is responsible for the costs of development and commercialization, with some exceptions. This agreement was terminated in December 2018. In connection with the Mutual Termination Agreement, in lieu of payment of the Accrued Expenses, the Company agreed to pay Intrexon an aggregate of up to $1.5 million, with $0.375 million paid at the time of entering into the Mutual Termination Agreement and $1.125 million payable within one year following any submission of a BLA to the FDA for NeoCart. We adjusted the accrued expenses to reflect $1.125 million balance as of December 31, 2018 and gain on extinguishment of liability of $1.5 million.

License Agreements

Costs associated with licenses of technology are expensed as incurred and are included in research and development expenses.

Patent Costs

Costs related to filing and pursuing patent applications are recorded as general and administrative expense as incurred since the recoverability of such expenditures is uncertain.

Stock-Based Compensation

The Company accounts for grants of stock options and restricted stock based on their grant date fair value and recognizes compensation expense over their vesting period. The Company estimates the fair value of stock options as of the date of grant using the Black-Scholes option pricing model and restricted stock based on the fair value of the underlying common stock as determined by management or the value of the services provided, whichever is more readily determinable.

Stock-based compensation expense represents the cost of the grant date fair value of employee stock option grants recognized over the requisite service period of the awards (usually the vesting period) on a straight-line basis, net of estimated forfeitures. The expense is adjusted for actual forfeitures at year end. Stock-based compensation expense recognized in the consolidated financial statements is based on awards that are ultimately expected to vest.

For stock option grants with performance-based milestones, the expense is recorded over the remaining service period after the point when the achievement of the milestone is probable or the performance condition has been achieved. For stock option grants with both performance-based milestones and market conditions, expense is recorded over the derived service period after the point when the achievement of the performance-based milestone is probable or the performance condition has been achieved. The Company did not issue performance-based awards in 2018 or 2017.

The Company accounts for stock options and restricted stock awards to non-employees using the fair value approach. Stock options and restricted stock awards to non-employees are subject to periodic revaluation over their vesting terms.

On October 1, 2018, the Compensation Committee of the Board of Directors approved a repricing (the "Repricing") of 3,807,779 stock options (the "Options") granted prior to September 1, 2018 pursuant to the 2013 Equity Incentive Plan and the 2012 Equity Incentive Plan to executive officers, employees and consultants of the Company. The Options had exercise prices between $0.75628 and $9.97 per share, which were reduced to $0.568 per share (the closing price of the Company's common stock on The Nasdaq Capital Market on October 1, 2018). The number of shares, vesting schedules and expiration period of the Options were not altered. The impact to the Company's financial statements in 2018 was immaterial.

Income Taxes

The Company accounts for income taxes under the liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements. Under this method, deferred tax assets and liabilities are determined on the basis of the differences between the financial statements and tax basis of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. The effect of a change in tax rates on deferred tax assets and liabilities is recognized in income in the period that includes the enactment date.

The Company recognizes net deferred tax assets to the extent that the Company believes these assets are more likely than not to be realized. In making such a determination, management considers all available positive and negative evidence, including future reversals of existing taxable temporary differences, projected future taxable income, tax-planning strategies, and results of recent operations. If management determines that the Company would be able to realize its deferred tax assets in the future, in excess of its net recorded amount, management would make an adjustment to the deferred tax asset valuation allowance, which would reduce the provision for income taxes.

The Company records uncertain tax positions on the basis of a two-step process whereby (1) management determines whether it is more likely than not that the tax positions will be sustained on the basis of the technical merits of the position and (2) for those tax positions that meet the more likely than not recognition threshold, management recognizes the largest amount of tax benefit that is more than 50 percent likely to be realized upon ultimate settlement with the related tax authority. The Company recognizes interest and penalties related to

unrecognized tax benefits within income tax expense. Any accrued interest and penalties are included within the related tax liability.

Loss per Common Share

Loss per common share is calculated using the two-class method, which is an earnings allocation formula that determines loss per share for the holders of the Company's common shares and participating securities. All series of preferred stock contain participation rights in any dividend paid by the Company and are deemed to be participating securities. Earnings available to common stockholders and participating convertible redeemable preferred shares are allocated to each share on an as-converted basis as if all of the earnings for the period had been distributed. The participating securities include a contractual obligation to share in losses of the Company and are included in the calculation of net loss per share in the periods that have a net loss.

Diluted earnings per share is computed using the more dilutive of (a) the two-class method, or (b) the if-converted method. The Company allocates earnings first to preferred stockholders based on dividend rights and then to common and preferred stockholders based on ownership interests. The weighted-average number of common shares included in the computation of diluted loss gives effect to all potentially dilutive common equivalent shares, including outstanding stock options, warrants, convertible redeemable preferred stock and the potential issuance of stock upon the conversion of the Company's convertible notes. Common stock equivalent shares are excluded from the computation of diluted loss per share if their effect is antidilutive.

Warrant Accounting

As noted in Note 9, the Company classifies warrants to purchase shares of its common stock as a liability on its consolidated balance sheet if the warrant is a free-standing financial instrument that may require the Company to transfer consideration upon exercise. Each warrant of this type is initially recorded at fair value on date of grant using a Monte Carlo simulation or Black Scholes model and net of issuance costs, and is subsequently re-measured to fair value at each subsequent balance sheet date. Changes in fair value of the warrants are recognized as a component of other income (expense), net in the consolidated statement of operations. The Company will continue to adjust the liability for changes in fair value until the earlier of the exercise or expiration of the warrants.

In the first quarter of 2019 the Company reduced the exercise price of all but 508,714 warrants issued in connection with the 2016 private placement and all of the warrants issued in connection with the October 2018 underwritten public offering. Refer to Note 15, *Subsequent Events* for further details on the amendments.

Recent Accounting Pronouncements

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

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

In August 2018, the SEC adopted the final rule under SEC Release No. 33-10532, Disclosure Update and Simplification. This final rule amends certain disclosure requirements that are redundant, duplicative, overlapping, outdated or superseded. In addition, the amendments expand the disclosure requirements on the analysis of stockholders' equity for interim financial statements. Under the amendments, an analysis of changes in each caption of stockholders' equity presented in the balance sheet must be provided in a note or separate statement. The analysis should present a reconciliation of the beginning balance to the ending balance of each period for which a statement of comprehensive income is required to be filed. This final rule is effective for the Company for all filings made on or after November 5, 2018. The SEC staff clarified that the first presentation of the changes in shareholders' equity may be included in the first Form 10-Q for the quarter that begins after the effective date of the amendments. The adoption of the final rule did not have a material impact on the Company's consolidated financial statements. In June 2018, the FASB issued ASU No. 2018-07, Compensation-Stock Compensation (Topic 718): Improvements to Nonemployee Share- Based Payment Accounting. This update is to simplify the aspects of accounting for nonemployee share-based payment transactions for acquiring goods or services from nonemployees. The amendments in this update are effective for fiscal years beginning after December 15, 2018, including interim periods within that year. The Company has concluded that this guidance has no material impact on the Company's consolidated financial statements and related disclosures.

In July 2017, the FASB issued ASU No. 2017-11, Earnings Per Share (Topic 260): Distinguishing Liabilities from Equity (Topic 480); Derivatives and Hedging (Topic 815): (PART I) Accounting for certain financial instruments with down round features. This update addresses the complexity of accounting for certain financial instruments with down round features. The guidance is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2018. The Company has concluded that this guidance has no impact on the presentation of its results of operations, financial position and disclosures.

In May 2017, the FASB issued ASU No. 2017-09, Compensation-Stock Compensation (Topic 718): Scope of Modification Accounting. This standard provides guidance on changes to the terms or conditions of a share-based payment award that requires an entity to apply modification accounting. The guidance is effective prospectively for annual periods beginning after December 15, 2017, and for interim periods and annual periods thereafter. The Company has concluded that this guidance has a immaterial no impact on the presentation of its results of operations, financial position and disclosures.

In November 2016, the FASB issued ASU 2016-18, Statement of Cash Flows: Restricted Cash ("ASU 2016-18"). The amendments in this update require that amounts generally described as restricted cash and restricted cash equivalents be included within cash and cash equivalents when reconciling the beginning-of-period and end-of-period total amounts shown on the statement of cash flows. ASU 2016-18 was effective January 1, 2018. As a result of adopting ASU 2016-18, the Company includes its restricted cash balance in the cash and cash equivalents reconciliation of operating, investing and financing activities. The following table provides a reconciliation of cash, cash equivalents, and restricted cash within the statement of financial position that sum to the total of the same such amounts shown in the statement of cash flows.

	As of December 31,	
	2018	2017
	(in thousands)	
Cash and cash equivalents	$ 15,542	$ 7,081
Restricted cash	137	137
Total cash, cash equivalents, and restricted cash shown in the statement of cash flows	$ 15,679	$ 7,218

In February 2016, the FASB issued ASU No. 2016-02- Leases (Topic 842). This standard requires companies to recognize on the balance sheet the assets and liabilities for the rights and obligations created by leased assets. ASU 2016-02 will be effective for the Company in the first quarter of 2019, with early adoption permitted. The Company estimates that it will recognize approximately $8 million to $10 million of right-of-use assets and corresponding lease liabilities on the balance sheet upon adoption. However, the population of contracts subject to balance sheet recognition and their initial measurement remains under evaluation; and the final impact on the balance sheet will depend on the lease portfolio as the time of adoption. The Company does not expect that adoption will have a material impact on its results of operations or statement of cash flows.

In May 2014, the FASB issued ASU No. 2014-09, Revenue from Contracts with Customers ("Topic 606"), which requires an entity to recognize the amount of revenue to which it expects to be entitled for the transfer of promised goods or services to customers. In the fourth quarter of 2017, the Company early adopted ASC 606 and this standard applies to all contracts with customers, except for contracts that are within the scope of other standards, such as leases, insurance, collaboration arrangements and financial instruments. The Company had only one revenue arrangement as of the adoption date. Topic 606 requires an entity to recognize the amount of revenue to which it expects to be entitled for the transfer of promised goods or services to customers. Topic 606 provides a five-step model for determining revenue recognition for arrangements that are within the scope of the standard: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation. The Company only applies the five-step model to contracts when it is probable that the entity will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer. At contract inception, once the contract is determined to be within the scope of Topic 606, the Company assesses the goods or services promised within each contract and determines those that are performance obligations, and assesses whether each promised good or service is distinct. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied. For a complete discussion of accounting for revenues, see Note 1, Summary of Significant Accounting Policies – Revenue Recognition

3. LOSS PER COMMON SHARE

Basic and diluted loss per common share are calculated as follows:

	For the Year Ended	
	2018	2017
	(In thousands, except share and per share data)	
Numerator:		
Net loss	$ (8,643)	$ (26,414)
Net Loss attributable to Series A Preferred Stock (a)	(121)	(3,915)
Numerator for basic EPS - loss attributable to common stockholders	$ (8,522)	$ (22,499)
Effect of dilutive securities:		
Deduct change in fair value of warrant liability	$ (20,601)	$ —
Numerator for diluted EPS - loss attributable to common stockholders after assumed conversions	$ (29,123)	$ (22,499)
Denominator:		
Weighted-average number of common shares used in loss per share—basic	36,398,450	22,669,819
Effect of dilutive securities:		
Nonparticipating warrants	691,747	—
Denominator for diluted EPS - adjusted weighted average shares	37,090,197	22,669,819
Loss per share—basic	$ (0.23)	$ (0.99)
Loss per share—diluted	$ (0.79)	$ (0.99)

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

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

	As of December 31,	
	2018	2017
Unvested restricted stock and options to purchase common stock	3,339,471	2,158,348
Series A preferred stock unconverted	177,996	2,046,957
Warrants exercisable into common stock	—	13,633,070

4. PREPAID EXPENSES AND OTHER CURRENT ASSETS

Prepaid expenses and other current assets consisted of the following:

	As of December 31,	
	2018	2017
	(in thousands)	
Insurance	686	72
Other current assets	172	122
Prepaid expenses and other current assets	$ 858	$ 194

5. PROPERTY AND EQUIPMENT

Property and equipment consisted of the following:

	December 31, 2018	December 31, 2017
	(in thousands)	
Office equipment	$ 266	$ 279
Laboratory equipment	4,561	4,565
Leasehold improvements	5,504	7,712
Construction in progress	—	990
Software	96	96
Total property and equipment	10,427	13,642
Less: accumulated depreciation	(10,286)	(10,919)
Property and equipment, net	$ 141	$ 2,723

Depreciation expense related to property and equipment amounted to $0.5 million and $1.5 million for the years ended December 31, 2018 and 2017, respectively.

For year ended December 31, 2018 the company deemed the value of its property and equipment to be impaired based on the triggering event that occurred in December 2018. In connection with the impairment, the Company reduced the net book value of its property and equipment to an estimated fair value which was calculated based on the present value of expected future cash flows from these assets. As a result, the Company incurred a charge of $4.3 million that was recorded in the Statement of Operations.

6. ACCRUED EXPENSES

Accrued expenses consisted of the following:

	As of December 31,	
	2018	2017
	(in thousands)	
Accrued compensation	$ 514	$ 1,671
Accrued audit fees	159	133
Accrued license fees	90	70
Accrued clinical expenses	86	199
Accrued other	151	632
Total accrued expenses	$ 1,000	$ 2,705

7. COMMITMENTS AND CONTINGENCIES

Operating Leases

The Company leases its office and research facilities in Waltham and Lexington, Massachusetts under non-cancellable operating leases. The Lexington, Massachusetts facility lease expires in June 2023. The lease provided for one extension term of five years. The Waltham, Massachusetts facility lease was extended in April 2017 with an effective date of January 2018. Under the terms of the extension, the lease will expire in December 2024 with one additional extension term of five years. Terms of the agreements generally provide for an initial rent-free period and future rent escalation, and provide that in addition to minimum lease rental payments, the Company is responsible for a pro-rata share of common area operating expenses.

Aggregate minimum annual lease commitments of the Company under its non-cancellable operating leases as of December 31, 2018, are as follows:

For the Year Ended December 31,	
	(in thousands)
2019	$ 1,845
2020	1,892
2021	1,941
2022	1,991
2023	1,728
Thereafter	1,460
Total minimum lease payments	$ 10,857

Rent expense under operating lease agreements amounted to $1.6 million and $1.0 million for the years ended December 31, 2018 and 2017, respectively.

As an inducement to enter into the Waltham facility lease extension, the lessor agreed to provide the Company with a construction allowance of up to $0.9 million towards the total cost of tenant improvements. As an inducement to enter into its Lexington facility lease, the lessor agreed to provide the Company with a construction allowance of up to $1.0 million towards the total cost of tenant improvements. The Company has recorded these costs in the consolidated balance sheet as leasehold improvements, with the corresponding liability as deferred lease incentive. These liabilities are amortized on a straight-line basis over the term of the lease as a reduction of rent expense.

License Agreements

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

Hydrogel License

In May 2005, the Company entered into an exclusive license agreement with Angiotech Pharmaceuticals (US), Inc. for the use of certain patents, patent applications, and knowledge related to the manufacture and use of a hydrogel material in conjunction with NeoCart and certain other products ("Hydrogel License Agreement"). As of December 31, 2018, the Company has paid an aggregate $3.2 million in commercialization milestones under the terms of the Hydrogel License Agreement, which has been expensed to research and development.

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

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

Tissue Regeneration License

In April 2001, the Company entered into an exclusive license agreement with The Board of Trustees of the Leland Stanford Junior University ("Stanford University") for the use of certain technology to develop, manufacture and sell licensed products in the field of growth and regeneration of cartilage ("Tissue Regeneration License Agreement"). The term of the Tissue Regeneration License Agreement extends to the expiration date of Stanford University's last to expire domestic or foreign patents. As of December 31, 2018, the Company has paid an aggregate $0.8 million in patent reimbursement costs, royalty fees, and commercialization milestone payments under the terms of the Tissue Regeneration License Agreement, which have been recorded to research and development expense.

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

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

Tissue Processor Sub-License

In December 2005, the Company entered into an exclusive agreement to sub-license certain technology from Purpose, Co. ("Purpose"), which is owned by a stockholder of the Company ("Sub-License Agreement"). Purpose entered into the original license agreement ("Original Agreement") with Brigham and Women's Hospital, Inc. ("Brigham and Women's") in August 2001. The Original Agreement shall remain in effect for the licensed patents owned by Brigham and Women's unless extended or terminated as provided for in the agreement. The technology is to be used to develop, manufacture, use and sell licensed products that cultivate cell or tissue development. The Sub-License Agreement extends to the expiration date of the last to expire domestic or foreign patents covered by the agreement. As of December 31, 2018, the Company has paid an aggregate $1.0 million in royalty and sub-license payments under the terms of the Sub-License Agreement.

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

In May 2016, the Original Agreement was amended whereby the Company acquired the development and commercialization rights to NeoCart for the Japanese market from Purpose. Under the terms of the amended agreement, the Company assumes sole responsibility for and rights to the development and commercialization of NeoCart in Japan. In exchange for the transfer of development and commercialization rights, the Company will pay

a success-based milestone to Purpose upon conditional approval of NeoCart in Japan, as well as commercial milestones and a low single digit royalty on Japanese sales of NeoCart, upon full approval, if any, in Japan

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

- A minimum non-refundable annual royalty fee of $20 thousand, for the life of the license;
- An additional, non-refundable annual royalty fee of $30 thousand from 2016 through 2019;
- $10.2 million in potential milestone payments; and
- Low single digit royalties on net sales of a licensed product.

Collagen Supply Agreement

In September 2015, the Company entered into an agreement with Collagen Solutions (UK) Limited (the "Supplier") to purchase soluble collagen that meets specifications provided by the Company. The initial term of the agreement is three years and will automatically renew from year to year thereafter unless otherwise terminated with at least 180 days' notice by either party. In February 2017, the Company entered into an amendment with the Supplier. Pursuant to the amendment, the Company agreed to pay the Supplier approximately $0.1 million in exchange for eliminating the minimum annual order of material and/or services and any other amounts due Supplier. The payment of $0.1 million will be made over the 18 months following the date of the amendment. As of December 31, 2018, the Company has paid all of the required payments totaling $0.1 million under the terms of the amendment.

8. CAPITAL STOCK .

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

In March 2018, the Company entered into an equity distribution agreement ("the Equity Distribution Agreement") with Canaccord Genuity Inc. ("Canaccord"), pursuant to which the Company may, from time to time, sell shares of its common stock having an aggregate offering price of up to $10.0 million (the "Shares") through Canaccord, as sales agent. During the year ended December 31, 2018, the Company sold an aggregate of 6,633,903 shares of common stock and received $4.5 million after deducting commissions related to the Equity Distribution Agreement and other offering costs.

In January 2018, the Company closed a registered direct offering where the Company issued 2,691,494 shares of common stock at a price of $2.35 per share. The underwriter option to purchase additional shares of 351,064 were fully exercised. The total net proceeds of the offering were approximately $5.9 million after deducting underwriting discounts and commissions.

In September 2016, the Company closed the private placement contemplated by the securities purchase agreement (the "Purchase Agreement"), dated September 15, 2016, between the Company and certain institutional and accredited investors in which the Company received gross proceeds of $30.0 million (the "Private Placement"). The net proceeds after deducting placement agent fees and other transaction-related expenses was $27.6 million. At the

closing, the Company issued 2,596,059 shares of the Company's common stock at a per share price of $2.25 and 24,158.8693 shares of the Company's newly-created Series A Convertible Preferred Stock ("Series A Preferred Stock"), which are convertible into approximately 10,737,275 shares of common stock. As of December 31, 2018, there were 400.4910 shares of Series A Preferred Stock outstanding, which remain convertible into 177,996 shares of the Company's common stock. As part of the Private Placement, the investors received warrants to purchase up to 13,333,334 shares of the Company's common stock at an exercise price of $2.25 per share. The placement agent for the Private Placement, H.C. Wainwright & Co. LLC ("HCW"), and certain of its affiliates were also granted warrants to purchase 133,333 shares of the Company's common stock at an exercise price of $2.25 per share in exchange for the services provided by HCW. The placement agent warrants were considered a financing cost of the Company and included in warrant expense within the consolidated statements of operations.

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

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

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

Common Stock -100,000,000 shares authorized

The holders of shares of common stock are entitled to one vote per share. The holders of shares of common stock are not entitled to receive dividends, unless declared by the Company's board of directors out of legally available funds, if ever.

Reserved for future issuance

The Company has reserved for future issuance the following number of shares of common stock:

	As of December 31,	
	2018	2017
Options to purchase common stock	3,339,471	2,158,348
Common stock warrants	33,145,228	13,633,070
Total	36,484,699	15,791,418

Preferred Stock -30,000 shares authorized

Series A Convertible Preferred Stock

On September 29, 2016, the Company issued 24,158.8693 shares of newly-created Series A Convertible Preferred Stock, which were convertible into approximately 10,737,275 shares of common stock at an initial conversion price

of $2.25. The Series A Preferred Stock has a par value of $0.01 and each share is convertible into 444.44 shares of common stock at the option of the holder. The holders of Series A Preferred Stock have no voting rights, share in both income and losses and are only entitled to dividends as declared on an as-converted basis. The Series A Preferred Stock contains no liquidation preferences or redemption rights and shares in the distribution of the Company on an as-converted basis with the common stock. The Series A Preferred Stock shall not be converted if, after giving effect to the conversion, the holder and its affiliated persons would own beneficially more than 4.99% of our common stock (subject to adjustment up to 9.99% solely at the holder's discretion upon 61 days' prior notice to us or, solely as to a holder, if such limitation is waived by such holder upon execution of the private placement agreement). As of December 31, 2018, there were 400.4910 shares of Series A Preferred Stock outstanding, which remain convertible into 177,996 shares of the Company's common stock.

9. WARRANTS

Issued	Classification	Warrants Outstanding	Exercise Price	Expiration
October 2018	Liability	19,616,250	$ 0.70	October 2028
September 2016	Liability	13,466,667	2.25	November 2022
March 2015	Equity	3,699	9.75	March 2025
July 2014	Equity	6,566	7.99	July 2024
July 2012	Equity	52,046	0.01	July 2022

In the first quarter of 2019 the Company reduced the exercise price for all but 508,714 of the warrants issued in September 2016 and all of the warrants issued in October 2018. Refer to Note 15, *Subsequent Events* for further details on the amendments.

10. EQUIPMENT LOAN PAYABLE

As of December 31, 2018 and 2017, the Company had the following outstanding borrowing obligations:

	December 31, 2018	December 31, 2017
	(in thousands)	
Silicon Valley Bank Equipment Loan Payable	$ —	$ 178
Less: current portion	—	(178)
Long-term debt, net	$ —	$ —

In July 2014, the Company entered into a loan and security agreement with Silicon Valley Bank, which provided for a line of credit to finance certain equipment purchases up to an aggregate of $1.8 million through March 31, 2015. The line has been fully drawn and is payable in 36 monthly installments of principal and interest, with an annual interest rate of 2.75% plus the greater of 3.25% or the prime rate in effect at the time of each draw, as published in the Wall Street Journal. The outstanding balance on the line of credit is secured by a first priority lien over all equipment purchased using the line of credit.

In accordance with the terms of the equipment line of credit, the Company issued a warrant to Silicon Valley Bank in July 2014 to purchase 6,566 shares of our common stock at an exercise price per share of $7.99.

The equipment line of credit includes customary operating but non-financial covenants, including limitations on the Company's ability to incur additional indebtedness, issue dividends, sell assets, engage in any business other than its current business, merge or consolidate with other entities, create liens on our assets, make investments, repurchase stock in certain instances, enter into transactions with affiliates, make payments on subordinated indebtedness and transfer or encumber any collateral securing the debt. The loan matured and was fully repaid in 2018.

11. STOCK-BASED COMPENSATION

Restricted Stock Awards and Stock Options

The Company adopted the 2012 Equity Incentive Plan, as amended ("2012 Plan") in July 2012 pursuant to which 609,389 shares of common stock were authorized for issuance to employees, officers, directors, consultants and advisors of the Company as of December 31, 2014. Upon the closing of the IPO on December 3, 2014, no further grants were made under the 2012 Plan as the 2013 Equity Incentive Plan ("2013 Plan") replaced the 2012 Plan on this date. The 2012 Plan provided for the grant of incentive stock options, non-statutory stock options, rights to purchase restricted stock, stock appreciation rights, phantom stock awards and stock units. In connection with the issuance of restricted common stock, the Company maintains a repurchase right and shares of restricted common stock are released from such repurchase right over a period of time of continued service by the recipient. Recipients of incentive stock options shall be eligible to purchase shares of the Company's common stock at an exercise price equal to no less than the estimated fair value of such stock on the date of grant. Stock options generally vest 25% on the first anniversary of the original vesting date, with the balance vesting monthly over the remaining three years, unless they contain specific performance and/or market-based vesting provisions. The maximum term of stock options granted under the 2012 Plan is ten years.

In determining the exercise prices for options granted, the board of directors considered the fair value of the common stock as of the measurement date. The fair value of the common stock was determined by the board of directors based on a variety of different factors, including valuations prepared by third party valuation specialists, the Company's financial position, the status of development efforts within the Company, the composition and ability of the current scientific and management teams, the current climate in the marketplace, the illiquid nature of the Company's common stock, any arm's length sale of the Company's preferred stock, the effect of the rights and preferences of the preferred stockholders, and the prospects of a liquidity event, among others.

2013 Equity Incentive Plan

The Company's board of directors adopted the 2013 Plan in November 2013 which the stockholders approved in October 2014. The 2013 Plan provides for the grant of incentive stock options, non-statutory stock options, rights to purchase restricted stock, stock appreciation rights and stock units. In connection with the issuance of restricted common stock, the Company maintains a repurchase right and shares of restricted common stock are released from such repurchase right over a period of time of continued service by the recipient. Recipients of stock options shall be eligible to purchase shares of the Company's common stock at an exercise price equal to no less than the estimated fair value of such stock on the date of grant. Stock options generally vest 25% on the first anniversary of the original vesting date, with the balance vesting monthly over the remaining three years, unless they contain specific performance and/or market-based vesting provisions. The maximum term of stock options granted under the 2013 Plan is ten years. In June 2016, the Company's stockholders approved an amendment to the EIP to increase the number of shares of common stock available for issuance under the 2013 Plan by 300,000 shares and increase the number of shares of common stock automatically added to the 2013 Plan on January 1 of each year during the term of the 2013 Plan, starting with January 1, 2017 (the "EIP Amendment"). Following adoption of the EIP Amendment, the number of shares of common stock available for issuance under the 2013 Plan is subject to an automatic annual increase on the first day of the Company's calendar year beginning in 2017 equal to the lesser of (a) 4.0% of the total number of shares of common stock outstanding on December 31 of the prior year or, (b) the number determined by the Company's Board of Directors. Accordingly, the number of shares of common stock available for issuance under the EIP was increased by 825,904 shares on January 1, 2017 and an additional 982,841 shares on January 1, 2018. To the extent any awards under the 2013 Plan are forfeited, terminate, expire, lapse without the issuance of shares, or if the Company repurchases shares subject to awards under the 2013 Plan, those shares will again become available for issuance under the 2013 Plan.

2013 Employee Stock Purchase Plan

The Company's board of directors adopted the 2013 Employee Stock Purchase Plan ("2013 ESPP") in November 2013 which the stockholders approved in October 2014. The 2013 ESPP became effective upon the closing of the IPO on December 3, 2014. The Company's 2013 ESPP qualifies under Section 423 of the Internal Revenue Code of 1986, as amended (the "Code"). Under the 2013 ESPP, 103,665 shares of the Company's common stock are authorized for issuance to eligible employees. The number of shares reserved for issuance under the 2013 ESPP is automatically increased on the first business day of each of the Company's fiscal years, commencing in 2015, by a

number equal to the lowest of (a) 51,832 shares of common stock,(b) 1% of the shares of common stock outstanding on the last business day of the prior fiscal year; or (c) the number of shares determined by the Company's Board of Directors. Accordingly, the number of authorized shares of the Company's common stock authorized for issuance to eligible employees under the 2013 ESPP was increased by 206,476 shares on January 1, 2017 and an additional 51,832 shares on January 1, 2018. The number of shares reserved under the 2013 ESPP will automatically be adjusted in the event of a stock split, stock dividend or a reverse stock split (including an adjustment to the per-purchase period share limit). The Company's 2013 ESPP permits each eligible employee to purchase common stock through payroll deductions. There was no activity under the Plan in 2018 and 2017.

Stock option activity under the 2012 and 2013 plans is summarized as follows:

	Number of Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2017	2,158,348	$ 4.40	8.1	$ 436
Granted	4,311,090	1.21		
Exercised	(919)	2.56		
Cancelled	(3,129,048)	3.60		
Outstanding at December 31, 2018	3,339,471	$ 1.03	8.1	$ -
Vested and expected to vest at December 31, 2018	3,314,542	$ 1.03	8.1	$ -
Exercisable at December 31, 2018	1,603,725	$ 1.37	7.1	$ -

As of December 31, 2018 and 2017, the unrecognized compensation cost related to outstanding options was $2.3 million and $1.4. million, respectively, and is expected to be recognized as expense over approximately 2.50 years and 1.70 years, respectively. The intrinsic value of options exercised during the years ended December 31, 2018 and 2017 was $0 and $8 thousand, respectively.

As of December 31, 2018, the weighted average grant date fair value of vested options was $0.76 and the weighted average grant date fair value of options outstanding was $0.52.

Additional information about the Company's stock option activity is as follows:

	Year Ended December 31,	
	2018	2017
Weighted-average grant date fair value per share of employee option grants within the year	$ 0.59	$ 1.02
Cash received upon exercise of options	2	6

As of December 31, 2016, the unrecognized compensation cost related to restricted stock awards was $1 thousand which was recognized as expense during the year ended December 31, 2017.

Stock-Based Compensation Expense

The Company granted stock options to employees for the years ended December 31, 2018 and 2017. The Company estimates the fair value of stock options as of the date of grant using the Black-Scholes option pricing model and restricted stock based on the fair value of the award. Stock options and restricted stock issued to non-board member, non-employees are accounted for using the fair value approach and are subject to periodic revaluation over their vesting terms.

For all periods from inception to date, stock-based compensation for all options granted and restricted stock awards are classified as research and development expense and general and administrative expense. Stock compensation

expense amounted to approximately $1.6 million and $1.6 million for the years ended December 31, 2018 and 2017, respectively.

Stock-based compensation is as follows:

	Year Ended December 31,	
	2018	2017
	(in thousands)	
Research and development	$ 488	$ 411
General and administrative	1,137	1,162
Total stock-based compensation expense	$ 1,625	$ 1,573

The weighted-average assumptions used in the Black-Scholes option pricing model to determine the fair value of the employee stock option grants were as follows:

	Year Ended December 31,	
	2018	2017
Risk-free interest rate	2.84%	2.03%
Expected volatility	84.4%	62.9%
Expected term (in years)	5.31	6.08
Expected dividend yield	0.0%	0.0%

The weighted-average assumptions used in the Black-Scholes option pricing model to determine the fair value of the non-employee stock option grants were as follows:

	Year Ended December 31,	
	2018	2017
Risk-free interest rate	2.57%	1.29%
Expected volatility	88.3%	62.3%
Expected term (in years)	6.08	6.08
Expected dividend yield	0.0%	0.0%

Risk-free Interest Rate. The risk-free interest rate assumption is based on observed interest rates appropriate for the expected term of the stock option grants.

Expected Volatility. Due to the Company's limited operating history and lack of company-specific historical or implied volatility, the expected volatility assumption is based on historical volatilities of a peer group of similar companies whose share prices are publicly available. The peer group was developed based on companies in the biotechnology and medical device industries.

Expected Term. The expected term represents the period of time that options are expected to be outstanding. Because the Company does not have historical exercise behavior, through December 31, 2018 it determined the expected life assumption using the simplified method, which is an average of the contractual term of the option and its vesting period.

Expected Dividend Yield. The expected dividend yield assumption is based on the fact that the Company has never paid cash dividends and has no present intention to pay cash dividends.

On October 1, 2018, the Compensation Committee of the Board of Directors approved a repricing (the "Repricing") of 3,807,779 stock options (the "Options") granted prior to September 1, 2018 pursuant to our 2013 Equity Incentive Plan and our 2012 Equity Incentive Plan to executive officers, employees and consultants of the Company. The Options had exercise prices between $0.75628 and $9.97 per share, which were reduced to $0.568 per share (the closing price of the Company's common stock on The Nasdaq Capital Market on October 1, 2018). The number of shares, vesting schedules and expiration period of the Options were not altered. The impact to the Company's financial statements in 2018 was immaterial.

12. INCOME TAXES

For the years ended December 31, 2018 and 2017, the Company did not record a current or deferred income tax expense or benefit due to current and historical losses incurred by the Company.

The components of loss before income taxes were as follows:

	As of December 31,	
	2018	2017
	(in thousands)	
U.S.	$ (8,503)	$ (26,275)
Foreign	(140)	(140)
Total	$ (8,643)	$ (26,415)

A reconciliation of income tax expense (benefit) computed at the statutory federal income tax rate to income taxes as reflected in the financial statements is as follows:

	As of December 31,	
	2018	2017
Federal income tax (benefit) at statutory rate	21.1%	33.7%
(Increase) decrease income tax benefit resulting from:		
State income tax benefit, net of federal benefit	22.5%	0.0%
Permanent differences	54.4%	(2.6)%
Net Operating Loss Limitation	0.0%	0.0%
Federal Tax Rate change	0%	(47.2)%
R&D Credit Limitation	0.9%	0.0%
Change in valuation allowance	(98.5)%	14.6%
Other	-0.4%	1.5%
Income tax expense (benefit)	0.0%	0.0%

Deferred taxes are recognized for temporary differences between the basis of assets and liabilities for financial statement and income tax purposes. The significant components of the Company's deferred tax assets and liabilities are comprised of the following:

	As of December 31,	
	2018	2017
	(in thousands)	
Deferred tax assets:		
Net operating loss carryforwards	$ 24,941	$ 18,540
Depreciation and amortization	4,878	4,121
Accrued expenses	141	1,484
Capitalized start-up costs	9,143	7,942
R&D credits	312	243
Other	1,155	808
Deferred tax assets before valuation allowance	40,570	33,138
Valuation allowance	(40,570)	(33,138)
	—	—
Deferred tax liabilities		
IPR&D	—	—
Change in accounting method	—	—
Net deferred tax assets	$ —	$ —

The Company has evaluated the positive and negative evidence bearing upon the realizability of its deferred tax assets. As of December 31, 2018 and 2017, based on the Company's history of operating losses, the Company has concluded that it is not more likely than not that the benefit of its deferred tax assets will be realized. Accordingly, the Company has provided a full valuation allowance for deferred tax assets as of December 31, 2018 and 2017. The valuation allowance decreased by $7.4 million during the year ended December 31, 2018, due primarily to net operating losses generated and capitalized expenses. The valuation allowance decreased $1.0 million during the year ended December 31, 2017, due primarily to net operating losses generated, net of the impact of a federal tax rate change of $11.5 million. In addition, the reduction in net operating losses were related to Section 382 limits as a result in a change in ownership.

As of December 31, 2018 and 2017, the Company had U.S. federal NOL carryforwards of $67 million and $43.9 million respectively, which may be available to offset future income tax liabilities and expire at various dates through 2037. As of December 31, 2018 and 2017, the Company also had U.S. state NOL carryforwards of $66.9 million and $43.6 million respectively, which may be available to offset future income tax liabilities and expire at various dates through 2037. At December 31, 2018 and 2017, the Company also had $26.2 and $26.1 respectively, of foreign NOL carryforwards which may be available to offset future income tax liabilities, which carryforwards do not expire. Utilization of the NOL and research and development credit carryforwards may be subject to a substantial annual limitation due to ownership change limitations that have occurred or that could occur in the future, as required by Section 382 and Section 383 of the Code, as well as similar state and foreign provisions. These ownership changes may limit the amount of NOL and research and development credit carryforwards that can be utilized annually to offset future taxable income and tax, respectively. In general, an "ownership change" as defined by Section 382 of the Code results from a transaction or series of transactions over a three-year period resulting in an ownership change of more than 50 percentage points of the outstanding stock of a company by certain stockholders. The Company has completed a study to assess whether an ownership change has occurred or whether there have been multiple ownership changes since its formation. The results of this study indicated that the Company experienced ownership changes as defined by Section 382 of the Code. The Company has not recorded NOLs that, as a result of these restrictions, from the 2016 ownership change, will expire unused. Accordingly, the Company has recorded NOL carryforwards net of these limitations, which are approximately $52.9 million.

TAX REFORM

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

The staff of the Securities and Exchange Commission issued Staff Accounting Bulletin No. 118 to address the application of U.S. GAAP in situations when a registrant does not have the necessary information available, prepared or analyzed (including computations) in reasonable detail to complete the accounting for certain income tax effects of the TCJA. In connection with the initial analysis of the impact of the TCJA, the Company remeasured its deferred tax assets and liabilities based on the rates at which they are expected to reverse in the future, which is generally 21%. The remeasurement of the Company's deferred tax assets and liabilities was offset by a corresponding change in the valuation allowance for the year ended December 31, 2017. As a result, there was no impact to the Company's consolidated statements of operations and comprehensive loss as a result of the reduction in tax rates. The other provisions of the TCJA did not have a material impact on the Company's consolidated financial statements. The Company's final determination of the TCJA impact and the remeasurement of its deferred assets and liabilities was completed prior to the deadline of one year from the enactment of the TCJA. For the year ended December 31, 2018, there were no material changes to the analysis originally performed as of December 31, 2017.

The changes in the Company's unrecognized tax benefits are summarized as follows:

	As of December 31,	
	2018	2017
	(in thousands)	
Unrecognized tax benefit, beginning of year	$ 303	$ 562
Increase (decrease) related to current year positions	—	(123)
Federal rate revision	—	(136)
Unrecognized tax benefit, end of year	$ 303	$ 303

As of December 31, 2018 and 2017, the total amount of unrecognized tax benefits was $0.3 million and $0.3 million, respectively which, if recognized, would favorably affect the effective income tax rate in future periods. Note that liabilities for unrecognized tax benefits have been recorded to the extent that they do not exceed the Company's available losses that are not limited as a result of ownership changes that have occurred under Section 382 of the Code. Reductions to unrecognized tax benefits for limitations on the utilization of net operating losses due to ownership changes occurring during the year has been reflected in the table as reductions based on tax positions related to the current year. The Company accrues interest and penalties related to unrecognized tax benefits as a component of its provision for income taxes. No accrued interest and penalties related to the Company's unrecognized tax benefits has been accrued as of December 31, 2018 and 2017. The Company believes that it is reasonably possible that none of its unrecognized tax benefits, may be recognized at the end of 2018. The Company or one of its subsidiaries files income tax returns in the United States and various states and Israel. The Company is subject to U.S. federal, state and local income tax examinations by tax authorities for years 2001 through present. Carryforward attributes that were generated in earlier periods remain subject to examination to the extent the year in which they were used or will be used remains open for examination. The tax years which remain subject to examination by tax authorities in Israel, as of December 31, 2018, include years 2014 through the present.

13. EMPLOYEE BENEFITS

The Company has a defined contribution 401(k) plan for employees who are at least 21 years of age. Employees are eligible to participate in the plan beginning on the first day of the calendar quarter following their date of hire. Under the terms of the plan, employees may make voluntary contributions as a percent of compensation. No matching contributions have been made by the Company since the adoption of the 401(k) plan.

14. RELATED PARTIES

Purpose, Co.

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

Under the June 2012 amendment, the Company received exclusive rights to all of Purpose, Co.'s technology related to the exogenous tissue processor, continued supply of exogenous tissue processors during the Company's clinical trials, and rights to manufacture the exogenous tissue processors at any location the Company chooses. In exchange for such consideration, the Company named Purpose, Co. the sole manufacturer of equipment and also clarified the geographic territories of the exclusive license that Purpose Co. was granted for use of the Company's technology. Also, the Company agreed to reimburse Purpose, Co. for $0.3 million of development costs on a next generation tissue processer. Refer to the discussion under Note 7, *Tissue Processor Sub-License*.

In May 2016, the Company acquired the development and commercialization rights to NeoCart for the Japanese market from Purpose, Co. Under the terms of the amended agreement, the Company assumes sole responsibility for and rights to the development and commercialization of NeoCart in Japan. In exchange for the transfer of development and commercialization rights, the Company will pay a success-based milestone to Purpose upon

conditional approval of NeoCart in Japan, as well as commercial milestones and a low single digit royalty on Japanese sales of NeoCart, upon full approval, if any, in Japan.

The amounts that have been paid to Purpose, Co. under this agreement were $0.1 and $0.1 million for the years ended December 31, 2018 and 2017, respectively.

Board of Director Affiliates

Affiliates of certain members of the Company's Board of Directors participated in the Private Placement as described in Note 8.

15. SUBSEQUENT EVENTS

Restructuring – Effective January 23, 2019, the Board of Directors of the Company approved a restructuring plan involving reductions in headcount as part of a plan to reduce operating costs following the Company's decision to discontinue the development of NeoCart. The positions eliminated together represent approximately 65% of the Company's workforce, including the Company's Chief Medical Officer and Chief Business Officer. The Company expects to substantially complete the initial restructuring efforts and record a one-time charge for severance and related expenses of approximately $1.4 million in the first quarter of 2019.

Additional Restructuring – On March 14, 2019, the Board of Directors approved a further restructuring of the Company that terminated all but one of the remaining employees. The effective date of the restructuring is March 22, 2019. In connection with this additional restructuring, the Company intends to engage, Mr. Adam Gridley, its Chief Executive Officer, Mr. Stephen Kennedy, its Chief Operating Officer, along with up to four additional employees as consultants to assist with the continuing evaluation of strategic alternatives. The Company expects to substantially complete the second restructuring and record an additional one-time charge for severance and related expenses of approximately $2.2 million also in the first quarter of 2019.

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

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

EXHIBIT 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We have issued our report dated March 21, 2019, with respect to the consolidated financial statements included in the Annual Report of Histogenics Corporation on Form 10-K for the year ended December 31, 2018. We consent to the incorporation by reference of said report in the Registration Statements of Histogenics Corporation on Forms S-3 (File No. 333-213980 and File No. 333-216741) and on Forms S-8 (File No. 333-201552, File No. 333-210075, File No. 333-212358, and File No. 333-216743, File No. 333-223673).

/s/ GRANT THORNTON LLP

Hartford, Connecticut
March 21, 2019

EXHIBIT 31.1

CERTIFICATION

I, Adam Gridley, certify that:

1. I have reviewed this annual report on Form 10-K of Histogenics Corporation;

2. Based on my knowledge, this report does not contain any untrue statements 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 consolidated 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 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, including its consolidated subsidiaries, 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.

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: March 21, 2019

/s/ Adam Gridley

Adam Gridley
President and Chief Executive Officer
(Principal Executive Officer)

EXHIBIT 31.2

CERTIFICATION

I, Jonathan Lieber, certify that:

1. I have reviewed this annual report on Form 10-K of Histogenics Corporation;

2. Based on my knowledge, this report does not contain any untrue statements 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 consolidated 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 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, including its consolidated subsidiaries, 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.

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: March 21, 2019

/s/ Jonathan Lieber

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

EXHIBIT 32.1

CERTIFICATION

In connection with the Annual Report of Histogenics Corporation (the "Registrant") on Form 10-K for the annual period ended December 31, 2018 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Adam Gridley, President, Chief Executive Officer and Director of the Registrant, and Jonathan Lieber, Chief Financial Officer of the Registrant, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to their respective knowledge:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Registrant.

Date: March 21, 2019

/s/ Adam Gridley

Adam Gridley
President and Chief Executive Officer
(Principal Executive Officer)

Date: March 21, 2019

/s/ Jonathan Lieber

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

This certification is made solely for the purposes of 18 U.S.C. Section 1350, subject to the knowledge standard contained therein, and not for any other purpose. A signed original of this written statement required by Section 906 has been provided to the Registrant and will be retained by the Registrant and furnished to the United States Securities and Exchange Commission or its staff upon request.

This certification accompanies the Form 10-K to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of the Registrant under the Securities Act of 1933 or the Securities Exchange Act of 1934, each as amended (whether made before or after the date of the Form 10-K), irrespective of any general incorporation language contained in such filing.