As confidentially submitted to the Securities and Exchange Commission on July 11, 2014. This fifth draft registration statement has not been publicly filed with the Securities and Exchange Commission and all information herein remains strictly confidential.

Registration No. 333-

## UNITED STATES SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

## FORM S-1 REGISTRATION STATEMENT

UNDER
THE SECURITIES ACT OF 1933

## HISTOGENICS CORPORATION

(Exact Name of Registrant as Specified in its Charter)

Delaware

(State or Other Jurisdiction of Incorporation or Organization)

3842

(Primary Standard Industrial Classification Code Number) 04-3522315 (I.R.S. Employer Identification Number)

830 Winter Street, 3rd Floor Waltham, Massachusetts 02451 (781) 547-7900

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

Adam Gridley Chief Executive Officer Histogenics Corporation 830 Winter Street, 3rd Floor Waltham, Massachusetts 02451 (781) 547-7900

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

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Approximate date of commencement of proposed sale to the public: As soon as practicable after the effective date of this Registration Statement.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box. 

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

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated

filer," and "smaller reporting company." in Rule 12b- $\bar{2}$  of the Exchange Act. (Check one): Large accelerated filer  $\Box$ 

Non-accelerated filer  $\qed$  (Do not check if a smaller reporting company)

Accelerated filer	
Smaller reporting company	×

### CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities to be Registered	Proposed Maximum Aggregate Offering Price <sup>(1)</sup>	Amount of Registration Fee <sup>(2)</sup>
Common Stock, \$0.001 par value		

(1) Estimated pursuant to Rule 457(o) under the Securities Act of 1933, as amended. Includes the offering price attributable to additional shares that the underwriters have the option to purchase to cover overallotments, if any.

(2) Calculated pursuant to Rule 457(o) based on an estimate of the proposed maximum aggregate offering price.

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

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

Subject to completion, dated July 11, 2014

## **Shares**



## Common Stock

### \$ per share

- · Histogenics Corporation is offering shares.
- We anticipate that the initial public offering price will be between \$
   and \$
   . per share.
- This is our initial public offering and no public market currently exists for our shares.
- Proposed trading symbol: NASDAQ Global Market—HSGX

#### This investment involves risk. See "Risk Factors" beginning on page 9.

We are an "emerging growth company" as defined by the Jumpstart Our Business Startups Act of 2012 and, as such, we have elected to comply with certain reduced public company reporting requirements for this prospectus and future filings.

	Per Share	Total
Public offering price	\$	\$
Underwriting discount(1)	\$	\$
Proceeds, before expenses, to Histogenics Corporation	\$	\$

(1) See "Underwriting" for additional information regarding underwriter compensation.

The underwriters have a 30-day option to purchase up to

additional shares of common stock from us to cover over-allotments, if any.

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

## **Cowen and Company**

**Needham & Company** 

## **Roth Capital Partners**

The date of this prospectus is

, 2014.

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You should rely only on the information contained in this prospectus and any free writing prospectus we may authorize to be delivered to you. We have not, and the underwriters have not, authorized anyone to provide you with information different from, or in addition to, that contained in this prospectus and any related free writing prospectus. We and the underwriters take no responsibility for, and can provide no assurances as to the reliability of, any information that others may give you. This prospectus is not an offer to sell, nor is it seeking an offer to buy, these securities in any jurisdiction where the offer or sale is not permitted. The information contained in this prospectus is only accurate as of the date of this prospectus, regardless of the time of delivery of this prospectus and any sale of shares of our common stock.

Until and including , 2014 (25 days after the date of this prospectus), all dealers that buy, sell or trade our common stock, whether or not participating in this offering, may be required to deliver a prospectus. This delivery requirement is in addition to the obligation of dealers to deliver a prospectus when acting as underwriters and with respect to their unsold allotments or subscriptions.

For investors outside of the United States: Neither we nor the underwriters have done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than the United States. Persons outside of the United States who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to, the offering of the shares of common stock and the distribution of this prospectus outside of the United States.

HISTOGENICS (and design), our logo design and NEOCART are our registered trademarks, and BIOCART is our trademark. This prospectus also contains trademarks, registered marks and trade names of other companies. Any other trademarks, registered marks and trade names appearing in this prospectus are the property of their respective holders.

#### PROSPECTUS SUMMARY

The following summary highlights selected information contained elsewhere in this prospectus. Because this is only a summary, it does not contain all of the information you should consider before investing in our common stock. You should carefully read the entire prospectus, especially the risks set forth under the heading "Risk Factors" and our consolidated financial statements and related notes included elsewhere in this prospectus, before making an investment decision. References in this prospectus to "Histogenics," "our company," "we," "us" and "our" and other similar references refer to Histogenics Corporation and our consolidated subsidiaries during the periods presented unless the context requires otherwise.

#### Overview

We are a regenerative medicine company focused on developing and commercializing products in the musculoskeletal segment of the marketplace. Our first product candidate, NeoCart, is being investigated in a Phase 3 clinical trial. NeoCart utilizes various aspects of our regenerative medicine platform to develop an innovative tissue implant intended to treat tissue injury in the field of orthopedics, specifically cartilage damage in the knee. NeoCart is an investigational product and has not been approved for sale in any jurisdiction, including the United States. We have no other products that are approved for sale in the United States and currently we are not selling any other products that may be approved for sale in other jurisdictions.

Our regenerative medicine platform provides the tools to develop NeoCart. Our regenerative medicine platform combines expertise in the following areas:

- Cell processing: the handling of a tissue biopsy, extraction of cells, and expansion of the cells;
- Scaffold: three-dimensional structures that enable the proper distribution of cells and organize cells in their natural environment to support tissue formation;
- Tissue engineering: the use of a combination of cells, engineering and materials to improve or replace biological functions;
- Bioadhesives: natural, biocompatible materials that act as adhesives for biological tissue; and
- Growth factors: naturally occurring substances capable of stimulating cellular growth, proliferation and differentiation.

NeoCart is a cartilage-like implant created using patient's own cartilage cells through a series of tissue engineering processes. First, the patient's cells are separated from a tissue biopsy specimen extracted from the patient by a surgeon and multiplied in our laboratory. The cells are then infused into our proprietary scaffold that provides structure for the developing implant. Before NeoCart is implanted in a patient, the cell- and scaffold construct undergoes a bioengineering process in our Tissue Engineering Processor (TEP). Our TEP is designed to mimic the conditions found in a joint so that the implant is prepared to begin functioning like normal healthy cartilage prior to implantation. When the NeoCart implant is implanted, a bioadhesive is used to anchor the NeoCart implant in the cartilage injury and seal the implant to the surrounding native cartilage interface. The use of the bioadhesive eliminates the need for complicated suturing. We believe that the Phase 1 and Phase 2 clinical trials provide preliminary evidence for the safety of the NeoCart implant and improvement in pain and function in patients treated with NeoCart.

We are currently enrolling a Phase 3 clinical trial for NeoCart in the United States to provide evidence of the safety and effectiveness of NeoCart, studying cartilage defects in the knees of 245 patients under a Special Protocol Assessment (SPA) with the U.S. Food and Drug Administration (FDA). Pursuant to the SPA, we formally and prospectively reached agreement with the FDA on key elements of the Phase 3 clinical trial protocol, including design, endpoints and statistical analyses of the resulting study data. The SPA is binding on the FDA review division with limited exceptions. If the clinical trial is successful, the data may be used to

support efficacy claims for NeoCart approval and demonstrate clinical superiority over the current standard of care, microfracture. Microfracture consists of the creation of tiny holes or "fractures" in the bone underneath the injured cartilage leading to formation of a blood clot in the affected area. The blood and bone marrow that form the clot contain stem cells, which are thought to grow into cartilage-building cells. If we are successful in demonstrating superiority to microfracture in improvement in pain and function at 12 months postoperative in our Phase 3 clinical trial and NeoCart is approved for sale in the United States, we believe it would be the first product approved for the first-line treatment of severe cartilage damage to demonstrate clinical superiority over microfracture.

Musculoskeletal-related conditions, including cartilage damage, are one of the most prevalent health problems in the United States. Based on recent publications, we estimate that 1,000,000 knee arthroscopies are performed each year in the United States and we believe cartilage damage is likely to be identified in over 60% of those knee arthroscopies. Cartilage damage is a leading cause of osteoarthritis, a chronic condition in which cartilage breaks down, and the condition most responsible for the estimated 750,000 knee replacements performed in the United States annually. We believe the current alternatives available to treat cartilage damage in the knee, including microfracture, the most frequently used procedure for severe cartilage damage, inadequately address this condition. We believe NeoCart would represent a superior solution to treat cartilage damage in the knee because it has the potential to solve for the limitations of the current treatment alternatives and has the potential to provide improved efficacy, long-term patient benefits, accelerated patient recovery and predictable patient outcomes through a technically straightforward surgical procedure. To date, we have completed two FDA-regulated human clinical trials in the United States. Specifically, we conducted a Phase 1 safety study of eight patients and a Phase 2 randomized controlled exploratory study of 30 patients. The objective of the Phase 1 clinical trial was to demonstrate the safety of NeoCart for use when implanted into cartilage defects in the knee. The objective of the Phase 2 clinical trial was to continue the safety evaluation of NeoCart, gather additional efficacy data compared to microfracture, identify endpoints that are meaningful to patients and physicians, identify appropriate patient populations to receive NeoCart and obtain additional data to be used in design of future clinical studies. NeoCart demonstrated improvement in clinical efficacy based on pain and function measures as compared to microfracture in our Phase 2 clini

The goal of our Phase 3 clinical trial, which we are currently enrolling, is to demonstrate advantages of NeoCart over microfracture with respect to efficacy, accelerated patient recovery, technically straightforward surgery, long-term patient benefits and positive safety profile. We believe the advantages will allow us to secure approval to sell NeoCart in the United States and will enable us to potentially become a market leader in cartilage repair. We expect to complete enrollment of our NeoCart Phase 3 clinical trial by the first half of 2016, but we may encounter difficulties enrolling patients in our clinical trials, which could delay or otherwise adversely affect our clinical development activities. We have over 20 sites eligible to enroll patients and have randomized 41 patients into the Phase 3 clinical trial as of July 1, 2014. We are enrolling the Phase 3 clinical trial using surgeon-investigators who screen patients with knee pain against a pre-specified set of eligibility criteria after obtaining their consent to participate in the trial. Once randomized into the trial based on eligibility, the patients undergo their surgical treatment and return for evaluation and data collection by the investigators at regular intervals for three years as set forth in the study protocol. We are financing the Phase 3 clinical trial with funds raised from our private financing activities and intend to use the proceeds from this offering to finance the trial through the expected completion of enrollment in the first half of 2016.

In anticipation of potential approval of NeoCart, we have begun to scale our internal current Good Manufacturing Practices manufacturing capabilities and transition the manufacture of all our products in-house at our facilities located in the greater Boston area. The transition commenced in March 2014 with the intent of having the ability to manufacture NeoCart and the critical components of NeoCart with minimal reliance on third parties prior to

commercialization of NeoCart in the event NeoCart is approved. Following this transition, we will be required to obtain FDA approval of the comparability of the critical NeoCart raw materials moved in-house, and if we fail to obtain, or if we experience a delay in obtaining such approval, our business, operating results and prospects will be adversely affected.

We believe our regenerative medicine platform may provide us with the ability to develop a strong pipeline, and that the positive clinical data we have seen in treating cartilage damage of the knee with NeoCart will be applicable to other joints such as the ankle, hip and shoulder. We also believe our regenerative medicine platform has the ability to translate the fundamental science to allow us to develop additional product candidates to treat other soft tissue damage throughout the body such as tendon, ligament and meniscus tears and complex joint degeneration. Although not utilized in connection with our current NeoCart development, our portfolio of proprietary fibroblast growth factors may be explored for their use in optimizing manufacturing yields and we believe they could also have various therapeutic applications including wound healing and fracture healing. We plan to continue investing in our intellectual property portfolio in order to expand and protect our regenerative medicine platform and future product candidates.

#### **Risks Related to Our Business**

Our business is subject to a number of risks, including risks that may prevent us from achieving our business objectives or may adversely affect our business, financial condition, results of operations, cash flows and prospects that you should consider before making a decision to invest in our common stock. These risks are discussed more fully in "Risk Factors" beginning on page 9. These risks include, but are not limited to, the following:

- We are developing clinical-stage regenerative medicine products and there is a limited amount of information about us upon which you can evaluate our product candidates and business prospects, making an investment in our common stock unsuitable for many investors.
- We have incurred significant losses since our inception, including net losses of \$16.9 million in 2012 and \$25.7 million in 2013 and \$3.4 million in the three months ended March 31, 2014, and anticipate that we will continue to incur substantial losses for the next several years.
- Our audited consolidated financial statements at December 31, 2013 and for the year then ended were prepared assuming that we will continue as a going concern, but state there is substantial doubt about our ability to continue as a going concern, meaning that we may not be able to continue in operation for the foreseeable future or be able to generate revenue and discharge liabilities in the ordinary course of operations.
- We may require substantial additional funding, which may not be available to us on acceptable terms, or at all, and, if not available, may require us to delay, scale back or cease our product development activities and operations.
- Failure to obtain, or any delay in obtaining, FDA approval regarding the comparability of critical NeoCart raw materials following our technology transfer and manufacturing location transition may have an adverse effect on our business, operating results and prospects.
- If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.
- We are heavily dependent on the success of our lead product candidate NeoCart, which is still under development. If we are unable to
  successfully commercialize NeoCart, or experience significant delays due to manufacturing or otherwise in doing so, our business will be
  materially harmed.
- We may experience delays in commencing or conducting our clinical trials or in receiving data from third parties or in the completion of clinical testing, which could result in increased costs to us and delay our ability to generate product candidate revenue.

- If we fail to complete clinical trials and obtain regulatory approval for NeoCart, our business would be significantly harmed.
- Our clinical development of NeoCart could be substantially delayed if the FDA requires us to conduct additional studies or trials or imposes other requirements or restrictions.

#### **Our 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 prospectus. You should not rely on any such information in making your decision whether to purchase our common stock.

#### **Implications of Being an Emerging Growth Company**

As a company with less than \$1.0 billion in revenue during our last fiscal year, we qualify as an "emerging growth company" as defined in the Jumpstart Our Business Startups Act. An emerging growth company may take advantage of specified reduced reporting and other reduced burdens that are otherwise applicable generally to public companies. These provisions include:

- we may present only two years of audited financial statements and only two years of related Management's Discussion and Analysis of Financial Condition and Results of Operations;
- we are currently exempt from the requirement to obtain an attestation and report from our auditors on our internal control over financial reporting pursuant to the Sarbanes-Oxley Act;
- · we are permitted to provide less extensive disclosure about our executive compensation arrangements; and
- · we are not required to give our stockholders non-binding advisory votes on executive compensation or golden parachute arrangements.

We may take advantage of these provisions until December 31, 2019 (the last day of our fiscal year following the fifth anniversary of the date of the first sale of our common equity securities pursuant to this offering) or until such earlier time that we are no longer an emerging growth company. We would cease to be an emerging growth company if we have more than \$1.0 billion in annual revenue, have more than \$700 million in market value of our capital stock held by non-affiliates, or issue more than \$1.0 billion of non-convertible debt over a three-year period. We have chosen to take advantage of some of these reduced burdens and, as such, the information that we provide stockholders may be different than you may receive from other public companies in which you hold equity interests.

#### THE OFFERING

Shares of common stock offered by us shares

Shares of common stock outstanding after this offering shares

Over-allotment option shares

Use of proceeds

We estimate that we will receive net proceeds from this offering of \$\ \text{million, assuming an initial public offering price of \$\text{per share, the midpoint of the initial public offering price range reflected on the cover page of this prospectus, and after deducting the estimated underwriting discount and offering expenses payable by us. If the underwriters' option to purchase additional shares in this offering is exercised in full, we estimate that our net proceeds will be \$\text{million.}

We intend to use the net proceeds of this offering primarily to develop and advance NeoCart through our current Phase 3 clinical trial and to build out our manufacturing facility, as well as for working capital and general corporate purposes. We expect that our current Phase 3 clinical trial will cost approximately \$ million to complete. See "Use of Proceeds."

Proposed NASDAQ Global Market symbol

HSGX

The number of shares of our common stock to be outstanding following this offering is based on 56,026,477 shares outstanding as of July 10, 2014, assuming the conversion of all shares of convertible preferred stock into common stock and excludes:

- shares issuable upon the exercise of warrants outstanding as of July 10, 2014, at a weighted average exercise price of \$0.0387 per share:
- 4,934,205 shares issuable upon the exercise of options outstanding under our 2012 Equity Incentive Plan as of July 10, 2014, at a weighted average exercise price of \$0.52 per share;
- 5,600,000 shares reserved for future issuance under our 2013 Equity Incentive Plan, which became effective in November 2013 but with respect to which no awards will be granted prior to the effective date of the registration statement of which this prospectus is a part, subject to automatic annual adjustment in accordance with the terms of the plan; and
- 1,120,000 shares reserved for future issuance under our 2013 Employee Stock Purchase Plan, which became effective in November 2013 but with respect to which no awards will be granted prior to the effective date of the registration statement of which this prospectus is a part, subject to automatic annual adjustment in accordance with the terms of the plan.

Unless otherwise indicated, this prospectus includes and assumes the following, each to occur upon completion of this offering:

• the net (or cashless) exercise of warrants outstanding as of July 10, 2014, to acquire an estimated shares of common stock, assuming an initial public offering price of \$ , which is the midpoint of the initial public offering price range reflected on the cover of this prospectus;

- the exercise of warrants outstanding as of July 10, 2014, to acquire share:
   shares of common stock at an exercise price of \$0.001 per
- the issuance of an estimated shares of common stock in payment of accrued dividends on outstanding shares of convertible preferred stock, assuming an initial public offering price of \$ , which is the midpoint of the initial public offering price range reflected on the cover of this prospectus;
- the automatic conversion of all outstanding shares of our convertible preferred stock into common stock;
- the amendment and restatement of our certificate of incorporation and bylaws; and
- no exercise by the underwriters of their over-allotment option.

The information we present in this prospectus does not reflect a reverse split of our common stock that we may effect prior to the effectiveness of the registration statement of which this prospectus forms a part.

#### SUMMARY CONSOLIDATED FINANCIAL INFORMATION

The following tables summarize our consolidated financial data for the periods indicated. The consolidated statement of operations data for the years ended December 31, 2012 and 2013 has been derived from our audited consolidated financial statements included elsewhere in this prospectus. The consolidated statement of operations data for the three months ended March 31, 2013 and 2014 and the consolidated balance sheet data as of March 31, 2014 have been derived from our unaudited consolidated financial statements include elsewhere in this prospectus. The unaudited consolidated financial statements include all adjustments, consisting of normal recurring accruals, which we consider necessary for a fair presentation of the financial position and the results of operations for these periods. Our historical results are not necessarily indicative of the results to be expected for any future period and the results in any interim period are not necessarily indicative of results to be expected for the full year or any other period. You should read this summary consolidated financial data in conjunction with the sections titled "Selected Consolidated Financial Information" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our consolidated financial statements and related notes, included elsewhere in this prospectus.

	Year Ended December 31,		Three Months Ended March 31,	
	2012	2013	2013	2014
Consolidated Statement of Operations Data:	(in th	(in thousands, except share and per share amounts)		
Revenue	<u>\$ 26</u>	\$ 8	<u>\$ 5</u>	<u>\$</u>
Operating expenses:				
Research and development	11,941	11,946	1,908	3.347
Selling, general and administrative	3,053	4,847	905	1,826
Impairment of goodwill and intangible assets	<u></u> _	60		
Total operating expense	14,994	16,853	2,813	5,173
Loss from operations	(14,968)	(16,845)	(2,808)	(5,173)
Interest expense, net	(798)	_	_	
Other expense, net	(13)	(52)	(15)	(2)
Gain on extinguishment of debt	687	_	_	_
Change in fair value of note payable to shareholder	(17)		-	
Change in fait value of warrant liability and other liability	(1,826)	(8,815)	107	1,738
Net loss	<u>\$ (16,935)</u>	\$ (25,712)	\$ (2,716)	\$ (3,437)
Earnings (loss) per common share <sup>(1)</sup>	<u></u>			
Basic	\$ 1.00	\$ (8.94)	\$ (0.53)	\$ (0.55)
Diluted	\$ 0.26	\$ (8.94)	\$ (0.53)	\$ (0.55)
Weighted-average shares used to compute earnings (loss) per common share <sup>(1)</sup>				
Basic	2,818,293	6,264,690	6,250,001	6,290,589
Diluted	12,898,629	6,264,690	6,250,001	6,290,589
Pro forma earnings (loss) per common share <sup>(1)</sup> :  Basic			<del></del>	
Diluted				
Pro forma weighted-average common shares outstanding <sup>(1)</sup> :				
Basic				
Diluted				

<sup>(1)</sup> Please see Note 2 to our consolidated financial statements included elsewhere in this prospectus for an explanation of the method used to calculate earning (loss) per common share attributable to common stockholders, including the method used to calculate the number of shares used in the computation of the per share amount.

		As of March 31, 2014		
	Actual	Pro Forma (in thousands)	Pro Forma As Adjusted	
Consolidated Balance Sheet Data:		(iii tilousanus)		
Cash and cash equivalents	\$ 3,360			
Working capital <sup>(2)</sup>	36			
Total assets	9,981			
Other long-term liabilities	26,297			
Convertible redeemable preferred stock	57,071			
Total stockholders' equity (deficit)	(78,915)			

<sup>(2)</sup> Working capital is calculated as current assets minus current liabilities.

The pro forma column in the consolidated balance sheet data table above reflects the following, which will occur upon completion of this offering: (1) the automatic conversion of all outstanding shares of our convertible preferred stock into common stock; (2) the net (or cashless) exercise of warrants to acquire an estimated shares of common stock, assuming an initial offering price of \$ which is the midpoint of the initial public offering price range reflected on the cover page of this prospectus; (3) the exercise of warrants to acquire a total of shares of common stock for an aggregate exercise price of \$ ; and (4) the issuance of an estimated shares of common stock in payment of accrued dividends on outstanding shares of convertible preferred stock. The pro forma as adjusted data further adjusts the pro forma balance sheet data to reflect our sale of shares of common stock in this offering at an assumed initial public offering price of \$ per share, the midpoint of the initial public offering price range reflected on the cover page of this prospectus, and after deducting the estimated underwriting discount and offering expenses payable by us.

#### RISK FACTORS

Investing in our common stock involves a high degree of risk. You should consider carefully the risks and uncertainties described below, together with all of the other information in this prospectus, including our consolidated financial statements and related notes, before deciding whether to purchase shares of our common stock. If any of the following risks are realized, our business, financial condition, results of operations, and prospects could be adversely affected. In that event, the price of our common stock could decline and you could lose part or all of your investment in our common stock.

#### Risks Related to Our Business and Commercialization of Our Product Candidates

We have a short operating history developing clinical-stage regenerative medicine products and there is a limited amount of information about us upon which you can evaluate our product candidates and business prospects, making an investment in our common stock unsuitable for many investors.

We are a clinical-stage regenerative medicine company, formed in 2000, with a limited operating history. Since inception we have devoted substantially all of our resources to the development of our regenerative medicine 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. If NeoCart or any of our future product candidates fails in clinical trials or preclinical development, or does not gain regulatory approval, or if our product candidates following regulatory approval, if any, do not achieve market acceptance, we may never become profitable or sustain profitability.

We commenced our first clinical trial in 2005, and we have a limited operating history developing clinical-stage regenerative medicine products upon which you can evaluate our business and prospects. In addition, we have never conducted clinical trials of a size required for regulatory approvals. Further, we have not yet demonstrated an ability to successfully overcome many of the risks and uncertainties frequently encountered by companies in new and rapidly evolving fields, such as regenerative medicine. For example, to execute our current business plan we will need to successfully:

- execute our research and development strategies, including successfully completing our clinical trial program for NeoCart;
- complete the transition of the NeoCart raw material manufacturing process to our in-house facilities and satisfy the U.S. Food and Drug Administration (FDA) as to the comparability of such raw materials to those manufactured by third parties for use in our NeoCart clinical trials;
- obtain required regulatory approvals for the commercialization of NeoCart;
- manage our spending as costs and expenses increase due to clinical trials, regulatory approvals, manufacturing and commercialization;
- continue to build and maintain a strong intellectual property portfolio;
- build and maintain appropriate research and development, clinical, sales, manufacturing, financial reporting, distribution and marketing capabilities on our own or through third parties;
- secure additional funding as may be needed;
- gain broad market acceptance for our product candidates; and
- develop and maintain successful strategic relationships.

If we are unsuccessful in accomplishing any of these objectives, we may not be able to develop product candidates, raise capital, expand our business or continue our operations.

#### 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 \$16.9 million in 2012, \$25.7 million in 2013 and \$3.4 million for the three months ended March 31, 2014. As of March 31, 2014 and December 31, 2013, we had an accumulated deficit of \$114.2 million and \$110.8 million, respectively. We expect to continue to incur substantial losses for the next several years, and we expect these losses to increase as we continue our development of and seek regulatory approval for, NeoCart and our future product candidates. In addition, if we receive regulatory approval to market NeoCart or any of our future product candidates, we will incur additional losses as we scale our manufacturing operations and build an internal sales and marketing organization to commercialize any approved products. In addition, we expect our expenditures to increase as we add infrastructure and personnel to support our operations as a public company. We anticipate that our net losses and accumulated deficit for the next several years will be significant as we conduct our planned operations.

Because of the numerous risks and uncertainties associated with regenerative medicine product development, we are unable to accurately predict the timing or amount of the development and clinical expenses or when, or if we will be able to achieve, or maintain, profitability. In addition, our expenses could increase if we are required by the FDA or comparable foreign regulatory authorities to perform preclinical or clinical studies or trials in addition to those currently expected, or if there are any delays in completing the technology transfer and manufacturing location transition of our NeoCart raw material manufacturing process or completing our clinical trials or the development of NeoCart or our future product candidates. The amount of our future net losses will depend, in part, on the amount and timing of our expenses, our ability to generate revenue and our ability to raise additional capital. These net losses have had, and will continue to have, an adverse effect on our stockholders' equity and working capital.

# We may require substantial additional funding, which may not be available to us on acceptable terms, or at all, and, if not available, may require us to delay, reduce or cease our product development activities and operations.

We are currently advancing our lead product candidate NeoCart through clinical development. Developing regenerative medicine products, including conducting preclinical studies and clinical trials, is expensive. In addition to the net proceeds of this offering, we may require substantial additional capital in order to complete the clinical development of, create additional manufacturing capacity and to commercialize NeoCart and to conduct the research and development and clinical and regulatory activities necessary to bring other product candidates to market. If the FDA or comparable foreign regulatory authorities require that we perform additional preclinical studies or clinical trials at any point or expand or extend our current trials, our expenses would further increase beyond what we currently expect, and the anticipated timing of any future clinical development activities and potential regulatory approvals will likely be delayed. Raising funds in the then-current economic environment may be difficult and additional funding may not be available on acceptable terms, or at all.

The amount and timing of our future near-term funding requirements will depend on many factors, including:

- the scope, progress, expansion, costs and results of our NeoCart clinical trials;
- the timing of and costs associated with obtaining FDA approval of the comparability of the NeoCart raw materials manufactured in our facilities with the raw materials that were manufactured by third parties for the use in our NeoCart clinical trials;
- the timing of and costs involved in obtaining NeoCart regulatory approvals;
- market acceptance of NeoCart following the receipt of regulatory approval, if any;
- the costs of maintaining, expanding and protecting our intellectual property portfolio, including potential litigation costs and liabilities associated therewith:
- the resources we devote to marketing and, if approved, commercializing NeoCart;

- the scope, progress, expansion and costs of manufacturing NeoCart;
- our need to implement additional internal systems and infrastructure, including financial and reporting systems, as we become a public company;
- the amount of funds we receive in this offering; and
- the costs associated with being a public company.

Many of these factors are outside of our control. Upon the completion of this offering, based upon our currently expected level of operating expenditures, we believe that we will be able to fund our operations and sustain currently projected cash needs through at least the end of 2017. Our expectations are based on management's current assumptions and clinical development plans, which may prove to be wrong, and we could spend our available financial resources much faster than we currently expect. This period could be shortened if there are any unanticipated increases in spending on development programs. In addition, the expected net proceeds from this offering will not be sufficient to complete the advanced clinical development of all of our product candidates that would be necessary to support an application for regulatory approval. Accordingly, we will continue to require substantial additional capital beyond the expected proceeds of this offering. In order to fund our future needs, we may seek additional funding through equity or debt financings, development partnering arrangements, lines of credit or other sources.

If we are required to secure additional financing, the fundraising efforts may divert our management from our day-to-day activities, which may adversely affect our ability to develop and commercialize our product candidates. In addition, we cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all. If we are unable to raise additional capital when required or on acceptable terms, we may be required to significantly delay, reduce or discontinue the development or commercialization of one or more of our product candidates or curtail our operations, which will have an adverse effect on our business, operating results and prospects.

Failure to obtain, or any delay in obtaining, FDA approval regarding the comparability of critical NeoCart raw materials following our technology transfer and manufacturing location transition may have an adverse effect on our business, operating results and prospects.

We are in the process of planning a technology transfer to transition the manufacturing of certain raw materials and components in the NeoCart supply chain from outsourced contract manufacturers to in-house manufacturing facilities. We currently have enough of, or access to, these raw materials and components in order to supply our Phase 3 clinical trial through the end of the first quarter of 2016. If our Phase 3 clinical trial enrollment is not complete by the end of the first quarter of 2016, our technology transfer will need to be completed by that time in order to manufacture the supply of raw materials and components to complete the Phase 3 clinical trial and commercialize NeoCart upon FDA approval, if any. This technology transfer extends to the three components of the CT3 bioadhesive—methylated collagen, curing component and activated polyethylene glycol—as well as our collagen preparation and collagen honeycomb scaffold, which are used in the production of NeoCart. Although we do not anticipate changes to the raw materials, formulations or properties, nor do we anticipate changes to the NeoCart manufacturing process or finished product specifications as a result of the transfer, we are required to demonstrate to the FDA that the raw materials manufactured in the new facility are comparable to the raw materials that were manufactured in the previous contract manufacturers' facilities. Demonstrating comparability requires evidence that the product is consistent with that produced for the clinical trial to assure that the technology transfer does not affect safety, identity, purity or efficacy during the expansion from pilot scale to full scale production.

In order to obtain FDA approval of the comparability of the raw materials, we intend to submit an amendment to our existing Investigational New Drug (IND) application file for FDA pre-approval. Prior to submission of the amendment to the IND application, we plan to meet with the FDA to obtain input and agreement with respect to our technology transfer and comparability plans. We currently expect to provide the FDA with a briefing package that will include our technology transfer plan, comparability data that we will have generated from materials

produced from pilot scale test production runs and a proposed analytical comparability protocol for materials produced from full scale production runs. This demonstration is based on various methods, as recommended in FDA and the International Conference on Harmonization regulatory guidelines, as well as other FDA recognized testing standards.

The FDA may determine that such analytical data is not sufficient to prove comparability of the raw materials produced at our in-house manufacturing sites to the raw materials sourced from external vendors for earlier clinical trial work, including the Phase 3 clinical trial. If this is the case, the FDA may require that we provide additional preclinical or clinical data to provide evidence to support the comparability of the raw materials. The size, scope, length and costs of any new or supplemental clinical trials that may be required by the FDA to provide such data are not known at this time. Failure or delay in obtaining FDA approval of the comparability of our NeoCart raw materials or the FDA requiring us to provide clinical data may result in delays to our current projected timelines and could have an adverse effect on our business, operating results and prospects.

Additionally, our manufacturing sites may not receive FDA approval to operate at all, resulting in delays while we implement improvements necessary to receive approval which would lead to delays in the initiation of commercial production. In addition, we could encounter difficulties involving production yields, quality control and quality assurance, as well as shortages of qualified personnel, leading to additional delays.

#### If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

We will be required to identify and enroll a sufficient number of patients that meet inclusion criteria under investigation for NeoCart. At the time of our voluntary pause of our NeoCart Phase 3 clinical trial upon discovery of discrepancies in the testing procedures used to assess one of the raw materials utilized in the manufacture of NeoCart implants, we had enrolled 30 patients and we will need to enroll the remaining 215 patients in a timely manner in order to complete the trial on schedule. As of May 1, 2014, we had enrolled five additional patients for a total enrollment of 35 patients. There is a limited patient population from which to draw participants in clinical trials. Due to the need to find patients with few or no concomitant joint disease, we may not be able to identify and enroll a sufficient number of patients, or those with required or desired characteristics and criteria, in a timely manner. In addition, there are a limited number of specialized orthopedic surgeons that perform cartilage repair implantation procedures and among physicians who perform such procedures, some may not choose to perform these procedures under conditions that fall within our protocols, which would have an adverse effect on our development of NeoCart. Our ability to enroll patients in our clinical trials is affected by a number of factors including:

- the size and nature of the patient population;
- the design of the trial protocol;
- the eligibility and exclusion criteria for the trial in question;
- the availability of competing therapies and clinical trials, and physician and patient perception of NeoCart and our other product candidates being studied in relation to these other potential options;
- the efforts to facilitate timely enrollment in clinical trials;
- the ability to identify, solicit and recruit a sufficient number of patients;
- · the ability to obtain and maintain patient consent;
- the number and location of clinical sites we enroll;
- the proximity and availability of clinical trial sites for prospective patients;
- the availability of time and resources at the institutions where clinical trials are and will be conducted;
- the availability of raw materials and the possibility of raw materials expiring prior to their use;

- the presence of concomitant joint disease in patients under investigation;
- the study endpoints such as pain that rely on subjective patient reported outcomes;
- the ability to monitor patients adequately during and after treatment; and
- the risk that enrolled subjects will drop out before study completion.

If we have difficulty enrolling a sufficient number of patients to conduct our clinical trials as planned, we may need to delay or terminate ongoing or planned clinical trials, either of which would have an adverse effect on our business.

A number of companies in the regenerative medicine industry have suffered significant setbacks in later stage clinical trials even after achieving promising results in earlier stages of development. Success in preclinical testing and early clinical trials does not ensure that later clinical trials will be successful, and initial results from a clinical trial do not necessarily predict final results. Even if early stage clinical trials are successful, we may need to conduct additional clinical trials for product candidates in additional patient populations or under different treatment conditions before we are able to seek approvals from the FDA and regulatory authorities outside the United States to market and sell these product candidates. Our failure to demonstrate the required characteristics to support marketing approval for NeoCart and our product candidates in our planned and future clinical trials would substantially harm our business and prospects.

We are heavily dependent on the success of our lead product candidate NeoCart, which is still under development. If we are unable to commercialize NeoCart, or experience significant delays due to manufacturing or otherwise in doing so, our business will be materially harmed.

We have invested a significant portion of our time and financial resources in the development of NeoCart, our product candidate in clinical development. We anticipate that in the near term our ability to generate revenues will depend solely on the successful development and commercialization of NeoCart. We may not complete our registration filings in our anticipated time frame. Even after we complete our Biologics License Application filing, the FDA may not accept our submission, may request additional information from us, including data from additional clinical trials, and, ultimately, may not grant marketing approval for NeoCart. In addition, the clinical data we have to date often is susceptible to varying interpretations and many companies that have believed that their products performed satisfactorily in clinical trials have nonetheless failed to obtain FDA approval for their products.

If we are not successful in commercializing NeoCart, or are significantly delayed in doing so, our business will be materially harmed and we may need to curtail or cease operations. Our ability to successfully commercialize NeoCart will depend, among other things, on our ability to:

- · successfully complete our clinical trials;
- produce, through a validated process, NeoCart in quantities sufficiently large to permit successful commercialization;
- · receive marketing approvals from the FDA and similar foreign regulatory authorities;
- · launch commercial sales of NeoCart; and
- secure acceptance of NeoCart in the medical community and with third-party payors.

NeoCart and our future product candidates are subject to extensive regulation, compliance with which is costly and time consuming, may cause unanticipated delays or prevent the receipt of the approvals required to commercialize NeoCart and our future product candidates.

The clinical development, manufacturing, labeling, storage, record-keeping, advertising, promotion, import, export, marketing and distribution of NeoCart and our future product candidates are subject to extensive regulation by the FDA in the United States and by comparable authorities in foreign markets. In the United States, we are not permitted to market our product candidates until we receive regulatory approval from the FDA. The process of obtaining regulatory approval is expensive, often takes many years, and can vary substantially based upon the type, complexity, and novelty of the products involved, as well as the target indications. Approval policies or regulations may change and the FDA has substantial discretion in the tissue regeneration approval

process, including the ability to delay, limit or deny approval of a product candidate for many reasons. Despite the time and expense invested in clinical development of product candidates, regulatory approval is never guaranteed.

The FDA or comparable foreign regulatory authorities can delay, limit or deny approval of a product candidate for many reasons, including:

- such authorities may disagree with the design or implementation of our or any of our future development partners' clinical trials;
- we or any of our future development partners may be unable to demonstrate to the satisfaction of the FDA or other regulatory authorities that a product candidate is safe and effective for any indication;
- such authorities may not accept clinical data from trials which are conducted at clinical facilities or in countries where the standard of care is potentially different from the United States;
- the results of clinical trials may not demonstrate the safety or efficacy required by such authorities for approval;
- we or any of our future development partners may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- such authorities may disagree with our interpretation of data from preclinical studies or clinical trials or the use of results from studies that served as precursors to our current or future product candidates;
- such authorities may find deficiencies in our manufacturing processes or facilities or those of third-party manufacturers with which we or any of our future development partners contract for clinical and commercial supplies; or
- the approval policies or regulations of such authorities may significantly change in a manner rendering our or any of our future development partners' clinical data insufficient for approval.

With respect to foreign markets, approval procedures vary among countries and, in addition to the risks described above, can involve additional product testing, administrative review periods, and agreements with pricing authorities. In addition, events raising questions about the safety of certain marketed pharmaceuticals or biologics may result in increased cautiousness by the FDA and comparable foreign regulatory authorities in reviewing new tissue regeneration products based on safety, efficacy or other regulatory considerations and may result in significant delays in obtaining regulatory approvals. Any delay in obtaining, or inability to obtain, applicable regulatory approvals would prevent us or any of our future development partners from commercializing our product candidates.

NeoCart or any future product candidate we or any of our future development partners advance into clinical trials may cause unacceptable adverse events or have other properties that may delay or prevent its regulatory approval or limit its commercial potential.

Unacceptable adverse events caused by any of our product candidates that we advance into clinical trials could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in the denial of regulatory approval by the FDA or other regulatory authorities for any or all targeted indications and markets. This in turn could prevent us from completing development or commercializing the affected product candidate and generating revenue from its sale.

We have not yet completed testing of any of our product candidates for the treatment of the indications for which we intend to seek approval, and we currently do not know the extent of adverse events, if any, that will be observed in individuals who receive any of our product candidates. If any of our product candidates cause unacceptable adverse events in clinical trials, we may not be able to obtain regulatory approval or commercialize such product candidate.

The results of preclinical studies and early clinical trials are not always predictive of future results. Any product candidate we or any of our future development partners advance into clinical trials may not have favorable results in later clinical trials, if any, or receive regulatory approval.

Regenerative medicine product development has inherent risk. We or any of our future development partners will be required to demonstrate through adequate and well-controlled clinical trials that our product candidates are effective, with a favorable benefit-risk profile, for use in their target indications before we can seek regulatory approvals for their commercial sale. Regenerative medicine product development is a long, expensive and uncertain process, and delay or failure can occur at any stage of development, including after commencement of any of our clinical trials. In addition, success in early clinical trials does not mean that later clinical trials will be successful because product candidates in later-stage clinical trials may fail to demonstrate sufficient safety or efficacy despite having progressed through initial clinical testing. Furthermore, our future trials will need to demonstrate sufficient safety and efficacy for approval by regulatory authorities in larger patient populations. Companies frequently suffer significant setbacks in advanced clinical trials, even after earlier clinical trials have shown promising results. In addition, only a small percentage of biologics under development result in the submission of a New Drug Application or Biologic Licensing Application to the FDA and even fewer are approved for commercialization.

We are subject to a multitude of manufacturing risks, any of which could substantially increase our costs and limit supply of our products.

The process of manufacturing NeoCart is complex, highly regulated and subject to several risks, including:

- The process of manufacturing NeoCart, including the use of autologous cells, is susceptible to product loss due to contamination, equipment failure or improper installation or operation of equipment, or surgeon or laboratory technician error. Even minor deviations from normal manufacturing processes could result in lost NeoCart production runs, product defects and other supply disruptions. If microbial, viral or other contaminations are discovered in our products or in the manufacturing process or facilities in which our products are made, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination.
- The manufacturing facilities in which NeoCart is made could be adversely affected by equipment failures, labor shortages, natural disasters, power failures and numerous other factors. For instance, in 2012, we voluntarily suspended manufacturing operations and paused enrollment of the NeoCart Phase 3 clinical trial upon discovery of discrepancies in the testing procedures used to assess one of the raw materials utilized in the manufacture of NeoCart implants and we could be required in the future to suspend manufacturing due to circumstances out of our control.
- We and our contract manufacturers, if any, must comply with the current Good Manufacturing Practices (cGMP) regulations and guidelines promulgated by the FDA. We and our contract manufacturers, if any, may encounter difficulties in achieving quality control and quality assurance and may experience shortages in qualified personnel. We and our contract manufacturers, if any, are subject to inspections by the FDA and comparable agencies in other jurisdictions to confirm compliance with applicable regulatory requirements. Any failure to follow cGMP or other regulatory requirements or delay, interruption or other issues that arise in the manufacture, packaging, storage or shipping of our products as a result of a failure of our facilities or operations, or the facilities or operations of third parties, to comply with regulatory requirements or pass any regulatory authority inspection could significantly impair our ability to develop and commercialize our products, including leading to significant delays in the availability of products for our clinical studies or the termination or hold on a clinical study, or the delay or prevention of a filing or approval of marketing applications for our product candidates. Significant noncompliance could also result in the imposition of sanctions, including fines, injunctions, civil penalties, failure of regulatory authorities to grant marketing approvals for our product candidates, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of products, operating restrictions and criminal prosecutions, any of

- which could damage our reputation. If we are not able to maintain regulatory compliance, we may not be permitted to market our products or may be subject to product recalls, seizures, injunctions, or criminal prosecution.
- Any adverse developments affecting manufacturing operations for our products may result in shipment delays, inventory shortages, lot failures, product withdrawals or recalls, or other interruptions in the supply of our products. We may also have to take inventory write-offs and incur other charges and expenses for products that fail to meet specifications, undertake costly remediation efforts or seek more costly manufacturing alternatives.

In order to manufacture NeoCart, we operate our own cGMP manufacturing facility in Waltham, Massachusetts for production of NeoCart. We are in the process of locating and subsequently developing a facility for our cGMP manufacturing in the Waltham, Massachusetts area which we plan to build out to produce key NeoCart raw materials, including CT3 components, collagen and scaffold. While we own the manufacturing process, unforeseen issues or outside influences could impact potential supply. For example:

- Our facility in Waltham may not meet FDA cGMP standards during the pre-approval inspection necessary for Biologic Licensing Application approval, delaying Biologic Licensing Application approval and resulting in added cost to mitigate issues identified during inspection.
- The anticipated site that we plan to build out for production of key raw materials may not be completed on our current schedule and once completed may not receive FDA approval to operate, resulting in delays while we implement improvements necessary to receive approval, leading to delays in the initiation of commercial production. We plan to meet with FDA during the course of 2014 to obtain the FDA's input and agreement with respect to our technology transfer and comparability plans.
- The raw material to be produced at the new facility site may not be comparable to the raw materials sourced from external vendors for earlier clinical trial work, including the ongoing NeoCart Phase 3 clinical trial, according to our current projected timelines, and the FDA may delay approval of the new raw material source or require additional studies to show comparability.
- We may not achieve our anticipated production throughput targets, resulting in lower than anticipated capacity, limiting supply of our products, lowering revenue and increasing costs. We may not hit our production cost target for a variety of reasons including increased raw material cost, underestimate of labor requirements, underestimate of capital requirement and other facility, personnel or materials issues that we have not anticipated. Increased costs will adversely impact gross margin achieved by our products.
- The FDA may not approve implementation of the multi-unit NeoCart reactor or approval may be delayed, which could result in capacity limitation or high unit costs, depending upon the length of the delay.

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.

We are a party to technology licenses that are important to our business and we may enter into additional licenses in the future. We currently hold material licenses from Purpose Co., Ltd., Angiotech Pharmaceuticals (US), Inc., Angiodevice International GmbH, the Board of Trustees of The Leland Stanford Junior University, Yeda Research and Development Co., Ltd., Koken Co., Ltd. and Advanced BioMatrix, Inc. The rights licensed under these agreements, including rights relating to our scaffolds, tissue processor, bioadhesives and growth factors, are material to our regenerative medicine platform and the continued development of NeoCart and our future product candidates. 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 our 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.

Development of regenerative medicine products is inherently expensive and risky and may not be understood by or accepted in the marketplace, which could adversely affect our future value.

The clinical development, commercialization and marketing of regenerative medicine products are at an early-stage, substantially research-oriented, and financially speculative. To date, very few companies have been successful in their efforts to develop and commercialize regenerative medicine products. In general, regenerative medicine products may be susceptible to various risks, including undesirable and unintended side effects, unintended immune system responses, inadequate therapeutic efficacy, potentially prohibitive costs or other characteristics that may prevent or limit their approval or commercial use. Furthermore, the number of people who may use cell- or tissue-based regenerative medicine therapies is difficult to forecast with accuracy. Our future success is dependent on the establishment of a large global market for regenerative medicine products and our ability to capture a share of this market with NeoCart and our future product candidates.

Our development efforts with our regenerative medicine platform are susceptible to the same risks of failure inherent in the development and commercialization of product candidates based on new technologies. The novel nature of regenerative medicine products creates significant challenges in the areas of product development and optimization, manufacturing, government regulation, third-party reimbursement and market acceptance. For example, the FDA has relatively limited experience regulating cell- or tissue-based regenerative medicine therapies, and there are few approved treatments utilizing regenerative medicine products.

Even if we successfully develop and obtain regulatory approval for NeoCart and our future product candidates, the market may not understand or accept them. NeoCart and our future product candidates represent novel treatments and are expected to compete with a number of surgical options and more conventional products and therapies manufactured and marketed by others, including major pharmaceutical and biotechnology companies. The degree of market acceptance of any of our developed and potential product candidates will depend on a number of factors, including:

- the clinical safety and effectiveness of NeoCart and our future product candidates and their perceived advantage over alternative treatment methods, if any;
- adverse events involving NeoCart and our future product candidates or the products or product candidates of others; and
- the cost of our products and the reimbursement policies of government and private third-party payors.

If the health care community does not accept NeoCart or our future product candidates for any of the foregoing reasons, or for any other reason, it could affect our sales, having an adverse effect on our business, financial condition and results of operations.

We will need additional capital to develop and commercialize our product candidates including NeoCart, and we may be unable to raise additional capital when needed at all, which could force us to reduce or discontinue such product candidates.

The amount and timing of our future, long-term funding requirements will depend on many factors, including:

- the type, number, costs and results of the product candidate development programs which we are pursuing or may choose to pursue in the future;
- the scope, progress, expansion, costs and results of our clinical trials;
- the timing of and costs involved in obtaining regulatory approvals;
- market acceptance of any products for which we receive approval;
- our ability to establish and maintain development partnering arrangements;

- the timing, receipt and amount of contingent, royalty and other payments from our future development partners, if any;
- the emergence of competing technologies and other adverse market developments;
- the costs of maintaining, expanding and protecting our intellectual property portfolio, including potential litigation costs and liabilities;
- the resources we devote to marketing and, if approved, commercializing our product candidates;
- the scope, progress, expansion and costs of manufacturing our product candidates; and
- the costs of financing the purchases of additional capital equipment and development technologies.

If we are unable to raise additional funding for our product candidates, including NeoCart, when needed, we may be required to delay, reduce or terminate some or all of our development programs and clinical trials. We may be required to sell or license to others our technologies, product candidates or development programs that we would have preferred to develop and commercialize ourselves.

If our competitors develop treatments for the target indications of NeoCart or our future product candidates that are approved more quickly, marketed more successfully or demonstrated to be safer or more effective than our product candidates, our commercial opportunity will be reduced or eliminated.

The regenerative medicine industry is intensely competitive and subject to rapid and significant technological change. We face competition from major multinational companies, established and early-stage biotechnology companies, and universities and other research institutions. Many of our competitors have greater financial and other resources, such as larger research and development staff and more experienced marketing and manufacturing organizations. Large pharmaceutical companies, in particular, have extensive experience in clinical testing, obtaining regulatory approvals, recruiting patients and manufacturing products. These companies also have significantly greater research, sales and marketing capabilities and collaborative arrangements in our target markets with leading companies and research institutions. Established companies may also invest heavily to accelerate discovery and development of novel therapeutics or to in-license novel therapeutics that could make the product candidates that we develop obsolete. As a result of all of these factors, our competitors may succeed in obtaining patent protection or FDA approval or discovering, developing and commercializing treatments in the regenerative medicine indications that we are targeting before we do. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies.

There are several clinical-stage development programs in various stages of development that seek to regenerate soft tissue and repair cartilage. In addition, many universities and private and public research institutes may develop technologies that are relevant to our product candidates, but license them to our competitors. Our competitors may succeed in developing, acquiring or licensing on an exclusive basis, technologies and products that are more effective, including a one-step alternative to NeoCart, or less costly than NeoCart or any future product candidates that we may develop, which could render our products obsolete and noncompetitive.

We believe that our ability to successfully compete will depend on, among other things:

- the results of our preclinical studies and clinical trials;
- our ability to recruit and enroll patients for our clinical trials;
- the efficacy, safety and reliability of our product candidates;
- the speed at which we develop our product candidates;
- our ability to design and successfully execute appropriate clinical trials;
- our ability to protect and develop intellectual property rights related to our products;
- our ability to maintain a good relationship with regulatory authorities;

- the timing and scope of regulatory approvals, if any;
- our ability to commercialize and market any of our product candidates that receive regulatory approval;
- market perception and acceptance of regenerative medicine products;
- acceptance of our product candidates by physicians, patients and institutions;
- the price of our products;
- · adequate levels of reimbursement under private and governmental health insurance plans, including Medicare; and
- our ability to manufacture and sell commercial quantities of any approved products to the market.

If our competitors market products that are more effective, safer or less expensive than our future products or that reach the market sooner than our future products, we may not achieve commercial success. Any inability to compete effectively will adversely impact our business and financial prospects.

# We have a limited manufacturing capacity for NeoCart and our future product candidates, which could inhibit the long-term growth prospects of this business.

We currently produce materials for clinical trials, including production of NeoCart, at our existing manufacturing facilities in Waltham, Massachusetts, which we have designed and operated to be compliant with FDA, cGMP and the current Good Tissue Practice as and if applicable, requirements. We estimate that we can produce approximately 500 NeoCart units per year in our existing facility once all equipment is purchased and operational. While we believe these facilities provide us with sufficient capacity to meet our expected clinical demand and possibly our commercial launch demand, it is possible that the demand for products could exceed our existing manufacturing capacity. It will become necessary or desirable for us to expand our manufacturing capabilities for our regenerative medicine platform in the future, which may require us to invest significant amounts of capital and to obtain regulatory approvals. If we are unable to meet rising demand for products on a timely basis or unable to maintain cGMP compliance standards, then it is likely that our clients and potential clients will elect to obtain the products from competitors, which could materially and adversely affect the level of our revenues and our prospects for growth.

The current tissue engineering processor (TEP) in our Waltham facility is resource dependent due to the single-unit capacity. We are developing a multi-unit NeoCart reactor design which would alleviate the capacity restraints currently resulting from our single-unit processors and will increase capacity to 2,500 units per year at the existing Waltham, Massachusetts facility. We currently expect to begin implementation of a multi-reactor unit during the first year of product commercialization, thus providing adequate capacity to meet expected demand through the first two years of commercialization from our Waltham facility. The FDA may not, however, approve implementation of the multi-unit NeoCart reactor or approval may be delayed which could result in capacity limitation or high unit costs depending upon the length of the delay. We are collaborating with ST3 Development Corporation to design the multi-unit reactor.

Components of regenerative medicine products approved for commercial sale or used in late-stage clinical trials must be manufactured in accordance with cGMP. In addition, the manufacturing process of regenerative medicine products may be required to be modified from time to time in response to FDA requests. Manufacture of cell- or tissue-based regenerative medicine products is complex and subjects companies to significant regulatory burdens that may change over time. We may encounter difficulties in the production of our product candidates due to our limited manufacturing experience.

# If we are not successful in discovering, developing, acquiring and commercializing additional product candidates, our ability to expand our business will be limited.

A substantial amount of our effort is focused on the continued clinical testing and potential approval of NeoCart and our future product candidates and expanding our product candidates to serve other indications of high unmet

medical needs. Research programs to identify other indications require substantial technical, financial and human resources, whether or not any product candidates for other indications are ultimately identified. Our research programs may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development for many reasons, including the following:

- the research methodology used may not be successful in identifying potential product candidates;
- competitors may develop alternatives that render our product candidates obsolete or less attractive;
- product candidates we develop may nevertheless be covered by third parties' patents or other exclusive rights;
- a product candidate may on further study be shown to have harmful side effects or other characteristics that indicate it is unlikely to be effective or otherwise does not meet applicable regulatory criteria;
- a product candidate may not be capable of being produced in commercial quantities at an acceptable cost, or at all; and
- a product candidate may not be accepted as safe and effective by patients, the medical community or third-party payors, if applicable.

If we do not successfully develop and commercialize product candidates for other indications, our business and future prospects may be limited and our business will be more vulnerable to problems that we encounter in developing and commercializing our current product candidates.

We may experience delays in commencing or conducting our clinical trials or in receiving data from third parties or in the completion of clinical testing, which could result in increased costs to us and delay our ability to generate product candidate revenue.

Before we can initiate clinical trials in the United States for our product candidates, we need to submit the results of preclinical testing to the FDA as part of an IND application, along with other information including information about product candidate chemistry, manufacturing and controls and our proposed clinical trial protocol. We may rely in part on preclinical, clinical and quality data generated by contract research organization and other third parties for regulatory submissions for our product candidates. If these third parties do not make timely regulatory submissions for our product candidates, it will delay our plans for our clinical trials. If those third parties do not make this data available to us, we will likely have to develop all necessary preclinical and clinical data on our own, which will lead to significant delays and increase development costs of the product candidate. In addition, the FDA may require us to conduct additional preclinical testing for any product candidate before it allows us to initiate clinical testing under any IND application, which may lead to additional delays and increase the costs of our preclinical development. Despite the presence of an active IND application for a product candidate, clinical trials can be delayed for a variety of reasons including delays in:

- identifying, recruiting and training suitable clinical investigators;
- reaching agreement on acceptable terms with prospective contract research organizations and trial sites, the terms of which can be subject to extensive negotiation, may be subject to modification from time to time, and may vary significantly among different contract research organizations and trial sites;
- obtaining sufficient quantities of a product candidate for use in clinical trials, including as a result of transferring the manufacturing of a product candidate to another site or manufacturer:
- obtaining and maintaining institutional review board or ethics committee approval to conduct a clinical trial at an existing or prospective site;
- identifying, recruiting and enrolling subjects to participate in a clinical trial; and

• retaining or replacing participants who have initiated a clinical trial but may withdraw due to adverse events from the therapy, insufficient efficacy, fatigue with the clinical trial process, or personal issues.

The FDA may also put a clinical trial on clinical hold at any time during product candidate development. In addition, we may voluntarily pause a clinical trial for a variety of reasons. For instance, in 2012 we voluntarily suspended manufacturing operations and paused enrollment of the NeoCart Phase 3 clinical trial upon discovery of discrepancies in the testing procedures used to assess one of the raw materials utilized in the manufacture of NeoCart implants and we could be required in the future to suspend manufacturing due to circumstances out of our control.

Once a clinical trial has begun, it may also be delayed as a result of ambiguous or negative interim results. Further, a clinical trial may be suspended or terminated by us, an institutional review board, an ethics committee or a data safety monitoring committee overseeing the clinical trial, any of our clinical trial sites with respect to that site or the FDA or other regulatory authorities due to a number of factors, including:

- failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols;
- inspection of the clinical trial operations or clinical trial site by the FDA or other regulatory authorities;
- unforeseen safety issues, known safety issues that occur at a greater frequency or severity than we anticipate, or any determination that the clinical trial presents unacceptable health risks; or
- lack of adequate funding to continue the clinical trial.

Any delays in the commencement of our clinical trials will delay our ability to pursue regulatory approval for our product candidates. Changes in U.S. and foreign regulatory requirements and guidance also may occur and we may need to amend clinical trial protocols to reflect these changes. Amendments may require us to resubmit our clinical trial protocols to institutional review boards for re-examination, which may affect the costs, timing and likelihood of a successful completion of a clinical trial. If we or any of our future development partners experience delays in the completion of, or if we or any of our future development partners must terminate, any clinical trial of any product candidate our ability to obtain regulatory approval for that product candidate will be delayed and the commercial prospects, if any, for the product candidate may suffer as a result. In addition, many of these factors may also ultimately lead to the denial of regulatory approval of a product candidate.

Regulatory authorities, including the FDA and the European Medicines Agency, may disagree with our interpretations of data from pre-clinical studies and clinical trials. Regulatory authorities also may approve a product for narrower indications than requested or may grant approval subject to the performance of post-marketing studies for a product. There can be no guarantee that such post-approval studies, if required, will corroborate the results of earlier trials. Furthermore, the market use of such products may show different safety and efficacy profiles to those demonstrated in the trials on which marketing approval was based. Such circumstances could lead to the withdrawal or suspension of marketing approval for the product, which could have a material adverse effect on our business, financial condition, operating results or cash flows. In addition, regulatory authorities may not approve or agree with the labeling claims that are necessary or desirable for the successful commercialization of our products.

If NeoCart or any future product candidate that we successfully develop does not achieve broad market acceptance among physicians, patients, healthcare payors and the medical community, the revenue that it generates may be limited.

Even if NeoCart or our future product candidates receive regulatory approval, they may not gain market acceptance among physicians, patients, healthcare payors and the medical community. Coverage and

reimbursement of our product candidates by third-party payors, including government payors, generally is also necessary for commercial success. The degree of market acceptance of any approved product candidates will depend on a number of factors, including:

- the efficacy and safety as demonstrated in clinical trials;
- the clinical indications for which the product candidate is approved;
- acceptance by physicians, major operators of hospitals and clinics and patients of the product candidate as a safe and effective treatment;
- the potential and perceived advantages of product candidates over alternative treatments;
- · the safety of product candidates seen in a broader patient group, including their use outside the approved indications;
- the cost of treatment in relation to alternative treatments;
- the availability of adequate reimbursement and pricing by third parties and government authorities;
- relative convenience and ease of administration;
- the prevalence and severity of adverse events;
- the effectiveness of our sales and marketing efforts; and
- · unfavorable publicity relating to the product candidate or regenerative medicine products, in general.

If any product candidate is approved but does not achieve an adequate level of acceptance by physicians, hospitals, healthcare payors and patients, we may not generate sufficient revenue from that product candidate and may not become or remain profitable. Ethical, social and legal concerns about regenerative medicine products could result in additional regulations restricting or prohibiting the use of our product candidates.

Insurance coverage and reimbursement may be limited or unavailable in certain market segments for our product candidates, which could make it difficult for us to sell our product candidates profitably.

Market acceptance and sales of NeoCart and our future product candidates will depend significantly on the availability of adequate insurance coverage and reimbursement from third-party payors for any of our product candidates and may be affected by existing and future health care reform measures. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which medical treatments they will pay for and establish reimbursement levels. Reimbursement by a third-party payor may depend upon a number of factors including the third-party payor's determination that use of a product candidate is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- · cost effective; and
- · neither experimental nor investigational.

Obtaining coverage and reimbursement approval for a product candidate from a government or other third-party payor is a time-consuming and costly process that could require us to provide supporting scientific, clinical and cost effectiveness data for the use of our product candidates to the payor. We may not be able to provide data sufficient to gain acceptance with respect to coverage and reimbursement. We cannot be sure that coverage or adequate reimbursement will be available for any of our product candidates. Also, we cannot be sure that

reimbursement amounts will not reduce the demand for, or the price of, NeoCart or our future product candidates. If reimbursement is not available or is available only to limited levels, we may not be able to commercialize certain of our product candidates profitably, or at all, even if approved.

In the United States and certain foreign jurisdictions, there have been a number of legislative and regulatory changes to health care systems that could affect our ability to sell our product candidates profitably. In particular, in 2003 the Medicare Modernization Act revised the payment methods for many product candidates under Medicare. This has resulted in lower rates of reimbursement. There have been numerous other federal and state initiatives designed to reduce payment for products.

As a result of legislative proposals and the trend toward managed health care in the United States, third-party payors are increasingly attempting to contain healthcare costs by limiting both coverage and the level of reimbursement of new tissue regenerative medicine products. They may also refuse to provide coverage of approved product candidates for medical indications other than those for which the FDA has granted market approvals. As a result, significant uncertainty exists as to whether and how much third-party payors will reimburse patients for their use of newly approved regenerative medicine products, which in turn will put pressure on the pricing of such products. We expect to experience pricing pressures in connection with the sale of our product candidates due to the trend toward managed health care, the increasing influence of health maintenance organizations, and additional legislative proposals as well as country, regional, or local healthcare budget limitations.

In addition, reimbursement agencies in foreign jurisdictions may be more conservative than those in the United States. Accordingly, in markets outside the United States, the reimbursement for our products may be more limited than in the United States and may be insufficient to generate commercially reasonable revenues and profits.

Failure to obtain or maintain adequate reimbursement for any products for which we receive marketing approval will adversely impact our ability to achieve commercial success.

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 and our future product candidates in clinical trials and the sale of any products for which we obtain marketing approval 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 our product candidates may induce adverse events, and that such adverse events may not be detected for a long period of time. If we cannot successfully defend against product liability claims, we could incur substantial liability and costs. In addition, regardless of merit or eventual outcome, product liability claims may result in:

- impairment of our business reputation;
- · withdrawal of clinical trial participants;
- termination of clinical trial sites or entire trial programs;
- increased costs due to related litigation;
- distraction of management's attention from our primary business;
- substantial monetary awards to patients or other claimants;
- · the inability to commercialize our product candidates; and
- decreased demand for our product candidates, if approved for commercial sale.

We carry product liability insurance that we believe is sufficient in light of our current 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. If and when we obtain marketing approval for product candidates, we intend to expand our insurance coverage to include the sale of commercial products; however, we may be unable to obtain product liability insurance on commercially reasonable terms or in adequate amounts. On occasion, large judgments have been awarded in class action lawsuits based on regenerative medicine products or medical treatments that had unanticipated adverse effects. In addition, under some of our agreements with clinical trial sites, we are 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 and, if judgments exceed our insurance coverage, could adversely affect our results of operations and business.

During the course of treatment, patients may suffer adverse events for reasons that may be related to our product candidates. Such events could subject us to costly litigation, require us to pay substantial amounts of money to injured patients, delay, negatively impact or end our opportunity to receive or maintain regulatory approval to market our products, or require us to suspend or abandon our commercialization efforts. Even in a circumstance in which we do not believe that an adverse event is related to our products, the investigation into the circumstance may be time-consuming or inconclusive. These investigations may interrupt our development and commercialization efforts, delay our regulatory approval process, or impact and limit the type of regulatory approvals our product candidates receive or maintain. As a result of these factors, a product liability claim, even if successfully defended, could have a material adverse effect on our business, financial condition or results of operations.

We do not carry insurance for all categories of risk that our business may encounter and we may not be able to 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.

If we are unable to establish sales and marketing capabilities or fail to enter into agreements with third parties to market and sell any product candidates we may successfully develop, we may not be able to effectively market and sell any such product candidates.

We have no experience selling and marketing any products. We do not currently have any infrastructure for the sale, marketing and distribution of any of our product candidates once approved, if at all, and we must build this infrastructure in order to commercialize any product candidates for which we may obtain approval in the United States or make arrangements with third parties to perform these functions for us outside of the United States. To successfully commercialize any products that may result from our development programs, we will need to develop these capabilities, either on our own or with others. The establishment and development of a sales force, either by us or jointly with a development partner, or the establishment of a contract sales force to market any product candidates we may develop will be expensive and time consuming and could delay any commercial launch. If we or any of our future development partners are unable to establish sales and marketing capabilities or any other nontechnical capabilities necessary to commercialize any product candidates we may successfully develop, we will need to contract with third parties to market and sell such product candidates. We may not be able to establish arrangements with third parties on acceptable terms, if at all.

Legislative or regulatory healthcare reforms in the United States and abroad may make it more difficult and costly for us to obtain regulatory approval of our product candidates and to produce, market and distribute our products after 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 our business and our products. 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. 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 one or more of our products;
- · the payment of additional taxes; or
- additional record keeping.

Each of these requirements would likely entail substantial time and cost and could adversely harm our business and our financial results. In addition, delays in receipt of or failure to receive regulatory approvals for any future products would harm our business, financial condition and results of operations. We intend to seek approval to market our product candidates in both the United States and in foreign jurisdictions. If we obtain approval in one or more foreign jurisdictions, we will be subject to rules and regulations in those jurisdictions relating to such product candidate. If reimbursement of our future products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, we may be unable to achieve or sustain profitability.

We currently rely on third parties in order to perform certain aspects of our business, including to support certain aspects of our clinical trials and to supply the NeoCart tissue engineering processor. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our product candidates and our business could be substantially harmed.

We have relied upon and plan to continue to rely upon third parties to monitor and manage data for our ongoing clinical programs. We rely on these parties for execution of our clinical trials, and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol and legal, regulatory and scientific standards, and our reliance on third parties does not relieve us of our regulatory responsibilities. We also rely on third parties to assist in conducting our nonclinical studies in accordance with good laboratory practices. We and our third-party service providers are required to comply with good clinical practices, which are regulations and guidelines enforced by the FDA, as well as comparable foreign regulations and guidelines, for all of our product candidates in clinical development. Regulatory authorities enforce these good clinical practices through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of our third-party service providers or clinical trial sites fail to comply with applicable good clinical practices, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with good clinical practices requirements. In addition, our clinical trials must be conducted with product produced under applicable good manufacturing practices requirements. Failure to comply with these regulations may require us to repeat nonclinical and clinical trials, which would delay the regulatory approval process.

Our third-party service providers are not our employees, and except for remedies available to us under our agreements with such third parties, we cannot control whether or not they devote sufficient time and resources to our on-going clinical and nonclinical programs. If third-party service providers do not successfully carry out their contractual duties or obligations or meet expected deadlines or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. As a result, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenues could be delayed.

Because we have relied on third parties, our internal capacity to perform these functions is limited. Outsourcing these functions involves risk that third parties may not perform to our standards, may not produce results in a timely manner or may fail to perform at all. In addition, the use of third-party service providers requires us to disclose our proprietary information to these parties, which could increase the risk that this information will be misappropriated. We currently have a small number of employees, which limits the internal resources we have available to identify and monitor our third-party service providers. To the extent we are unable to identify and successfully manage the performance of third-party service providers in the future, our business may be adversely affected. Although we carefully manage our relationships with our third-party service providers, there can be no assurance that we will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects.

We are also dependent on third-party suppliers, most of which are sole source suppliers of the components used to manufacture our TEP. If these third-party suppliers do not supply sufficient quantities to us on a timely basis and in accordance with applicable specifications and other regulatory requirements, there could be a significant interruption of our ability to supply, which would adversely affect clinical development or commercial production of the product candidate. Furthermore, if any of these third parties cannot successfully supply TEPs that we require for our production that conforms to our specifications and with regulatory requirements, we will not be able to meet demand, for our product candidates.

We do not expect to have the resources or capacity to commercially manufacture TEPs required to manufacture our proposed product candidates if approved, and will likely continue to be dependent on third-party suppliers. Our dependence on third parties to manufacture and supply us with these TEPs may adversely affect our ability to develop and commercialize our product candidates on a timely basis.

We may not be successful in establishing and maintaining development or other strategic partnerships, which could adversely affect our ability to develop and commercialize product candidates.

As part of our strategy, we intend to enter into development or other strategic partnerships in the future, including collaborations with major biotechnology or pharmaceutical companies. We face significant competition in seeking appropriate partners and the negotiation process is time consuming and complex. Moreover, we may not be successful in our efforts to establish a development partnership or other alternative arrangements for any of our other existing or future product candidates and programs because our research and development pipeline may be insufficient, our product candidates and programs may be deemed to be at too early a stage of development for collaborative effort or third parties may not view our product candidates and programs as having the requisite potential to demonstrate safety and efficacy. Even if we are successful in our efforts to establish development partnerships, the terms that we agree upon may not be favorable to us and we may not be able to maintain such development partnerships if, for example, development or approval of a product candidate is delayed or sales of an approved product candidate are disappointing. Any delay in entering into development partnership agreements related to our product candidates could delay the development and commercialization of our product candidates and reduce their competitiveness if they reach the market.

Moreover, if we fail to establish and maintain development or other strategic partnerships related to our product candidates:

- the development of certain of our current or future product candidates may be terminated or delayed;
- our cash expenditures related to development of certain of our current or future product candidates would increase significantly and we may need to seek additional financing;
- we may be required to hire additional employees or otherwise develop expertise, such as sales and marketing expertise, for which we have not budgeted; and
- we will bear all of the risk related to the development of any such product candidates.

#### We may need to expand our operations and increase the size of our company and we may experience difficulties in managing any such growth.

As we continue to advance NeoCart towards potential commercialization, increase the number of ongoing product development programs and advance our future product candidates through preclinical studies and clinical trials, we will need to expand our development, regulatory, manufacturing, marketing and sales capabilities and, in some cases, collaborate and contract with third parties to provide these capabilities for us. Our management, personnel and systems currently in place may not be adequate to support this future growth. Our need to effectively manage our operations, growth and various projects requires that we:

- successfully attract and recruit new employees or consultants with the requisite expertise and experience;
- manage our clinical programs effectively;
- develop a marketing and sales infrastructure if we receive regulatory approval for any product candidate;
- continue to improve our operational, financial and management controls, reporting systems and procedures, including those related to being a
  public company; and
- construct, validate and effectively operate new and expanded manufacturing facilities.

If we are unable to successfully manage this growth and increased complexity of operations, our business may be adversely affected.

# If we fail to hire and effectively integrate new executive officers into our organization, the future development and commercialization of our product candidates may suffer, harming future regulatory approvals, sales of our product candidates or our results of operations.

Our current management team has only been working together for a relatively short period of time and a majority of our current management team has been employed by us for less than a year. In addition, effective as of February 28, 2014, Peter Greenleaf resigned as our president and chief executive officer and as one of our directors. Adam Gridley joined us as our president and chief executive officer in May 2014 and we expect to continue to expand our management team in the future. Our future performance will depend significantly on our ability to successfully integrate our new chief executive officer and other recently and subsequently hired executive officers into our management team, and on those officers' ability to develop and maintain an effective working relationship. Our failure to integrate recently and subsequently hired executive officers, including our new chief executive officer, with other members of management could result in inefficiencies in the development and commercialization of our product candidates, harming future regulatory approvals, sales of our product candidates and our results of operations.

# We may not be able to manage our business effectively if we are unable to attract and retain key personnel and consultants, including a qualified new chief executive officer.

Given the specialized nature of regenerative cell therapy and that it is a relatively new field, there is an inherent scarcity of experienced personnel in the field. We may not be able to attract or retain qualified management (including a new chief executive officer), finance, scientific and clinical personnel and consultants due to the intense competition for qualified personnel and consultants among biotechnology, pharmaceutical and other businesses. If we are not able to attract and retain necessary personnel and consultants to accomplish our business objectives, we may experience constraints that will significantly impede the achievement of our development objectives, our ability to raise additional capital and our ability to implement our business strategy.

Our industry has experienced high turnover of management personnel in recent years. We are highly dependent on the development, regulatory, commercialization and business development expertise of our senior management team. The loss of Mr. Gridley or one or more additional executive officers or key employees, could

seriously harm our ability to implement our business strategy successfully. While we have entered into employment contracts with each of our executive officers, including our new chief executive officer, any of them could leave our employment at any time, as all of our employees are at-will employees. Replacing key personnel and consultants may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to develop, gain regulatory approval of and commercialize products successfully. Competition to hire and retain employees and consultants from this limited pool is intense, and we may be unable to hire, train, retain or motivate these additional key personnel and consultants. Our failure to retain key personnel or consultants could materially harm our business, and the transition to any replacement personnel, particularly at the chief executive officer position, may cause or result in:

- speculation and uncertainty about our business and future direction;
- · distraction of our employees and management;
- difficulty in recruiting, hiring, motivating and retaining talented and skilled personnel;
- · volatility in our stock price; and
- difficulty in negotiating, maintaining or consummating business or strategic relationships or transactions.

We rely on our scientific and clinical advisors and consultants to assist us in formulating our research, development and clinical strategies. These advisors and consultants are not our employees and may have commitments to, or consulting or advisory contracts with, other entities that may limit their availability to us. In addition, these advisors and consultants typically will not enter into non-compete agreements with us. If a conflict of interest arises between their work for us and their work for another entity, we may lose their services. Furthermore, our advisors may have arrangements with other companies to assist them in developing products or technologies that may compete with ours. If we are unable to maintain consulting relationships with our key advisors or consultants or if they provide services to our competitors, our development and commercialization efforts will be impaired, and our business will be significantly harmed.

Our independent registered public accounting firm has included an explanatory paragraph relating to our ability to continue as a going concern in its report on our audited financial statements included in this prospectus.

Our audited consolidated financial statements at December 31, 2013 and for the year then ended were prepared assuming that we will continue as a going concern. However, the report of our independent registered public accounting firm included elsewhere in this prospectus contains an explanatory paragraph on our consolidated financial statements stating there is substantial doubt about our ability to continue as a going concern, meaning that we may not be able to continue in operation for the foreseeable future or be able to realize assets and discharge liabilities in the ordinary course of operations. Such an opinion could materially limit our ability to raise additional funds through the issuance of new debt or equity securities or otherwise. There is no assurance that sufficient financing will be available when needed to allow us to continue as a going concern. The perception that we may not be able to continue as a going concern may also make it more difficult to operate our business due to concerns about our ability to meet our contractual obligations.

Failure to build our finance infrastructure and improve our accounting systems and controls could impair our ability to comply with the financial reporting and internal control requirements for publicly traded companies.

As a public company, we will operate in an increasingly demanding regulatory environment, which requires us to comply with the Sarbanes-Oxley Act and the related rules and regulations of the SEC, expanded disclosure requirements, accelerated reporting requirements and more complex accounting rules. Company responsibilities required by the Sarbanes-Oxley Act include establishing corporate oversight and adequate internal control over financial reporting and disclosure controls and procedures. Effective internal controls are necessary for us to produce reliable financial reports and are important to help prevent financial fraud.

Pursuant to Section 404 of the Sarbanes-Oxley Act and related rules, our management will be required to report upon the effectiveness of our internal control over financial reporting. When and if we are a "large accelerated filer" or an "accelerated filer" and are no longer an "emerging growth company," each as defined in the Securities Exchange Act, our independent registered public accounting firm will be required to attest to the effectiveness of our internal control over financial reporting. However, for so long as we remain an emerging growth company, we intend to take advantage of certain exemptions from various reporting requirements that are applicable to public companies that are not emerging growth companies, including not being required to comply with the auditor attestation requirements of Section 404 for a period of no more than 5 years. Once we are no longer an emerging growth company or, if prior to such date, we opt to no longer take advantage of the applicable exemption, we will be required to include an opinion from our independent registered public accounting firm on the effectiveness of our internal control over financial reporting. The rules governing the standards that must be met for management to assess our internal control over financial reporting are complex and require significant documentation, testing, and possible remediation. To comply with the requirements of being a reporting company under the Securities Exchange Act, we need to: upgrade our systems, including information technology; implement additional financial and management controls, reporting systems and procedures; and hire additional accounting and finance staff.

We have identified material weaknesses in our internal control 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.

During the course of preparing for this offering, our management team determined that we had material weaknesses in our internal control over financial reporting. The material weaknesses are or were as follows:

- Adequate controls are not in place to appropriately segregate duties in areas such as journal entries, cash disbursements, impairment of
  intangible assets and the calculation and recording of income taxes.
- Our controls and procedures over the accounting for and reporting of complex accounting matters were not effectively designed due to a failure
  to design and implement appropriate policies and procedures to ensure that the accounting and valuation of complex debt and equity transactions
  is in accordance with GAAP.
- Our controls were not effectively implemented in the financial statement close process to ensure that proper cut-off of accrued expenses was
  achieved at interim periods.

The material weakness identified in the second bullet point above resulted in restatements of our consolidated financial statements for the period from June 28, 2000 (date of inception) to December 31, 2009 that affected the carrying value of various series of preferred stock, additional paid-in capital, accumulated deficit, interest expense and change in fair value of warrant liability and other liability. We engaged external resources to provide technical expertise to ensure that appropriate controls were in place to properly account for complex debt and equity transactions for the year ended December 31, 2012.

We have remediated the material weaknesses noted above in the second and third bullet points which related to the years ended December 31, 2011 and 2012 and the period ended September 30, 2013, and we are continuing to take the necessary steps to remediate the material weakness identified in the first bullet point relating to segregation of duties. However, we cannot assure you that our remediative measures will be sufficient or that we

will not have other material weaknesses or significant deficiencies in our internal control over financial reporting. If we are unable to successfully remediate any material weakness or significant deficiency in our internal control over financial reporting, or identify any 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, and our stock price may decline materially as a result.

Historically, we have not had sufficient accounting and supervisory personnel with the appropriate level of technical accounting experience and training necessary, or adequate formally documented accounting policies and procedures, to support effective internal control and appropriate segregation of duties. We have commenced the process of formally documenting, reviewing and improving our internal control over financial reporting. We have made efforts to improve our internal control and accounting policies and procedures. These efforts include hiring new accounting personnel and engaging external temporary resources to supplement our accounting function until full time accounting personnel can be hired.

Pursuant to Section 404(a) of the Sarbanes-Oxley Act, we will be required to furnish a report by our management on our internal control over financial reporting. We have begun the process of documenting and evaluating our system of internal control over financial reporting necessary for our management to issue this report. However, we anticipate that we will need to retain additional finance capabilities and build our financial infrastructure as we transition to operating as a public company, including complying with the requirements of Section 404 of the Sarbanes-Oxley Act. As we begin operating as a public company following this offering, we will need to continue improving our financial infrastructure with the retention of additional financial and accounting capabilities, the enhancement of internal control and additional training for our financial and accounting staff.

Until we are able to expand our finance and administrative capabilities and establish necessary financial reporting infrastructure, we may not be able to prepare and disclose, in a timely manner, our financial statements and other required disclosures or comply with the Sarbanes-Oxley Act or existing or new reporting requirements. If we cannot provide reliable financial reports or prevent fraud, our business and results of operations could be harmed and investors could lose confidence in our reported financial information.

If we engage in an acquisition, reorganization or business combination, we will incur a variety of risks that could adversely affect our business operations or our stockholders.

From time to time we have considered, and we will continue to consider in the future, strategic business initiatives intended to further the expansion and development of our business. These initiatives may include acquiring businesses, technologies or products or entering into a business combination with another company. For instance, in 2011, we acquired ProChon Biotech Ltd. Although we intend to evaluate and consider acquisitions, reorganizations and business combinations in the future, we have no agreements or understandings with respect to any acquisition, reorganization or business combination at this time. Any acquisitions we undertake, including our prior acquisition of ProChon Biotech Ltd., will likely be accompanied by business risks which may include:

- the effect of the acquisition on our financial and strategic position and reputation;
- the need to reprioritize our development programs and even cease development and commercialization of our product candidates;
- the failure of an acquisition to result in expected benefits, which may include benefits relating to enhanced revenues, technology, human resources, costs savings, operating efficiencies, goodwill and other synergies;
- the difficulty, cost and management effort required to integrate the acquired businesses, including costs and delays in implementing common systems and procedures and costs and delays caused by communication difficulties;

- the assumption of certain known or unknown liabilities of the acquired business, including litigation-related liabilities;
- the reduction of our cash available for operations and other uses, the increase in amortization expense related to identifiable assets acquired, potentially dilutive issuances of equity securities or the incurrence of debt;
- a lack of experience in new markets, new business culture, products or technologies or an initial dependence on unfamiliar distribution partners;
- the possibility that we will pay more than the value we derive from the acquisition;
- the impairment of relationships with customers, partners or suppliers of the acquired business; and
- the potential loss of key employees of the acquired company.

These factors could harm our business, results of operations or financial condition.

In addition to the risks commonly encountered in the acquisition of a business or assets as described above, we may also experience risks relating to the challenges and costs of evaluating or closing a transaction, including distraction of our management team from normal business operations. The risks described above may be exacerbated as a result of managing multiple acquisitions at once.

#### Our ability to utilize our net operating loss carryforwards and certain other tax attributes may be limited.

We have incurred substantial losses during our history and do not expect to become profitable in the foreseeable future and may never achieve profitability. To the extent that we continue to generate taxable losses, unused losses will carry forward to offset future taxable income, if any, until such unused losses expire. We may be unable to use these losses to offset income before such unused losses expire. Under Section 382 of the Internal Revenue Code, Under Section 382 and 383 of the Internal Revenue Code (Code), utilization of net operating losses 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. 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. We have in the past experienced ownership changes that have resulted in limitations on the use of a portion of our net operating loss carryforwards. If we experience further ownership changes in connection with or after this offering, our ability to utilize our net operating loss carryforwards could be further limited.

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 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 clinical trial data for any of our product candidates 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 of our product candidates could be delayed.

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 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 fraud or other misconduct. Misconduct by employees 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 or disclose unauthorized activities to us. 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 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 and employees 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 or employee from trading in our common stock on the basis of, or while having access to, material, nonpublic information. If a director, executive or employee was to be investigated or an action was to be brought against a director, executive or employee 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.

Requirements associated with being a public reporting company will increase our costs significantly, as well as divert significant company resources and management attention.

We will be subject to the reporting requirements of the Securities Exchange Act and the other rules and regulations of the SEC upon consummation of this offering. We are working with our legal, independent

accounting and financial advisors to identify those areas in which changes should be made to our financial and management control systems to manage our growth and our obligations as a public reporting company. These areas include corporate governance, corporate control, disclosure controls and procedures, and financial reporting and accounting systems. We have made, and will continue to make, changes in these and other areas. Compliance with the various reporting and other requirements applicable to public reporting companies will require considerable time, attention of management and financial resources. In addition, the changes we make may not be sufficient to allow us to satisfy our obligations as a public reporting company on a timely basis.

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 attract and retain qualified persons to serve as our directors or executive officers, or 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, this would force us to delay or halt our clinical trial or commercial production processes. We currently produce materials for our clinical trials at our manufacturing facilities located in Waltham, Massachusetts. If these facilities or the equipment in them are significantly damaged or destroyed, we may not be able to quickly or inexpensively replace our manufacturing capacity. In addition, natural disasters could affect our third-party service providers' and manufacturers ability to perform services and provide materials for us on a timely basis. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, our efforts to obtain regulatory approvals for, and to commercialize, our product candidates may be delayed or prevented. For example, if a central laboratory holding all of our clinical product supply were to suffer a catastrophic loss of their facility, we would be required to delay our clinical trials. In addition, 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.

#### Our loan and security agreement contains operating covenants and restrictions that may restrict our business and financing activities.

We are party to a loan and security agreement with Silicon Valley Bank, which provides for a line of credit of up to \$1.5 million in the aggregate to finance certain equipment purchases. Borrowings under this agreement are secured by a first priority lien over all equipment purchased using the line of credit. This agreement restricts our ability to, among other things:

- sell assets;
- engage in any business other than our current business;
- merge or consolidate with other entities;
- incur additional indebtedness;
- create liens on our assets;
- make investments:
- pay or declare dividends, or, in certain cases, repurchase our stock;

- enter into transactions with affiliates; or
- make any payment on subordinated indebtedness.

The operating covenants and restrictions in the loan and security agreement, as well as covenants and restrictions in any future financing agreements that we may enter into, may restrict our ability to finance our operations, engage in business activities or expand or fully pursue our business strategies. Our ability to comply with these covenants may be affected by events beyond our control, and we may not be able to meet those covenants. A breach of any of these covenants could result in a default under the loan and security agreement or any future financing agreement, which could cause all of the outstanding indebtedness under the facility to become immediately due and payable and terminate all commitments to extend further credit.

We cannot assure you that we will continue to maintain sufficient cash reserves or that our business will ever generate cash flow from operations at levels sufficient to permit us to pay principal, premium, if any, and interest on our indebtedness, or that our cash needs will not increase. If we are unable to generate sufficient cash flow or otherwise obtain funds necessary to make required payments, or if we fail to comply with the various requirements of our loan and security agreement with Silicon Valley Bank, or any indebtedness which we may incur in the future, we would be in default under our agreement with Silicon Valley Bank, or any indebtedness that we may incur in the future, could have a material adverse effect on our business, results of operations and financial condition.

#### Risks Related to Regulatory Approval

## If we fail to complete clinical trials and obtain regulatory approval for NeoCart, our business would be significantly harmed.

We have not completed clinical development for any of our product candidates and will only obtain regulatory approval to commercialize a product candidate if we can demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities in well-designed and conducted clinical trials that the product candidate is safe, effective, and otherwise meets the appropriate standards required for approval for a particular class of products or indication. Clinical trials are lengthy, complex and extremely expensive processes with uncertain results. A failure of one or more clinical trials may occur at any stage. Of the large number of products in development, only a small percentage successfully complete the FDA regulatory approval process and are commercialized.

We have never obtained marketing approval from the FDA or any comparable foreign regulatory authority for any product candidate. Our ability to obtain regulatory approval of our product candidates depends on, among other things, whether our clinical trials demonstrate statistically significant efficacy with safety issues that do not potentially outweigh the therapeutic benefit of the product candidates, and whether the regulatory agencies agree that the data from our future clinical trials is sufficient to support approval for any of our product candidates. The final results of our current and future clinical trials may not meet the FDA's or other regulatory agencies' requirements to approve a product candidate for marketing, and the regulatory agencies may otherwise determine that our manufacturing processes or facilities are insufficient to support approval. We may need to conduct more clinical trials than we currently anticipate. Even if we do receive FDA or other regulatory agency approval, we may not be successful in commercializing approved product candidates. If any of these events occur, our business could be materially harmed and the value of our common stock would likely decline.

# Our clinical development of NeoCart could be substantially delayed if the FDA requires us to conduct additional studies or trials or imposes other requirements or restrictions.

We will need to generate and provide the FDA with comparability data from our new raw material production for the collagen critical raw materials used in our manufacturing process and intended for clinical use. The FDA may also require us to generate additional preclinical or clinical data to support the use of these new critical raw

material suppliers in our NeoCart trial. Additionally, the FDA may impose other requirements on the protocol for our NeoCart trial. These additional requirements may cause further delays in our NeoCart trial which could require us to incur additional development costs, seek funding for these increased costs or delay or cease our clinical development activities for NeoCart. Any inability to advance NeoCart or any other product candidate through clinical development would have a material adverse effect on our business. For example, the recently enacted Food and Drug Administration Safety and Innovation Act made permanent the Pediatric Research Equity Act, which requires a sponsor to conduct pediatric studies for most tissue regeneration products for a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration. Under the Pediatric Research Equity Act, original New Drug Applications and Biologic Licensing Applications and supplements thereto must contain a pediatric assessment unless the sponsor has received a deferral or waiver. The required assessment must evaluate the safety and effectiveness of the product for the claimed indications in all relevant pediatric subpopulations and support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The sponsor or FDA may request a deferral of pediatric studies for some or all of the pediatric subpopulations, and it is likely that we will request such a deferral. A deferral may be granted for several reasons, including a finding that the tissue regeneration products is ready for approval for use in adults before pediatric studies are complete or that additional safety or effectiveness data needs to be collected before the pediatric studies begin. The FDA must send a non-compliance letter to any sponsor that fails to submit the required assessment, keep a deferral current or fails to submit a request for approval of a pediatric formulation.

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.

If one or more of our product candidates is approved, we will be subject to U.S. federal and state laws intended to prevent health care fraud and abuse. The federal anti-kickback statute prohibits the offer, receipt, or payment of remuneration in exchange for or to induce the referral of patients or the use of products or services that would be paid for in whole or part by Medicare, Medicaid or other federal health care programs. Remuneration has been broadly defined to include anything of value, including cash, improper discounts, and free or reduced price items and services. Many states have similar laws that apply to their state health care programs as well as private payors. Violations of the anti-kickback laws can result in exclusion from federal health care programs and substantial civil and criminal penalties.

The False Claims Act imposes liability on persons who, among other things, present or cause to be presented false or fraudulent claims for payment by a federal health care program. The False Claims Act has been used to prosecute persons submitting claims for payment that are inaccurate or fraudulent, that are for services not provided as claimed, or for services that are not medically necessary. The False Claims Act includes a whistleblower provision that allows individuals to bring actions on behalf of the federal government and share a portion of the recovery of successful claims. If our marketing or other arrangements were determined to violate the False Claims Act or anti-kickback or related laws, then our revenue could be adversely affected, which would likely harm our business, financial condition and results of operations.

State and federal authorities have aggressively targeted medical technology companies for alleged violations of these anti-fraud statutes, based on improper research or consulting contracts with doctors, certain marketing arrangements that rely on volume-based pricing, off-label marketing schemes and other improper promotional practices. Companies targeted in such prosecutions have paid substantial fines in the hundreds of millions of dollars or more, have been forced to implement extensive corrective action plans or Corporate Integrity Agreements, and have often become subject to consent decrees severely restricting the manner in which they conduct their business. If we become the target of such an investigation or prosecution based on our contractual relationships with providers or institutions, or our marketing and promotional practices, we could face similar sanctions, which would materially harm our business.

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.

Also, the Physician Payment Sunshine Act imposes new reporting and disclosure requirements on drug, device, biologic and medical supply manufacturers for any "transfer of value" made or distributed to prescribers and other healthcare providers. In addition, device and drug manufacturers will also be required to report and disclose any investment interests held by physicians and their immediate family members during the preceding calendar year. Failure to submit required information may result in significant civil monetary penalties.

## Our failure to comply with extensive governmental regulation may significantly affect our operating results.

Even if we obtain regulatory approval for some or all of our product candidates, we will continue to be subject to extensive ongoing requirements by the FDA, as well as by a number of foreign, national, state and local agencies. These regulations will impact many aspects of our operations, including testing, research and development, manufacturing, safety, efficacy, labeling, storage, quality control, adverse event reporting, import and export, record keeping, approval, distribution, advertising and promotion of our future products. We must also submit new or supplemental applications and obtain FDA approval for certain changes to an approved product, product labeling or manufacturing process. Application holders must also submit advertising and other promotional material to the FDA and report on ongoing clinical trials. The FDA enforces post-marketing regulatory requirements, including cGMP requirements, through periodic unannounced inspections. We do not know whether we will pass any future FDA inspections. Failure to pass an inspection could disrupt, delay or shut down our manufacturing operations. Failure to comply with applicable regulatory requirements could, among other things, result in:

- administrative or judicial enforcement actions;
- · changes to advertising;
- · failure to obtain marketing approvals for our product candidates;
- revocation or suspension of regulatory approvals of products;
- product seizures or recalls;
- · court-ordered injunctions;
- import detentions;
- · delay, interruption or suspension of product manufacturing, distribution, marketing and sales; or
- · civil or criminal sanctions.

The discovery of previously unknown problems with our product candidates or future products may result in restrictions of the products, including withdrawal from the market. In addition, the FDA may revisit and change its prior determinations with regard to the safety or efficacy of our future products. If the FDA's position changes, we may be required to change our labeling or cease to manufacture and market our future products. Even prior to any formal regulatory action, we could voluntarily decide to cease the distribution and sale or recall any of our future products if concerns about their safety or efficacy develop.

In their regulation of advertising and other promotion, the FDA and the U.S. Federal Trade Commission may issue correspondence alleging that some advertising or promotional practices are false, misleading or deceptive. The FDA and the U.S. Federal Trade Commission are authorized to impose a wide array of sanctions on companies for such advertising and promotion practices, which could result in any of the following:

- our incurrence of substantial expenses, including fines, penalties, legal fees and costs to comply with the FDA's requirements;
- our being required to change in the methods of marketing and selling products;
- our being required to take FDA mandated corrective action, which may include placing advertisements or sending letters to physicians rescinding previous advertisements or promotions; or
- a disruption in the distribution of products and loss of sales until compliance with the FDA's position is obtained.

Improper promotional activities may also lead to investigations by federal or state prosecutors, and result in criminal and civil penalties. If we become subject to any of the above requirements, it could be damaging to our reputation and restrict our ability to sell or market our future products, and our business condition could be adversely affected. We may also incur significant expenses in defending ourselves.

Physicians may prescribe pharmaceutical or biologic products for uses that are not described in a product's labeling or differ from those tested by us and approved by the FDA. While such "off-label" uses are common and the FDA does not regulate physicians' choice of treatments, the FDA does restrict a manufacturer's communications on the subject of off-label use. Companies cannot promote FDA-approved pharmaceutical or biologic products for off-label uses, but under certain limited circumstances they may disseminate to practitioners' articles published in peer-reviewed journals. To the extent allowed by the FDA, we intend to disseminate peer-reviewed articles on our future products to practitioners. If, however, our activities fail to comply with the FDA's regulations or guidelines, we may be subject to warnings from, or enforcement action by, the FDA or other regulatory or law enforcement authorities.

Depending on the circumstances, failure to meet post-approval requirements can result in criminal prosecution, fines or other penalties, injunctions, recall or seizure of products, total or partial suspension of production, denial or withdrawal of pre-marketing product approvals, or refusal to allow us to enter into supply contracts, including government contracts. Any government investigation of alleged violations of law could require us to expend significant time and resources in response, and could generate negative publicity.

# Even if we obtain regulatory approval for a product candidate, our products will remain subject to regulatory scrutiny.

Any product candidate for which we obtain marketing approval, along with the manufacturing processes, qualification testing, post-approval clinical data, labeling and promotional activities for such product, will be subject to continuing and additional requirements of the FDA and other regulatory authorities. These requirements include submissions of safety and other post-marketing information, reports, registration and listing requirements, cGMP requirements relating to quality control, quality assurance and corresponding maintenance

of records and documents, and recordkeeping. Even if marketing approval of a product candidate is granted, the approval may be subject to limitations on the indicated uses for which the product may be marketed or to conditions of approval, or contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the product. The FDA closely regulates the post-approval marketing and promotion of pharmaceutical and biological products to ensure such products are marketed only for the approved indications and in accordance with the provisions of the approved labeling.

In addition, later discovery of previously unknown problems with our products, manufacturing processes, or failure to comply with regulatory requirements, may lead to various adverse results, including:

- restrictions on such products, manufacturers or manufacturing processes;
- restrictions on the labeling or marketing of a product;
- restrictions on product distribution or use;
- requirements to conduct post-marketing clinical trials;
- requirements to institute a risk evaluation and mitigation strategy to monitor safety of the product post-approval;
- warning letters issued by the FDA or other regulatory authorities;
- withdrawal of the products from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- recalls of products, fines, restitution or disgorgement of profits or revenue;
- suspension, revocation or withdrawal of marketing approvals;
- refusal to permit the import or export of our products; or
- injunctions or the imposition of civil or criminal penalties.

The FDA's policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, which would adversely affect our business, prospects and ability to achieve or sustain profitability.

# **Risks Related to Our Intellectual Property**

#### Our success depends on our ability to protect our intellectual property and our proprietary technologies.

Our commercial success depends in part on our ability to obtain and 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.

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 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 future development 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. 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.

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.

Competitors 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.

# Our issued patents could be found invalid or unenforceable if challenged in court which could have a material adverse effect on our business.

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, 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.

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.

#### 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 effect our business.

# 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 and this Offering

# The trading price of our common stock is likely to be volatile, and you might not be able to sell your shares at or above the initial public offering price.

There has been no public market for our common stock prior to this offering, and the initial public offering price of our common stock was determined by negotiations between us and the underwriters and may not be indicative of the future prices of our common stock. The market price of our common stock could be subject to wide fluctuations in response to various factors, many of which are beyond our control. These factors include those discussed elsewhere in this "Risk Factors" section and others such as:

- the delay or failure in initiating or completing preclinical studies or clinical trials, or unsatisfactory results of these trials;
- announcements about us or about our competitors including clinical trial results, regulatory approvals, or new product candidate introductions;
- developments concerning our current or future development partner, 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 and the economy as a whole;
- governmental regulation and legislation;
- the recruitment or departure of members of our board of directors, management team or other key personnel, including recruitment of a new chief executive officer;
- 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 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. Broad market and industry factors may seriously affect the market price of our common stock, regardless of our actual operating performance. These fluctuations may be even more pronounced in the trading market for our stock shortly following this offering.

As a newly public company, our stock price may be volatile, and securities class action litigation has often been instituted against companies following periods of volatility of their stock price. 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.

## No public market for our common stock currently exists, and an active trading market may not develop or be sustained following this offering.

Prior to this offering, there has been no public market for our common stock. An active trading market may not develop following the closing of this offering or, if developed, may not be sustained. The lack of an active market may impair your ability to sell your shares at the time you wish to sell them or at a price that you consider reasonable. The lack of an active market may also reduce the fair market value of your shares. An inactive market may also impair our ability to raise capital to continue to fund operations by selling shares and may impair our ability to acquire other companies or technologies by using our shares as consideration.

# If securities analysts do not publish research or publish unfavorable research about our business, 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. We do not currently have and may never obtain research coverage by securities analysts. If no or few securities or industry analysts commence coverage of our company, the trading price for our stock could suffer. In the event we obtain securities or industry analyst coverage, if 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. If one or more of these 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.

# As an investor participating in this offering, you will experience substantial dilution as a result of this offering and future equity issuances.

The initial public offering price per share is substantially higher than the pro forma net tangible book value per share of our common stock outstanding prior to this offering. As a result, investors purchasing common stock in this offering will experience immediate substantial dilution of \$ per share, based on the initial public offering price of \$ per share the midpoint of the initial public offering price range reflected on the cover page of this prospectus. In addition, to the extent currently outstanding options or warrants are exercised, there will be further dilution to investors in this offering. In addition, we may raise additional capital through public or private equity or debt offerings, subject to market conditions. To the extent that additional capital is raised through the sale of equity or convertible debt securities, the issuance could result in further dilution to our stockholders.

# 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.

We will need to raise additional funding in order to complete the clinical development of, create additional manufacturing capacity and to commercialize NeoCart and to conduct the research and development and clinical and regulatory activities necessary to bring other product candidates to market. 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.

# Our management will have broad discretion over the actual amounts and timing of the expenditures of the proceeds we receive in this offering and might not apply the proceeds in ways that enhance our operating results or increase the value of your investment.

We expect to use the net proceeds from this offering primarily to develop and advance NeoCart through clinical trials, as well as for working capital and general corporate purposes. Our management will have broad discretion as to the actual amounts and timing of the expenditures of the net proceeds from this offering, and you will be relying on the judgment of our management regarding the application of these proceeds. Our management might not apply the net proceeds of this offering in ways that enhance our operating results or increase the value of your investment. Additionally, until the net proceeds we receive are used, they may be placed in investments that do not produce income or that lose value.

# 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.

# Our principal stockholders and management own a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval.

As of July 10, 2014, our executive officers, directors, holders of more than 5% of our capital stock and their respective affiliates beneficially owned 84.3% of our outstanding capital stock and, upon the closing of this offering, that same group will beneficially own % of our outstanding capital stock (assuming no exercise of the underwriters' over-allotment option). Therefore, these stockholders will have the ability to influence us through their ownership position after this offering. These stockholders may be able to determine all matters requiring stockholder approval. For example, these stockholders may be able to control elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest as one of our stockholders.

## Substantial future sales of shares by existing stockholders, or the perception that such sales may occur, could cause our stock price to decline.

If our existing stockholders, particularly our directors and executive officers and the venture capital funds affiliated with our current and former directors, sell substantial amounts of our common stock in the public market, or are perceived by the public market as intending to sell substantial amounts of our common stock, the

trading price of our common stock could decline below the initial public offering price. Based on shares outstanding as of July 10, 2014, upon completion of this offering, we will have outstanding shares of common stock. Of these shares, only the shares of common stock sold in this offering and registered shares issued pursuant to our equity plans will be freely tradable in the public market, subject to any applicable lock-up agreements or Rule 144 transfer restrictions applicable to affiliates. Our officers, directors and holders of substantially all of our equity securities have entered into contractual lock-up agreements with the underwriters pursuant to which they have agreed, subject to certain exceptions, not to sell or otherwise transfer any of their common stock or securities convertible into or exchangeable for shares of common stock for a period of 180 days after the date of the final prospectus for this offering. However, we and the lead underwriter in this offering may permit these holders to sell shares prior to the expiration of the lock-up agreements with the underwriters.

Based on shares outstanding as of July 10, 2014, after the contractual lock-up agreements pertaining to this offering expire 180 days from the date of this prospectus, up to an additional 56,026,477 shares will be eligible for sale in the public market, 47,208,556 of which are held by directors, executive officers and other affiliates and will be subject to volume and other limitations under Rule 144 under the Securities Act.

The 4,934,205 shares that were subject to outstanding options as of July 10, 2014 will become eligible for sale in the public market to the extent permitted by the provisions of various vesting agreements, the contractual lock-up agreements, and Rules 144 and 701 under the Securities Act.

Some of our existing security holders have demand and piggyback rights to require us to register with the SEC up to 49,249,999 shares of our common stock, subject to expiration of the contractual lock-up agreements. If we register these shares of common stock, the stockholders would be able to sell those shares freely in the public market, subject to Rule 144 transfer restrictions applicable to affiliates.

We plan to register an additional shares of our common stock that we may issue under our equity plans. Once we issue these shares, they can be freely sold in the public market upon issuance, subject to any vesting restriction, contractual lock-up agreements, or Rule 144 transfer restrictions applicable to affiliates.

If any of these additional shares described are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline. For additional information, see "Shares Eligible for Future Sale."

Provisions in our certificate of incorporation and 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.

For information regarding these and other provisions, see "Description of Capital 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 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 billion or more during such fiscal year, (3) the date on which we issue more than \$1 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 this offering.

#### SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains forward-looking statements that involve risks and uncertainties. All statements, other than statements of historical facts, included in this prospectus regarding our strategy, future operations, future financial position, future revenue, projected costs, prospects, plans and objectives of management are forward-looking statements. The forward-looking statements are contained principally in "Prospectus Summary," "Risk Factors," "Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Business." In some cases, you can identify forward-looking statements by terms such as "may," "might," "will," "objective," "intend," "should," "could," "can," "would," "expect," "believe," "anticipate," "project," "target," "design," "estimate," "predict," "potential," "plan" or the negative of these terms, and similar expressions intended to identify forward-looking statements. These statements reflect our current views with respect to future events and are based on assumptions and subject to risks and uncertainties. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Forward-looking statements include statements about:

- the timing and success of preclinical studies and clinical trials conducted by us and our development partners;
- the ability to obtain and maintain regulatory approval of our product candidates and the labeling for any approved products;
- the scope, progress, expansion and costs of developing and commercializing our product candidates;
- our expectations regarding our expenses and revenue, the sufficiency of our cash resources, our future profitability and needs for additional financing:
- our technology transfer and manufacturing location transition;
- · our ability to adequately manufacture our product candidates and the raw materials utilized therein;
- our ability to obtain and maintain intellectual property protection for our product candidates;
- our expectations regarding competition;
- the size and growth of the potential markets for our product candidates and the ability to serve those markets;
- the rate and degree of market acceptance of any of our product candidates;
- our anticipated growth strategies;
- the anticipated trends and challenges in our business and the market in which we operate;
- our ability to establish and maintain development partnerships;
- our ability to attract or retain key personnel;
- our ability to operate our business in compliance with the covenants and restrictions that we are subject to under our loan and security
  agreement;
- our expectations regarding federal, state and foreign regulatory requirements;
- · regulatory developments in the United States and foreign countries; and
- our expectations regarding the use of proceeds from this offering.

Forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performances or achievements expressed or implied by the forward-looking statements.

Any forward-looking statement made by us in this prospectus speaks only as of the date on which it is made. Except as required by law, we assume no obligation to update these statements publicly, or to update the reasons actual results could differ materially from those anticipated in these statements, even if new information becomes available in the future.

We discuss many of these risks in this prospectus in greater detail under "Risk Factors." You should read this prospectus and the documents that we reference in this prospectus and have filed as exhibits to the registration statement, of which this prospectus is a part, completely and with the understanding that our actual future results may be materially different from what we expect. We qualify all of our forward-looking statements by these cautionary statements.

This prospectus also contains market data related to our business and industry. This market data includes projections that are based on a number of assumptions. If these assumptions turn out to be incorrect, actual results may differ from the projections based on these assumptions. As a result, our markets may not grow at the rates projected by this data, or at all. The failure of these markets to grow at these projected rates may have a material adverse effect on our business, results of operations, financial condition and the market price of our common stock.

This prospectus includes statistical data, estimates and forecasts that we obtained from industry publications and reports generated by third-party market research firms, including MedMarket Diligence. While we are not aware of any misstatements regarding any third-party data presented in this prospectus, their estimates, in particular as they relate to projections, involve numerous assumptions and are subject to risks and uncertainties as well as change based on various factors, including those discussed under "Risk Factors."

#### **USE OF PROCEEDS**

We estimate that we will receive net proceeds from this offering of \$\frac{1}{2}\$ million, assuming an initial public offering price of \$\frac{1}{2}\$ per share, the midpoint of the initial public offering price range reflected on the cover page of this prospectus, and after deducting the estimated underwriting discount and offering expenses payable by us. If the underwriters' option to purchase additional shares in this offering is exercised in full, we estimate that our net proceeds will be \$\frac{1}{2}\$ million.

We intend to use the net proceeds of this offering primarily to develop and advance NeoCart through our currently enrolling Phase 3 clinical trial and to build out our manufacturing facilities, as well as for working capital and general corporate purposes. We estimate that it will cost approximately \$ million to complete or Phase 3 clinical trial.

The expected use of net proceeds of this offering represents our current intentions based upon our present plans and business conditions. The amounts we actually expend in these areas may vary significantly from our current intentions and will depend upon a number of factors, including success of our product development and commercialization efforts, cash generated from future operations, if any, and actual expenses to operate our business. As of the date of this prospectus, we cannot specify with certainty all of the particular uses for the net proceeds to be received upon the closing of this offering. Accordingly, our management will have broad discretion in the application of the net proceeds, and investors will be relying on the judgment of our management regarding the application of the net proceeds.

Pending use of proceeds from this offering, we intend to invest the proceeds in short-term, investment-grade, interest-bearing instruments, certificates of deposit or direct or guaranteed obligations of the U.S. government, or hold as cash.

#### DIVIDEND POLICY

We have never declared or paid cash dividends on our capital stock. We currently intend to retain all available funds and any future earnings for use in the operation of our business and do not anticipate paying any cash dividends in the foreseeable future. The terms of our loan and security agreement also restrict our ability to pay dividends. Any future determination to declare cash dividends will be made at the discretion of our board of directors and will depend on our financial condition, results of operations, capital requirements, contractual restrictions, general business conditions and other factors that our board of directors may deem relevant.

#### **CAPITALIZATION**

The table below sets forth our capitalization as of March 31, 2014 on:

- an actual basis;
- a pro forma basis to reflect the following, which will occur upon the completion of this offering: (1) the automatic conversion of all outstanding shares of our convertible preferred stock into common stock; (2) the net exercise of warrants to acquire shares of common stock; (3) the exercise of warrants to acquire a total of shares of common stock for an aggregate exercise price of \$ ; (4) the issuance of an estimated shares of common stock in payment of accrued dividends on outstanding shares of convertible preferred stock; and (5) the amendment and restatement of our certificate of incorporation; and
- a pro forma as adjusted basis to further adjust the pro forma amounts to reflect the sale of shares of common stock in this offering at an assumed initial public offering price of \$ per share, the midpoint of the initial public offering price range reflected on the cover page of this prospectus, after deducting the estimated underwriting discounts and offering expenses payable by us.

You should read the information in this table together with "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our consolidated financial statements and related notes appearing elsewhere in this prospectus.

	As of March 31, 2014			
	Actual	Pro Forma	Pro Forma As Adjusted	
		, except share and per sh		
Long-term liabilities, including current portion	\$ 26,806			
Series A convertible redeemable preferred stock, \$0.001 par value: 28,602,031 shares authorized; 28,602,031 shares issued and outstanding, actual; no shares authorized, issued or outstanding,				
pro forma and pro forma as adjusted	42,617	_	_	
Series A-1 convertible redeemable preferred stock, \$0.001 par value: 20,647,969 shares authorized; 10,323,988 shares issued and outstanding, actual; no shares authorized, issued or outstanding, pro forma and pro forma as adjusted	14,454			
Stockholders' equity (deficit):				
Preferred stock, \$0.001 par value per share: no shares authorized, issued or outstanding, actual; shares authorized, no shares issued or outstanding, pro forma and pro forma as adjusted	_	_	_	
Common stock, \$0.001 par value: 70,000,000 shares authorized; 6,418,033 shares issued and outstanding, actual; shares authorized, shares issued and outstanding, pro forma; shares authorized, shares issued and outstanding pro forma as adjusted	6			
Additional paid-in capital	35,264			
Deficit accumulated during the development stage	(114,185)			
Total stockholders' (deficit) equity	(78,915)			
Total capitalization	\$ 4,962	\$	\$	

The table above excludes each of the following as of March 31, 2014:

• 2,981,190 shares issuable upon the exercise of options outstanding under our 2012 Equity Incentive Plan as of March 31, 2014, at a weighted average exercise price of \$0.30 per share;

- 5,600,000 shares reserved for future issuance under our 2013 Equity Incentive Plan, which became effective in November 2013 but with respect to which no awards will be granted prior to the effective date of the registration statement of which this prospectus is a part, subject to automatic annual adjustment in accordance with the terms of the plan; and
- 1,120,000 shares reserved for future issuance under our 2013 Employee Stock Purchase Plan, which became effective in November 2013 but with respect to which no awards will be granted prior to the effective date of the registration statement of which this prospectus is a part, subject to automatic annual adjustment in accordance with the terms of the plan.

#### **DILUTION**

If you invest in our common stock in this offering, your ownership interest will be diluted immediately to the extent of the difference between the initial public offering price per share you will pay in this offering and the pro forma as adjusted net tangible book value per share of our common stock immediately after this offering. As of March 31, 2014, the historical net tangible book deficit of our common stock was \$(79.5) million, or \$(12.38) per share. Our historical net tangible book deficit represents total tangible assets less total liabilities and convertible preferred stock, all divided by the number of shares of common stock outstanding on March 31, 2014.

As of March 31, 2014, the pro forma net tangible book value of our common stock would have been \$ million, or \$ per share, after giving effect to the following, which will occur upon the completion of this offering: (1) the automatic conversion of all outstanding shares of our convertible preferred stock into common stock; (2) the net exercise of warrants to acquire shares of common stock; (3) the exercise of warrants to acquire a total of shares of common stock for an aggregate exercise price of \$ ; and (4) the issuance of an estimated shares of common stock in payment of accrued dividends on outstanding shares of convertible preferred stock.

After giving effect to the sale of shares of common stock in this offering at an assumed initial public offering price of \$ per share, the midpoint of the price range set forth on the cover page of this prospectus, and after deducting the estimated underwriting discount and offering expenses payable by us, the proforma as adjusted net tangible book value of our common stock as of March 31, 2014 would have been \$ million, or \$ per share. This represents an immediate increase in pro forma as adjusted net tangible book value of \$ per share to our existing stockholders and an immediate dilution of \$ per share to purchasers of common stock in this offering. The following table illustrates this per share dilution:

Assumed initial public offering price per share		\$
Historical net tangible book value (deficit) per share as of March 31, 2014	\$(12.38)	
Increase in net tangible book value (deficit) per share attributable to pro forma transactions described above		
Pro forma net tangible book value per share before this offering	\$	
Increase in pro forma net tangible book value per share attributable to this offering		
Pro forma as adjusted net tangible book value per share after this offering		
Dilution per share to purchasers of common stock in this offering		\$

Each \$1.00 increase (decrease) in the assumed initial public offering price of \$ per share, the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) the pro forma net tangible book value by \$ per share and the dilution per share to purchasers of common stock in this offering by \$ per share, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting the estimated underwriting discount and offering expenses payable by us. We may also increase (decrease) the number of shares we are offering. An increase (decrease) of 1,000,000 in the number of shares offered by us would increase (decrease) the pro forma net tangible book value by \$ per share and the dilution per share to purchasers of common stock in this offering by \$ per share, assuming that the assumed initial public offering price remains the same and after deducting estimated underwriting discount and offering expenses payable by us. The pro forma information discussed above is illustrative only and will adjust based on the actual initial public offering price and other terms of this offering determined at pricing.

If the underwriters exercise their over-allotment option in full, the pro forma as adjusted net tangible book value per share after this offering would be \$ per share, the increase in pro forma net tangible book value per share to existing stockholders would be \$ per share and the dilution to purchasers of common stock in this offering would be \$ per share.

The following table summarizes, on a pro forma as adjusted basis as of March 31, 2014, the differences between existing stockholders and purchasers of common stock in this offering with respect to the number of shares of common stock purchased from us, the total consideration paid to us and the average price per share paid. The calculation below is based on the assumed initial public offering price of \$ per share, the midpoint of the price range set forth on the cover page of this prospectus, before deducting the estimated underwriting discount and offering expenses payable by us.

	Shares Pr	Shares Purchased		sideration	Average Price
	Number	Percent	Amount	Percent	Per Share
Existing stockholders		%		<del>%</del>	\$
Purchasers of common stock in this offering					
Totals		100.0%		100.0%	

Except as otherwise indicated, the above discussion and tables assume no exercise of the underwriters' over-allotment option. If the underwriters exercise their over-allotment option in full, our existing stockholders would own % and purchasers of common stock in this offering would own % of the total number of shares of our common stock outstanding upon completion of this offering. The total consideration paid by existing stockholders would be approximately \$ million, or %, and the total consideration paid by purchasers of common stock in this offering would be \$ million, or %.

The foregoing tables and calculations exclude:

- 2,981,190 shares issuable upon the exercise of options outstanding under our 2012 Equity Incentive Plan as of March 31, 2014, at a weighted average exercise price of \$0.30 per share;
- 5,600,000 shares reserved for future issuance under our 2013 Equity Incentive Plan, which became effective in November 2013 but with respect to which no awards will be granted prior to the effective date of the registration statement of which this prospectus is a part, subject to automatic annual adjustment in accordance with the terms of the plan; and
- 1,120,000 shares reserved for future issuance under our 2013 Employee Stock Purchase Plan, which became effective in November 2013 but with respect to which no awards will be granted prior to the effective date of the registration statement of which this prospectus is a part, subject to automatic annual adjustment in accordance with the terms of the plan.

#### SELECTED CONSOLIDATED FINANCIAL INFORMATION

The following tables set forth selected consolidated financial information. We derived the consolidated statement of operations data for the years ended December 31, 2012 and 2013 and the consolidated balance sheet data as of December 31, 2012 and 2013 from the audited consolidated financial statements included elsewhere in this prospectus. We derived the consolidated statement of operations data for the three months ended March 31, 2013 and 2014 and the consolidated balance sheet data as of March 31, 2014 from our unaudited consolidated financial statements included elsewhere in this prospectus. The unaudited financial statements include all adjustments, consisting of normal recurring accruals, which we consider necessary for a fair presentation of the financial position and the results of operations for those periods. Our historical results are not necessarily indicative of the results to be expected for any future period, and the results in any interim period are not necessarily indicative of results to be expected for the full year or any other period. The following should be read in conjunction with "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our consolidated financial statements and related notes included elsewhere in this prospectus.

	Year Ended December 31,			Three Months Ende March 31,			ed	
	2	2012		2013		2013		2014
Consolidated Statement of Operations Data:		(iı	n thousa	nds, except shar	e and per	share amounts	)	
Revenue	\$	26	\$	8	\$	5	\$	
Operating expenses:	Ψ	20	Ψ	0	Ψ	<u> </u>	Ψ	
Research and development		11,941		11,946		1,908		3.347
Selling, general and administrative		3,053		4.847		905		1,826
Impairment of goodwill and intangible assets				60				
Total operating expense		14,994		16,853		2,813		5,173
Loss from operations		(14,968)	_	(16,845)		(2,808)	_	(5,173)
Interest expense, net	,	(798)		(10,010)				(0,17 <i>0</i> )
Other expense, net		(13)		(52)		(15)		(2)
Gain on extinguishment of debt		687		<del>-</del>		_		
Change in fair value of note payable to stockholder		(17)		_		_		_
Change in fair value of warrant liability and other liability		(1,826)		(8,815)		107		1,738
Net loss	\$	(16,935)	\$	(25,712)	\$	(2,716)	\$	(3,437)
Earnings (loss) per common share <sup>(1)</sup>			_		_		_	
Basic	\$	1.00	\$	(8.94)	\$	(0.53)	\$	(0.55)
Diluted	\$	0.26	\$	(8.94)	\$	(0.53)	\$	(0.55)
Weighted-average shares used to compute earnings (loss) per common share <sup>(1)</sup>			_		_			
Basic	2,8	318,293	(	5,264,690	6,	250,001	6	,290,589
Diluted	12,8	398,629	(	5,264,690	6,	250,001	6	,290,589
Pro forma earnings (loss) per common share <sup>(1)</sup> :			_				_	
Basic								
Diluted			=				_	
Pro forma weighted-average common shares outstanding <sup>(1)</sup> :			_		_			,
Basic								
Diluted			=				_	
Diffica			_		_		_	

<sup>(1)</sup> Please see Note 2 to our consolidated financial statements included elsewhere in this prospectus for an explanation of the method used to calculate earnings (loss) per common share, including the method used to calculate the number of shares used in the computation of the per share amount.

In the preceding table, cost of net revenue and operating expenses include stock-based compensation as follows:

	Year Ended December 31,				Months Ended Tarch 31,
	2012	201	3	2013	2014
	(in thousands)				
Stock-based Compensation Expense:					
Selling, general and administrative	\$ 14	<b>\$</b> 1	.58	\$ 10	\$ 76

	As of Dece	As of December 31,		
	2012	2013	2014	
		(in thousands)		
Consolidated Balance Sheet Data:				
Cash and cash equivalents	\$ 14,716	\$ 8,734	\$	3,360
Working capital (deficit)	10,675	5,259		36
Total assets	21,044	14,796		9,981
Total liabilities	11,136	33,279		31,825
Convertible preferred stock	29,619	57,071		57,071
Stockholders' deficit	(19,711)	(75,554)		(78,915)

#### MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion and analysis of our financial condition and results of operations in conjunction with the "Selected Consolidated Financial Information" and our consolidated financial statements and related notes appearing elsewhere in this prospectus. In addition to historical consolidated financial information, the following discussion and analysis contains forward-looking statements that involve risks, uncertainties, and assumptions. Our actual results could differ materially from those anticipated by these forward-looking statements as a result of many factors. We discuss factors that we believe could cause or contribute to these differences below and elsewhere in this prospectus, including those set forth under "Risk Factors" and "Special Note Regarding Forward-Looking Statements."

#### Overview

We are a regenerative medicine company focused on developing and commercializing products in the musculoskeletal segment of the marketplace. Our first product candidate, NeoCart, is being investigated in a Phase 3 clinical trial. NeoCart utilizes various aspects of our regenerative medicine platform to develop an innovative tissue implant intended to treat tissue injury in the field of orthopedics, specifically cartilage damage in the knee. NeoCart is an investigational product and has not been approved for sale in any jurisdiction, including the United States. We we have no other products that are approved for sale in the United States and currently we are not selling any products that may be approved for sale in other jurisdictions. Our regenerative medicine platform provides the tools to develop NeoCart.

Our regenerative medicine platform combines expertise in the following areas:

- Cell processing: the handling of a tissue biopsy, extraction of cells, and expansion of the cells;
- Scaffold: three-dimensional structures that enable the proper distribution of cells and organize cells in their natural environment to support tissue formation;
- Tissue engineering: the use of a combination of cells, engineering and materials to improve or replace biological functions;
- Bioadhesives: natural, biocompatible materials that act as adhesives for biological tissue; and
- Growth factors: naturally occurring substances capable of stimulating cellular growth, proliferation and differentiation.

NeoCart is a cartilage-like implant created using patient's own cartilage cells through a series of tissue engineering processes.

Since our inception on June 28, 2000, we have devoted substantially all of our resources to the development of our regenerative medicine platform, the preclinical and clinical advancement of our product candidates, the creation and protection of related intellectual property and the provision of selling, general and administrative support for these operations. We have generated revenue from product sales, collaboration activities and grants. We have funded our operations primarily through the private placement of preferred stock and convertible promissory notes and through commercial bank debt. We continue to be classified as a development stage company for financial reporting purposes.

We have never been profitable and have incurred net losses in each year since inception. Our net loss was \$114.2 million for the period from inception to March 31, 2014. Substantially all of our net losses resulted from costs incurred in connection with our research and development programs and from selling, general and administrative costs associated with our operations. We expect to continue to incur significant expenses and increasing operating losses for at least the next several years. Our net losses may fluctuate significantly from quarter to quarter and year to year. We expect our expenses will increase substantially in connection with our ongoing activities as we:

- conduct clinical trials of our product candidates;
- continue scale up and improvement of our manufacturing processes;

- transition our technology transfer and manufacturing location;
- continue our research and development efforts;
- manufacture preclinical study and clinical trial materials;
- maintain, expand and protect our intellectual property portfolio;
- seek regulatory approvals for our product candidates that successfully complete clinical trials;
- hire additional clinical, quality control and technical personnel to conduct our clinical trials;
- hire additional scientific personnel to support our product development efforts;
- implement operational, financial and management systems; and
- hire additional selling, general and administrative personnel to operate as a public company.

We do not expect to generate any future revenue from therapeutic product sales until we successfully complete development and obtain regulatory approval for one or more of our product candidates, which we expect will take a number of years. If we obtain regulatory approval for any of our product candidates, 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 and ability to develop our product candidates.

#### **Financial Operations Overview**

We conduct operations in two geographic regions: Histogenics Corporation (Histogenics), a Delaware corporation, at our facility in Waltham, 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 operating segments have been aggregated into one reporting segment.

On May 13, 2011, we acquired ProChon, a privately held biotechnology company focused on modulating the fibroblast growth factor system to enable it to create more effective solutions for tissue regeneration. Prior to the acquisition, ProChon was conducting a Phase 2 clinical trial in the United States and commercializing its lead product candidate, the BioCart cartilage regeneration system, in Israel. ProChon's products combined cell regeneration technologies with proprietary growth factors and biocompatible scaffolds to restore injured or chronically damaged tissues to normal. The acquisition of ProChon provided us with access to a portfolio of intellectual property, including proprietary cell growth factors, in addition to furthering opportunities for the use of biomaterials to create more effective solutions for regenerating human tissue.

The ProChon acquisition was accounted for as a business combination. The results of operations of ProChon have been included in our consolidated statements of operations since May 13, 2011, the date we obtained control of ProChon. Following the completion of the acquisition, ProChon became our wholly owned subsidiary and was integrated into our operations.

Unless otherwise indicated, the following information is presented on a consolidated basis to include our accounts and those of ProChon subsequent to the May 2011 acquisition. All intercompany transactions and balances are eliminated in consolidation.

#### Revenue

From inception to March 31, 2014, we generated product revenue of \$53,000 in Israel through commercial sales of BioCart. In 2011, we made a strategic decision to no longer provide BioCart commercially in Israel. Since December 31, 2011, we have not generated any revenue from therapeutic product sales.

We generated collaboration revenue exclusively from a license agreement with AT Grade S.R.L. (AT Grade) for distribution of BioCart in Italy. The agreement included a combination of diligence milestone payments, minimum royalty payments and royalties for commercial activity in Italy. In 2011, we determined with AT Grade that the licensing agreement was no longer part of our strategic programs. From inception through December 31, 2011, we recorded \$70,000 of collaboration revenue from this license agreement. The license agreement was formally terminated in March 2012. We continued to generate collaboration revenue from this license agreement through the date of termination. We recorded \$26,000, \$8,000 and \$0 of collaboration revenue for the years ended December 31, 2012 and 2013 and the three months ended March 31, 2014, respectively.

From inception to March 31, 2014, we recorded grant revenue of \$244,000 related to a cash grant received during the year ended December 31, 2010 from the U.S. Internal Revenue Service as a qualifying therapeutic discovery project tax credit program established pursuant to the Patient Protection and Affordable Care Act. Under this program, the tax credits and grants are made available to companies with no more than 250 employees that have a project which, among other requirements, can demonstrate new or cost saving therapies, support high quality jobs and increase U.S. competitiveness in the fields of life, biological and medical sciences.

#### **Research and Development Expenses**

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

- compensation and employee-related costs;
- costs associated with conducting our preclinical, clinical and regulatory activities, including fees paid to third-party professional consultants and service providers;
- costs incurred under clinical trial agreements with investigative sites;
- costs for laboratory supplies and laboratory equipment;
- costs to acquire, develop and manufacture preclinical study and clinical trial materials;
- 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.

From inception through March 31, 2014, we incurred \$60.0 million in research and development expenses. We plan to increase our current level of research and development expenses for the foreseeable future as we continue the development of our regenerative medicine platform and our initial therapeutic product candidates. Our current planned research and development activities include the following:

- advancing NeoCart in a Phase 3 clinical superiority trial to microfracture;
- leveraging our regenerative medicine platform to expand into additional therapeutic applications; and
- expanding and protecting our intellectual property platform.

We cannot determine with certainty the timing of initiation, the duration and the completion costs of current or future preclinical studies and clinical trials of our product candidates. At this time, due to the inherently unpredictable nature of preclinical and clinical development and given the early stage of our product candidates, we are unable to estimate with any certainty the costs we will incur and the timelines we will require in the continued

development of our product candidates, including NeoCart. Clinical and preclinical development timelines, the probability of success and development costs can differ materially from expectations. In addition, we cannot forecast which product candidates may be subject to future collaborations, when such 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 products as these expenses are deployed across all of our products.

#### Selling, General and Administrative Expenses

From inception through March 31, 2014, we incurred \$39.2 million in selling, general and administrative expenses. Selling, general and administrative expenses consist primarily of salaries and employee-related costs, including stock-based compensation and travel expenses for our employees in executive, finance and human resource functions. Other selling, general and administrative expenses include facility-related costs and professional fees for directors, accounting and legal services, and expenses associated with obtaining and maintaining patents.

We anticipate that our selling, general and administrative expenses will increase in the future as we increase our headcount to support our continued research and development and potential commercialization of our product development programs. We also anticipate increased expenses related to audit, legal, regulatory and tax-related services associated with maintaining compliance with exchange listing and SEC requirements, director and officer insurance premiums, and investor relations costs associated with being a public company.

#### Total Other Income (Expense), Net

Total other income (expense), net consists primarily of interest income earned on cash and cash equivalents; interest expense on convertible promissory notes and on prior commercial bank debt; and changes in fair value of the warrant liability relating to our outstanding common stock warrants.

#### Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of our consolidated financial condition and results of operations are based on our consolidated financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles. The preparation of these consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenue and expenses and the disclosure of contingent assets and liabilities in our consolidated financial statements. On an ongoing basis, we evaluate our estimates and judgments, including those related to accrued expenses and stock-based compensation. We base our estimates on historical experience, known trends and events, and various other factors that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are described in more detail in the notes to our consolidated financial statements appearing elsewhere in this prospectus, 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.

#### **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.

#### 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. There may be instances in which payments made to our service providers will exceed the level of services provided and result in a prepayment of the clinical expense. 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, an impairment loss would be recognized in earnings. The long-lived asset would be written down to the estimated fair value, calculated based on the present value of expected future cash flows. While our current and historical operating losses and negative cash flows are indicators of impairment, we believe that future cash flows to be received support the carrying value of our long-lived assets and, accordingly, have not recognized any impairment losses on long-lived assets from inception to March 31, 2014.

#### 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. 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 consist of in-process research and development (IPR&D) obtained through the acquisition of ProChon and the AT Grade license. Our current and historical operating losses and negative cash flows are indicators of impairment and we have recognized an impairment charge of \$330,000 during the year ended December 31, 2011, and an impairment charge of \$60,000 during the year ended December 31, 2011 resulted from our determination that the licensing agreement to distribute BioCart in Italy was no longer part of our strategic programs due to our suspension of production and commercialization of BioCart in 2011. We agreed with AT Grade to formally terminate the license agreement in March 2012. The results of our 2013 year end impairment testing indicated a decline in the fair market value of the IPR&D, resulting in an impairment charge of \$60,000. We also note that as our core focus has been on and will continue to be on the development of NeoCart, there is a risk of further impairment in the near future.

#### Impairment of Goodwill

Goodwill represents the difference between the purchase price and the fair value of the net assets acquired under the acquisition method of accounting for business combinations. Goodwill is not amortized but is evaluated for impairment within each reporting unit on an annual basis at year end each year for impairment, or if indicators are present or changes in circumstances suggest that impairment may exist.

Our impairment testing for goodwill of \$1.8 million from the 2011 acquisition of ProChon involved assessment at the reporting unit level using an income approach to determine whether it is more likely than not that the fair value of a reporting unit or the fair value of goodwill is less than its carrying amount. This assessment requires judgment on the potential impact of each qualitative factor.

We recorded an impairment charge of \$1.8 million to goodwill in 2011 resulting from the suspension of production and commercialization of BioCart.

# 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 the vesting periods. We estimate the fair value of stock options as of the date of grant using the Black-Scholes option pricing model, and we estimate the fair value of restricted stock based on the fair value of the underlying common stock as determined by our board of directors or the value of the services provided, whichever is more readily determinable. We account 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.

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. We estimate the fair value of stock option grants using the Black-Scholes option pricing model, which requires the input of highly subjective assumptions, including (a) the risk-free interest rate, (b) the expected volatility of our stock, (c) the expected term of the award and (d) the expected dividend yield. The risk-free interest rates for periods within the expected life of the option are based on the yields of zero-coupon U.S. Treasury securities. Due to the lack of a public market for the trading of our common stock and a lack of company specific historical and implied volatility data, we have based our estimate of expected volatility on the historical volatility of a group of similar companies that are publicly traded. For these analyses, we have selected companies with comparable characteristics to ours including enterprise value, risk profiles, position within the industry, and with historical share price information sufficient to meet the expected life of the stock-based awards. We compute the historical volatility data using the daily closing prices for the selected companies' shares during the equivalent period of the calculated expected term of our stock-based awards. We will continue to apply this process until a sufficient amount of historical information regarding the volatility of our own stock price becomes available. The expected term represents the period of time that options are expected to be outstanding. Because there was not enough historical exercise behavior through March 31, 2014, for 2012 stock option grants, we determined the expected life assumption using the simplified method, which is an average of the contractual term of the option and the vesting period. In 2013, the stock option grants through August 1, 2013 were in-the-money, based on the retrospective fair value determinations, so we determined the expected life assumption for these stock options using a risk-adjusted method, which adjusts the average of the contractual term of the option and its vesting period for risk, reducing the expected life. For stock option grants in December 2013, which were granted at-the-money, we determined the expected life assumption using the simplified method. The expected dividend yield assumption is based on the fact that we have never paid cash dividends and have no present intention to pay cash dividends.

For employee stock option grants made during the years ended December 31, 2012 and 2013 and the three months ended March 31, 2013 and 2014, the weighted-average assumptions used in the Black-Scholes option pricing model to determine the fair value of those grants were as follows:

	Years er Decembe		Three mont March	
	2012	2013	2013 (unaudited)	2014 (unaudited)
Risk-free interest rate	0.93%	1.01%	0.89%	1.01%
Expected volatility	89.0%	87.9%	88.3%	87.9%
Expected term (in years)	6.08	5.36	5.92	5.36
Expected dividend yield	0.0%	0.0%	0.0%	0.0%

We had no non-employee stock options grants for the year ended December 31, 2012. For non-employee stock option grants made for the year ended December 31, 2013 and the three months ended March 31, 2013 and 2014, the weighted-average assumptions used in the Black-Scholes option pricing model to determine the fair value of those grants were as follows:

	Years Decem		Three mont March	
	2012	2013	2013 (unaudited)	2014 (unaudited)
Risk-free interest rate	_	0.23%	0.28%	0.57%
Expected volatility	_	145.2%	82.0%	109.9%
Expected term (in years)	_	0.98	1.73	2.13
Expected dividend yield	_	0.0%	0.0%	0.0%

The following table summarizes by grant date the number of shares of common stock underlying stock options granted from January 1, 2012 through March 31, 2014, as well as the associated per share exercise price and the estimated fair value per share of our common stock on the grant date:

Grant Dates	Number of Common Shares Underlying Options Granted	Exercise Price per Common Share	Estimated Fair Value per Common Share
August 15, 2012	2,797,253	\$ 0.07	\$ 0.07
October 31, 2012 (restricted stock)	61,095	0.07	0.07
March 5, 2013	288,206	0.07	0.13
March 5, 2013 (non-employee)	354,395	0.07	0.13
March 21, 2013 (non-employee)	101,825	0.07	0.13
April 23, 2013	48,603	0.07	0.11
April 23, 2013 (restricted stock)	81,623	0.07	0.11
May 17, 2013	459,877	0.07	0.11
July 16, 2013	2,236,042	0.07	0.15
August 1, 2013 (non-employee)	40,516	0.07	0.15
December 11, 2013	1,353,211	0.66	0.66

As of December 31, 2012, December 31, 2013 and March 31, 2014, the unrecognized compensation cost related to outstanding options was \$130,000, \$1.0 million and \$939,000, respectively, and is expected to be recognized as expense over 3.28 years, 3.21 years and 2.77 years, respectively.

As of December 31, 2012, December 31, 2013 and March 31, 2014, the unrecognized compensation cost related to restricted stock awards was \$4,000 \$14,000 and \$10,000, respectively, and is expected to be recognized as expense over 3.84 years, 3.14 years and 2.94 years, respectively.

Based on the assumed initial public offering (IPO) price of \$ per share (the midpoint of the price range set forth on the cover page of this prospectus), the intrinsic value of stock options outstanding as of December 31, 2013 would be \$ , of which \$ and \$ would have been related to stock options that were vested and unvested, respectively, at that date.

#### Determination of the Fair Value of Common Stock

We are required to estimate the fair value of the common stock underlying our stock-based awards when performing fair value calculations. All options to purchase shares of our common stock are intended to be granted with an exercise price per share no less than the fair value per share of our common stock underlying those options on the date of grant, based on the information known to us on the date of grant. In the absence of a public trading market for our common stock, on each grant date we develop an estimate of the fair value of our common stock with the assistance of a third party valuation specialist to determine an exercise price for the option grants.

In November 2013, our board of directors reviewed and reconsidered the fair value of our common stock with the assistance of a third party valuation specialist for the preceding periods of that year. In reconsidering the fair value of our common stock, the board of directors took into account the methodologies, approaches and assumptions provided by American Institute of Certified Public Accountants Audit and Accounting Practice Aid Series: Valuation of Privately Held Company Equity Securities Issued as Compensation (Practice Aid). This reconsideration resulted in the board of directors' determination that the fair value of the common stock was greater than the exercise price for certain options granted in 2013.

There are significant judgments and estimates inherent in the determination of the fair value of our common stock. These judgments and estimates include assumptions regarding our future operating performance, the time

to completing an IPO or other liquidity event and the determination of the appropriate valuation methods. If we had made different assumptions, our stock-based compensation expense, net loss and net loss per common share could have been significantly different.

In accordance with the Practice Aid, we considered the various methods for allocating the enterprise value across our classes and series of capital stock to determine the fair value of our common stock at each valuation date. The methods we considered consisted of the following:

- *Current Value Method.* Under the current value method, once the fair value of the enterprise is established, the value is allocated to the various series of preferred and common stock based on their respective seniority, liquidation preferences or conversion values, whichever is greatest. This method was considered but not utilized in any of the valuations discussed below.
- Option Pricing Method (OM). Under the OM, shares are valued by creating a series of call options with exercise prices based on the liquidation preferences and conversion terms of each equity class. The values of the preferred stock and common stock are inferred by analyzing these options.
- **Probability-Weighted Expected Return Method (PWERM).** The PWERM is a scenario-based analysis that estimates the value per share based on the probability-weighted present value of expected future investment returns, considering each of the possible outcomes available to us, as well as the economic and control rights of each share class.

Management determined the fair value of common stock for financial reporting purposes as of each valuation date as follows:

Valuation Date	non Stock ir Value
July 20, 2012	\$ 0.07
December 31, 2012	0.13
March 31, 2013	0.11
June 30, 2013	0.15
September 30, 2013	0.23
December 6, 2013	0.66
December 31, 2013	0.82
March 31, 2014	0.74

July 20, 2012 Valuation and August 2012 and October 2012 Grants

For the contemporaneous valuation at July 20, 2012, we utilized the OM to determine the value of our common stock, relying on the Series A Preferred Stock financing that closed in July 2012 at \$1.00 per share price for the Series A Preferred Stock and applying a discount for lack of marketability to the unadjusted common stock value to determine the fair market value of the common stock as of the valuation date of July 20, 2012.

As stated above, the OM treats common stock and preferred stock as call options on the total equity value of a company, with exercise prices based on the value thresholds at which the allocation among the various holders of a company's securities changes. Under this method, the common stock has value only if the funds available for distribution to stockholders exceed the value of the liquidation preference at the time of a liquidity event, such as a strategic sale, merger or IPO, assuming the enterprise has funds available to make a liquidation preference meaningful and collectible by the holders of preferred stock. The common stock is modeled as a call option on the underlying equity value at a predetermined exercise price. In the model, the exercise price is based on a comparison with the total equity value rather than, as in the case of a regular call option, a comparison with a per share stock price. Thus, common stock is considered to be a call option with a claim on the enterprise at an exercise price equal to the remaining value immediately after the preferred stock is liquidated. The OM uses the Black-Scholes option pricing model to price the call options. This model defines the securities' fair values as functions of the current fair value of a company and uses assumptions such as the anticipated timing of a potential liquidity event and the estimated volatility of the equity securities.

The following table summarizes the significant assumptions used to determine the fair value of our common stock of \$0.07 as of July 20, 2012:

July 20, 2012 valuation	
Key assumptions:	
Estimated time to liquidity	1.7 years
Annual volatility	99%
Risk-free interest rate	0.22%
Discount for lack of marketability	25%

#### December 2012 and 2013-Valuations and Grants

For the retrospective valuations at December 31, 2012, March 31, 2013, June 30, 2013 and September 30, 2013, as well as the contemporaneous valuations at December 6, 2013 and December 31, 2013, we used the PWERM. The change in valuation methodologies was made from the OM at July 20, 2012 to the PWERM at December 31, 2012 and beyond because we believed that the likely liquidity scenarios were more focused from our increased interaction with our new investor base and board of directors, and we began entertaining the concept of an IPO creating a higher probability of a liquidity event in next 15 to 24 months. Also, the PWERM is able to capture the changes in timing, probability, and values of the liquidity based upon developments in our company and the markets which will better meet our needs to obtain quarterly updates in valuation. We had gained visibility into restarting clinical trials as of December 2012 with an expectation of restarting in March 2013. The heightened visibility allowed us to gain comfort in estimating the timing, probability, and values of liquidity events required for the PWERM as progress in the clinical trials was the main driver of an IPO or acquisition. As stated above, under the PWERM, share value is derived from the probability-weighted present value of expected future investment returns, considering possible outcomes available to us, as well as the economic and control rights of each share class. Our December 31, 2012 and subsequent valuations consider several possible liquidity scenarios that include an acquisition, an IPO and dissolution. Prior to December 2012, we were in a transition phase in which a major recapitalization was completed. We did not have a long term business plan that contemplated future exit scenarios prior to the July 2012 financing, and therefore did not have visibility into the timing, probability, and value of liquidity events to use the PWERM as a reliable indicator of value.

The determination of the enterprise value of our company for each scenario uses the market approach, specifically the transaction multiple method. This method rests on the assumption that the value of business ownership interests can be determined by analysis of how much is paid to acquire similar ownership interests in similar businesses. This method derives indications of value based on the prices at which entire companies or operating units of companies have been sold, or the prices at which significant interests in companies changed hands. Multiples are developed based on: (a) the actual price paid for a company that has been acquired and (b) operating performance and financial condition indicators such as earnings (at various levels) or revenue. We identified relevant transactions for target companies operating in the biotechnology or orthopedic device industry in the determination of the enterprise value of our company and identified relevant IPOs in the biotechnology, specialized pharmaceutical and orthopedic device industries. The equity values for each scenario were then allocated to the various classes of stock based upon the claims of each class of stock.

The following table summarizes the significant assumptions used to determine the fair value of our common stock of \$0.13, \$0.11, \$0.15, \$0.23, \$0.66, \$0.82 and \$0.74 as of December 31, 2012, March 31, 2013, June 30, 2013, September 30, 2013, December 6, 2013, December 31, 2013 and March 31, 2014, respectively. The discussion following the table describes the changes in valuation for each period.

	Common Stock Valuation Assumptions as of							
	December 31, 2012	March 31, 2013 (unaudited)	June 30, 2013 (unaudited)	September 30, 2013 (unaudited)	December 6, 2013 (unaudited)	December 31, 2013	March 31, 2014 (unaudited)	
Acquisition scenarios		()	(	(	(		(4444444)	
Liquidity value	\$50 to \$250 million	\$50 to \$250 million	\$50 to \$250 million	\$50 to \$250 million	\$50 to \$250 million	\$50 to \$250 million	\$50 to \$250 million	
Probability of occurrence	10.00% to 50.00%	10.00% to 50.00%	10.00% to 40.00%	5.33% to 26.67%	5.00% to 10.00%	5.00% to 10.00%	5.00% to 10.00%	
Time to event	2.25 years	2.75 years	2.84 years	2.58 years	2.40 years	3.5 years	3.2 years	
IPO scenarios								
Pre-money valuation	\$ 75 to \$150 million	\$ 75 to \$150 million	\$75 to \$150 million	\$ 75 to \$150 million	\$75 to \$150 million	\$81 to \$150 million	\$81 to \$150 million	
Probability of occurrence	0.67% to 3.33%	0.67% to 3.33%	2.00% to 10.00%	5.33% to 26.67%	5.00% to 35.00%	5.00% to 38.00%	5.00% to 38.00%	
Time to event	1.25 to 2.25 years	1.00 to 2.75 years	0.75 to 2.84 years	0.5 to 2.58 years	0.32 to 2.4 years	0.5 to 3.5 years	0.5 to 3.2 years	
Probability of liquidation scenario	20%	20%	20%	20%	10%	5%	5%	
Discount for lack of marketability	28%	31%	32%	31%	15%	15%	5% to 20%	

#### July 20, 2012 to December 31, 2012

The estimated per share fair value of our common stock calculated in our valuation as of December 31, 2012 of \$0.13 per share increased from the July 20, 2012 valuation of \$0.07 per share. This is primarily due to the following factors:

- We closed the first tranche of the Series A Preferred Stock financing and eliminated uncertainty within our operations. Further, the new long-term capital structure was put in place, which helped stabilize the standing of common stockholders after the July 2012 recapitalization of our equity.
- Our fundraising, which included a second tranche of the Series A Preferred stock financing, was expected to be issued in the first quarter of 2014, which would be used to continue funding our operations and development milestones to ensure an return on investment.
- We switched to the PWERM for our common stock valuation as opposed to the OM to better reflect the multiple scenarios available to us, including scenarios contemplating an IPO.

#### December 31, 2012 to March 31, 2013

The estimated per share fair value of our common stock calculated in our valuation as of March 31, 2013 of \$0.11 per share decreased from the December 31, 2012 valuation of \$0.13 per share. This is primarily due to the following factors:

- We voluntarily paused our Phase 3 clinical trial to address issues in our supply chain discussed elsewhere in this prospectus, and to perform validation testing on our methods and equipment as a way to eliminate regulatory risk.
- We had turnover at the chief executive officer position.

#### March 31, 2013 to June 30, 2013

The estimated per share fair value of our common stock calculated in our valuation as of June 30, 2013 of \$0.15 per share increased from the March 31, 2013 valuation of \$0.11 per share. This is primarily due to the following factors:

- We began developing new supply chain capabilities, both externally and internally, including the exploration of a new production facility in Massachusetts to manufacture component parts used in the production of NeoCart for the Phase 3 clinical trial and beyond.
- The likelihood of an IPO increased due to improving market conditions for clinical stage life sciences companies and improved optimism internally for achievement of milestones.

June 30, 2013 to September 30, 2013

The estimated per share fair value of our common stock calculated in our valuation as of September 30, 2013 of \$0.23 per share increased from the June 30, 2013 valuation of \$0.15 per share. This is primarily due to the following factors:

- We hired a seasoned chief executive officer.
- Several new members of our management team were added to improve quality capabilities, bolster supply chain capabilities and provide clinical leadership.
- We anticipated the clinical trial would end its pause in November 2013, and during the pause our efforts to enroll additional sites would likely result in more sites treating patients than when the pause began.
- The likelihood of an IPO increased as market conditions continued to demonstrate strong momentum for life science companies, and we had even higher internal optimism about our ability to execute on milestones, particularly with our new management team.

#### September 30, 2013 to December 6, 2013

The estimated per share fair value of our common stock calculated in our valuation as of December 6, 2013 of \$0.66 per share increased from the September 30, 2013 valuation of \$0.23 per share. This is primarily due to the following factors:

- We selected investment bankers to act as underwriters for a planned IPO in the first half of 2014.
- We began our efforts on the preparation of our initial registration statement.
- We added an independent director to our board of directors.
- We finalized the aseptic validation of our clean room to comply with good manufacturing standards.
- We began enrolling patients to restart our Phase 3 clinical trial of NeoCart.

#### December 6, 2013 to December 31, 2013

The estimated per share fair value of our common stock calculated in our valuation as of December 31, 2013 of \$0.82 per share increased from the December 6, 2013 valuation of \$0.66 per share. This is primarily due to the following factors:

- We closed the Series A-1 Preferred stock financing on December 18, 2013.
- We continued to make progress on drafting our initial registration statement with the intent of submitting a draft registration statement with 2011 and 2012 financial statements in January 2014 and an amended draft registration statement with 2012 and 2013 financial statements by March 2014.
- We restarted our Phase 3 clinical trial of NeoCart and were nearing the release of five year data on our Phase 2 clinical trial and two year data on our Phase 3 clinical trial.
- The likelihood of an IPO increased as market conditions continued to demonstrate strong momentum for life science companies, and we had
  even higher internal optimism about our ability to execute on milestones, particularly with the progress made in drafting the initial registration
  statement.

# December 31, 2013 to March 31, 2014

The estimated fair value of our common stock as of March 31, 2014 was \$0.74 per share. This represents a decrease of \$0.08 per share since the December 31, 2013 valuation. The decrease is primarily due to the following factors:

• IPO scenarios were delayed due to senior management turnover in February 2014.

- The delay of the IPO scenario resulted in our decision to call an available \$10.3 million of the Series A-1 Preferred stock financing to sustain operations, which the December 31, 2013 valuation reflected as being invested in the IPO.
- The continued enrollment of patients in our Phase 3 clinical trial resulted in exit scenarios and the expected data window remaining the same.

Partially offsetting the factors causing a decrease in the valuation include our submission of a draft registration statement on February 14, 2014 and receiving initial comments from the SEC on March 13, 2014. Also, market conditions continued to demonstrate strong momentum for life science companies.

Warrants, Other Liability and Net Sales Distribution Payment Liability

In connection with the issuance of Series A Preferred Stock on July 20, 2012, we issued common stock warrants (Common Stock Warrants) to each participating investor. The Common Stock Warrants are convertible into 516,841 shares of our common stock upon a defined liquidity event of either an acquisition or an IPO. The number of shares of common stock may be decreased in the event that the percentage of the total equity required to be paid as part of the contingent payment payable to Purpose, Co. (Other Liability) is decreased. The Common Stock Warrants are exercisable at \$0.07 per share and are only exercisable in the event that the contingent payment is required to be settled for the Other Liability. The fair value of the Common Stock Warrants is classified as a long-term liability in our consolidated balance sheets.

The warrant liability was initially recorded on July 20, 2012 at fair value using the OM. We determined the fair value of the liability from the calculated equity value. At each reporting date, the fair value of the warrant liability is adjusted using the PWERM. The PWERM considers the changes in timing, probability, and values of preferred stock and common stock and other equity-linked securities based upon developments in our company and the market utilizing management's assumptions and various future outcomes.

The change in valuation methodologies was made from the OM at July 20, 2012 to the PWERM at December 31, 2012 and beyond because we believed that there was a higher probability of a liquidity event in the following 15 months. As stated above, the PWERM is able to capture the changes in timing, probability and values of the liquidity based upon developments in our company and the markets which will better address our need to obtain quarterly updates in valuation.

The Other Liability was initially recorded based on a combination of the PWERM and OM, utilizing management's assumptions. The fair value of the Other Liability is adjusted using PWERM at each reporting date. Changes in the fair value of the warrant liability and the Other Liability have been recorded as "change in fair value of warrant liability and other liability" in our consolidated statements of operations.

The OM that was used to estimate the fair value of the warrant liability used our valuation of our common stock as of the issuance date, July 20, 2012, to establish a basis of our equity value. A series of breakpoints was then determined based upon the contractual rights of our outstanding instruments with an equity claim that can be settled upon a liquidity event. The Black-Scholes option pricing model was then used to determine the fair value of each equity value breakpoint. The model utilized the following inputs: (a) risk-free interest rate of 0.22%; (b) implied volatility of our common stock of 99%; and (c) the expected term to a liquidity event of 1.7 years.

As part of the sale of our Series A-1 Preferred Stock, purchasers of Series A Preferred Stock forfeited their right to receive a 2% net sales distribution payment. The 2% net sales distribution payment was replaced with a new royalty agreement under which the purchasers of Series A-1 Preferred Stock (Royalty Recipients) are entitled to receive a net sales distribution payment equal to 3% of net sales during the calendar year (Net Sales Distribution Payment). At the election of the Royalty Recipients, we are required to redeem all or a portion of the net sales payments. The Royalty Recipients can elect to have each net sales percentage point redeemed for \$10.0 million payable in cash or shares of our common stock. As this represents a fixed monetary amount known upon issuance, the fair value of the

net sales distribution payment is classified as a long-term liability in our consolidated balance sheet as the "Net Sales Distribution Payment Liability" in the amount of \$13.1 million and \$13.8 million as of December 31, 2013 and March 31, 2014, respectively. For a further discussion of this obligation, see "Certain Relationships and Related Party Transactions—Series A and Series A-1 Financings."

The following table provides quantitative information about the fair value measurement, including the range of assumptions for the significant unobservable inputs used in the PWERM valuations of the warrant liability, Other Liability and Net Sales Distribution Payment Liability:

		Valuation Assumptions as of			
	December 31, 2012	December 31, 2013	March 31, 2014		
			(unaudited)		
Acquisition scenarios					
Liquidity value	\$50 to \$250 million	\$50 to \$250 million	\$50 to \$250 million		
Probability of occurrence	10.00% to 50.00%	5.00% to 10.00%	5.00% to 10.00%		
Time to event	2.25 years	3.5 years	3.2 years		
IPO scenarios					
Pre-money valuation	\$75 to \$150 million	\$81 to \$150 million	\$81 to \$150 million		
Probability of occurrence	0.67% to 3.33%	5.00% to 38.00%	5.00% to 38.00%		
Time to event	1.25 to 2.25 years	0.5 to 3.5 years	0.5 to 3.2 years		
Probability of liquidation scenarios	20%	5%	5%		
Discount for lack of market ability	28%	15%	5% to 20%		

The above assumptions remained relatively consistent for the periods presented as a result of only minor changes in the remaining contractual term of the Common Stock Warrants due to the passage of time, with the largest change being the probability of occurrence as the IPO became a more realistic scenario. The increase in the time to event for the acquisition scenarios is due to the change in the timing of expected patient enrollment in the clinical trial from December 2014 to April 2015 as a result of the pause in the clinical trial, which pause ended in December 2013. The decrease in the probability of liquidation scenarios is due to the re-start of the clinical trial in December 2013 as well as the increased probability of an IPO. The fair values per share of our underlying preferred stock were estimated using the same methodologies described above for the valuation of our common stock except the exceptions noted in the description above specific to each Common Stock Warrant, Other Liability and Net Sales Distribution Payment Liability.

The completion of this offering will result in the automatic conversion of our convertible preferred stock into common stock and the warrants will become exercisable. Upon such conversion, the Common Stock Warrants will be classified as a component of stockholders' equity (deficit) and will no longer be subject to remeasurement. Based on the assumed initial public offering price of \$ per share (the midpoint of the price range set forth on the cover page of this prospectus), and assuming all other inputs into our valuation model remain unchanged from those as of March 31, 2014, we would expect to record a charge of approximately \$ million to adjust the warrant and other liability to its then-current fair value upon the closing of the IPO.

# **Other Company Information**

# **Net Operating Loss Carryforwards**

Utilization of the net operating loss (NOL) and research and development credit carryforwards may be subject to a substantial annual limitation due to ownership change limitations that have occurred or that could occur in the future, as required by Section 382 and 383 of the Internal Revenue Code (Code), as well as similar state and foreign provisions. These ownership changes may limit the amount of NOL and research and development credit carryforwards that can be utilized annually to offset future taxable income and tax, respectively. In general, an "ownership change" as defined by Section 382 of the Code results from a transaction or series of transactions over a three-year period resulting in an ownership change of more than 50 percentage points 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 and 2013. We have not recorded NOLs that as a result of these restrictions will expire unused. Accordingly, we have recorded NOL carryforwards net of these limitations, which are \$3.9 million, \$30.5 million, \$36.7 million and \$49.7 million, in 2010, 2011, 2012 and 2013, respectively.

At December 31, 2013, we had U.S. federal and Israeli NOL carryforwards of \$17.1 million and \$26.6 million, respectively, which may be available to offset future taxable income. The U.S. federal NOL carryforwards begin to expire in 2032 and the Israeli NOL carryforward does not expire.

As of December 31, 2013, we have provided a full valuation allowance for deferred tax assets.

#### Income Taxes

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 total pre-tax beginning and ending amounts of uncertain tax positions is as follows:

<u></u>	ax Positions
(in	ı thousands)
Balance at January 1, 2013 \$	(13,280)
Reductions based on tax positions related to the period	11,051
Balance at December 31, 2013 \$	(2,229)

The uncertain tax positions giving rise to the unrecognized tax benefits of \$935,000 at December 31, 2013 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.

#### IORS 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 this 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.

#### **Recently Adopted Accounting Pronouncements**

In July 2013, the Financial Accounting Standards Board issued guidance that eliminates diversity in practice surrounding the presentation of unrecognized tax benefits when an NOL carryforward, a similar tax loss, or a tax credit carryforward exists. An entity is required to net an unrecognized tax benefit with a deferred tax asset for an NOL carryforward, a similar tax loss, or a tax credit carryforward if the carryforward would be used to settle additional tax due upon disallowance of a tax position. The adoption of this guidance on January 1, 2014 is not expected to have a material impact on our consolidated financial statements.

### **Results of Operations**

#### Three Months Ended March 31, 2013 and 2014

The following table summarizes the results of our operations for the three months ended March 31, 2013 and 2014:

	Three Months Ended Marc			h 31,	
		2013		2014	
		(in thousands)			
Collaboration revenue	\$	5	\$	_	
Research and development expenses		1,908		3,347	
Selling, general and administrative expenses		905		1,826	
Other income (expense), net		92		1,736	

**Revenue.** Revenue was \$0 for the three months ended March 31, 2014, compared to \$5,000 for the three months ended March 31, 2013. The decrease of \$5,000 was due to the termination of a collaboration agreement with AT Grade. We agreed with AT Grade that the relationship was no longer part of our strategic programs. We do not expect any future revenue until we have successfully completed the commercialization of NeoCart or future product candidates.

**Research and Development Expenses.** Research and development expenses were \$3.3 million for the three months ended March 31, 2014 as compared to \$1.9 million for the three months ended March 31, 2013. The increase of \$1.4 million was due to the resumption of the NeoCart Phase 3 clinical trial in December 2013.

Selling, General and Administrative Expenses. Selling, general and administrative expenses were \$1.8 million for the three months ended March 31, 2014, compared to \$905,000 for the three months ended March 31, 2013. The increase in spending of \$921,000 was the result in part of the preparation of the registration statement for our IPO, which drove the need for more marketing and executive involvement, as well as the need to engage an independent registered public accounting firm to perform an audit of the financial statements included in the registration statement. Costs included in the increased spending were an increase in employee compensation related expenses associated with severance and the expansion of our executive management and finance team, an increase of \$799,000 in professional service provider fees to support the audit of the inception to date consolidated financial statements and an increase in professional service provider fees to support awareness of the NeoCart Phase 3 clinical trial.

**Other Income (Expense)**, **Net.** Other income (expense), net was \$1.7 million for the three months ended March 31, 2014, compared to \$92,000 for the three months ended March 31, 2013. The \$1.6 million increase in other income (expense), net was primarily the result of a \$1.6 million increase to the periodic fair value adjustment of warrant liability and other liability.

#### Years Ended December 31, 2012 and 2013

The following table summarizes the results of our operations for the years ended December 31, 2012 and 2013:

	Years Ended December 31,			,	
	2012			2013	
	(in thousands)				
Collaboration revenue	\$	26	\$	8	
Research and development expenses		11,941		11,946	
Selling, general and administrative expenses		3,053		4,847	
Impairment of goodwill and intangible assets				60	
Other income (expense), net		(1,967)		(8,867)	

**Revenue.** Revenue was \$8,000 for the year ended December 31, 2013, compared to \$26,000 for the year ended December 31, 2012. The decrease of \$18,000 was due to the termination of a collaboration agreement with AT Grade. We agreed with AT Grade that the relationship was no longer part of our strategic programs. We do not expect any future revenue until we have successfully completed the commercialization of NeoCart or future product candidates.

**Research and Development Expenses.** Research and development expenses were \$11.9 million for each of the years ended December 31, 2013 and 2012. We currently expect research and development expenses to increase in 2014 due to the resumption of the NeoCart Phase 3 clinical trial in December 2013.

Selling, General and Administrative Expenses. Selling, general and administrative expenses were \$4.8 million for the year ended December 31, 2013, compared to \$3.1 million for the year ended December 31, 2012. The increase in spending of \$1.7 million was the result in part of the preparation of the registration statement for our IPO which drove the need for more marketing and executive involvement, as well as the need to engage an independent registered public accounting firm to perform an audit of the financial statements included in the registration statement. Costs included a \$500,000 increase in employee compensation-related expenses associated with severance and the expansion of our executive management and finance team, an increase of \$1.1 million in professional service provider fees to support the audit of the inception to date consolidated financial statements and a \$137,000 increase in professional service provider fees to support awareness of the NeoCart Phase 3 clinical trial. We expect selling, general and administrative expenses to increase in 2014 as the NeoCart Phase 3 clinical trial continues and as we increase our administrative structure to support our IPO and obligations as a public company thereafter.

**Impairment of Goodwill and Intangible Assets.** Impairment of goodwill and intangible assets was \$60,000 for the year ended December 31, 2013, compared to \$0 for the year ended December 31, 2012. The increase was due to the impairment of IPR&D identified during our annual impairment testing for the year ended December 31, 2013.

Other Income (Expense), Net. Other income (expense), net was \$(8.9) million for the year ended December 31, 2013, compared to \$(2.0) million for the year ended December 31, 2012. Contributing to the \$6.9 million decrease in other income (expense), net was a \$7.0 million decrease to the periodic fair value adjustment of warrant liability and other liability. In addition a decrease of \$687,000 in gains created from the cancellation of debt recorded in 2012 was offset by a decrease in interest expense of \$798,000 from interest expense related to convertible debt instruments issued in 2011 and 2012 that were converted into equity as part of our Series A Preferred stock financing in July 2012.

# **Liquidity and Capital Resources**

We have incurred losses and negative cash flows from operations since inception. From our inception through March 31, 2014, we had an accumulated deficit of \$114.2 million and anticipate that we will continue to incur net losses for the next several years.

Since our inception, we have funded our consolidated operations primarily through the private placement of preferred stock and convertible notes, commercial bank debt and, to a limited extent, revenue from product sales, collaboration activities and grants. As of March 31, 2014, we had cash and cash equivalents of \$3.4 million.

We believe that the net proceeds from this offering and our existing cash and cash equivalents will be sufficient to fund our projected cash needs through at least the end of 2017. We will require additional capital for the further development of our existing product candidates and may also need to raise additional funds sooner to pursue other development activities related to additional product candidates. Our recurring losses from operations and negative cash flows raise substantial doubt about our ability to continue as a going concern. We may never become profitable, or if we do, we may not be able to sustain profitability on a recurring basis.

Beginning in January 2012, we issued \$6.0 million of convertible promissory notes with a maturity date of one year and accruing interest at eight percent per year. On July 20, 2012, we issued 28,602,031 shares of our Series A Preferred Stock for net proceeds of \$20.7 million in cash and the conversion of the \$6.0 million of outstanding convertible promissory notes. In December 2013, we issued 10,323,988 shares of our Series A-1 Preferred Stock for net proceeds of \$10.3 million in cash.

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

	Years Ended December 31,		Three Months Ended March 31,		
	2012	2013	2013	2014	
	-	(in thou	sands)		
Net cash used in operating activities	\$ (12,232)	\$ (15,282)	\$ (2,759)	\$ (5,019)	
Net cash provided by (used in) investing activities	(79)	(554)	(1)	(120)	
Net cash provided by (used in) financing activities	26,688	9,854	_	(235)	
Net increase (decrease) in cash and cash equivalents	\$ 14,377	\$ (5,982)	\$ (2,760)	\$ (5,734)	

# **Operating Activities**

Cash used in operating activities increased \$2.2 million from \$2.8 million for the three months ended March 31, 2013 to \$5.0 million for the three months ended March 31, 2014. The primary driver of operating cash requirements was our research and development and selling, general and administrative activities in each period. During the three months ended March 31, 2013, we used cash from operating activities of \$2.8 million which consisted primarily of our net loss of \$2.7 million. During the three months ended March 31, 2014, we used cash from operating activities of \$5.0 million, which consisted primarily of our net loss of \$3.4 million and a change in the fair value of certain liabilities of \$1.7 million. The liabilities remeasured each period are the warrant liability, Other Liability and Net Sales Distribution Payment Liability. The \$2.2 million increase in cash used in operating activities as compared to the prior year period is due to an increased change in the fair value of these liabilities of \$1.6 million and the increase in net loss of \$721,000.

Cash used in operating activities increased \$3.1 million from \$12.2 million for the year ended December 31, 2012 to \$15.3 million for the year ended December 31, 2013. During the year ended December 31, 2012, we used cash from operating activities of \$12.2 million, which consisted primarily of our net loss of \$16.9 million partially offset by a \$3.1 million non-cash charge related to a technology license agreement and \$1.8 million related to the change in fair value of warrants. During the year ended December 31, 2013, we used cash from operating activities of \$15.3 million, which consisted primarily of our net loss of \$25.7 million offset by an increase of \$8.8 million related to the change in fair value of warrants, a \$617,000 increase in accrued expenses, a \$804,000 increase in accounts payable, a \$158,000 increase in stock-based compensation, and a \$60,000 increase in the impairment intangible assets. The \$3.1 million increase in cash used in operating activities as compared to the prior year is primarily due to a \$3.1 million non-cash charge related to a technology license agreement which had the effect of increasing cash flows during the prior year period but did not recur in the current year period, partially offset by a \$1.0 million increase in accounts payable that had the effect of decreasing cash flows during the prior year period but did not recur in the current year period.

#### **Investing Activities**

Cash used in investing activities increased \$119,000 from \$1,000 for the three months ended March 31, 2013 to \$120,000 for the three months ended March 31, 2014. The difference was primarily related to increased purchases of property and equipment.

Cash used in investing activities increased \$475,000 from \$79,000 for the year ended December 31, 2012 to \$554,000 for the year ended December 31, 2013. The difference was primarily related to increased purchases of property and equipment.

#### **Financing Activities**

Cash used in financing activities increased from \$0 for the three months ended March 31, 2013 to \$235,000 for the three months ended March 31, 2014. During the three months ended March 31, 2014, we incurred costs related to the IPO that we did not incur during the three months ended March 31, 2013.

Cash provided by financing activities decreased \$16.8 million from \$26.7 million for the year ended December 31, 2012 to \$9.9 million for the year ended December 31, 2013. During the year ended December 31, 2012, we received \$6.0 million of proceeds from the issuance of convertible bridge loans that were subsequently converted into 5,950,000 shares of Series A Preferred Stock on July 20, 2012, and \$20.7 million in net proceeds from the sale of Series A Preferred Stock on July 20, 2012 to outside investors. In December 2013, we amended the terms of the Series A Preferred stock financing and sold 10,323,988 shares of our Series A-1 Preferred Stock for an aggregate purchase price of \$10.3 million to existing investors, which is partially offset by costs associated with the IPO of \$409,000.

### **Operating Capital Requirements**

To date, we have generated product revenue from therapeutic product sales of BioCart in Israel. In 2011, we suspended sales of BioCart in the Israeli market for strategic reasons. We do not know when, or if, we will generate any future revenue from therapeutic product sales. We do not expect to generate significant revenue from therapeutic product sales unless and until we obtain regulatory approval of and commercialize NeoCart or our future product candidates. We anticipate that we will continue to incur losses for the next several years, and we expect the losses to increase as we continue the development of, and seek regulatory approvals for, NeoCart and our future product candidates, and begin to commercialize any approved products. We are subject to all of the 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. Upon the completion of this offering, we will incur additional costs associated with operating as a public company. We anticipate that we will need substantial additional funding in connection with our continuing operations.

Until we can generate a sufficient amount of revenue from our regenerative medicine products, if ever, we expect to finance future cash needs through public or private equity or debt offerings. In any event, we do not expect to achieve significant revenue from regenerative medicine product sales prior to the use of the net proceeds from this offering. 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 significantly delay, scale back or discontinue the development or commercialization of one or more of our product candidates. If we raise additional funds through the issuance of additional debt or equity securities, it could result in dilution to our existing stockholders, increased fixed payment obligations and the existence of securities with rights that may be senior to those of our common stock. If we incur indebtedness, we could become subject to covenants that would restrict our operations and potentially impair our competitiveness, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. Any of these events could significantly harm our business, financial condition and prospects.

Our forecast of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement and involves risks and uncertainties, and actual results could vary as a

result of a number of factors. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect. The amount and timing of future funding requirements, both near- and long-term, will depend on many factors, including:

- the design, initiation, progress, size, timing, costs and results of preclinical studies and clinical trials for our product candidates;
- the outcome, timing and cost of regulatory approvals by the U.S. Food and Drug Administration (FDA) and comparable foreign regulatory authorities, including the potential for the FDA or comparable foreign regulatory authorities to require that we perform more studies than, or evaluate clinical endpoints other than those that we currently expect;
- the timing and costs associated with our technology transfer and manufacturing location transition;
- the timing and costs associated with manufacturing NeoCart and our future product candidates for clinical trials, preclinical studies and, if approved, for commercial sale;
- the number and characteristics of product candidates that we pursue;
- the extent to which we are required to pay milestone or other payments under our in-license agreements and the timing of such payments;
- the cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;
- our need to expand our research and development activities, including our need and ability to hire additional employees;
- · our need to implement additional infrastructure and internal systems and hire additional employees to operate as a public company;
- · the effect of competing technological and market developments; and
- the cost of establishing sales, marketing and distribution capabilities for any products for which we may receive regulatory approval.

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.

#### **Contractual Obligations and Commitments**

The following table summarizes our contractual obligations and commitments as of December 31, 2013 that will affect our future liquidity:

	Less than			More than	
Total	al 1 year 1-3 years 3-5 y		3-5 years	rs 5 years	
		(in thousands)			
\$4,101	\$ 1,135	\$ 1,998	\$ 968	\$ —	
345	107	64	64	110	
59	59	_	_	_	
417	417	_	_		
\$4,922	\$ 1,718	\$ 2,062	\$ 1,032	\$ 110	
	\$4,101 345 59 417	Total         1 year           \$4,101         \$ 1,135           345         107           59         59           417         417	Total         1 year         1-3 years           (in thousands)           \$4,101         \$ 1,135         \$ 1,998           345         107         64           59         59         —           417         417         —	Total         1 year         1-3 years         3-5 years           (in thousands)           \$4,101         \$ 1,135         \$ 1,998         \$ 968           345         107         64         64           59         59         —         —           417         417         —         —	

Operating lease obligations represent future minimum lease payments under non-cancelable operating leases in effect as of December 31, 2013, including remaining lease payments for our current facilities in Waltham, Massachusetts, Woburn, Massachusetts, and Tel Aviv, Israel.

Research and development contract obligations represent minimum future payments to third parties under our license agreements that become due and payable on the achievement of certain development, regulatory and commercial milestones (such as the start of a clinical trial, filing for product approval with the FDA or other regulatory agencies, product launch or product sales) or on the sublicense of our rights to another party. To the extent the achievement and timing of these events is not fixed and determinable, we have not included such commitments on our consolidated balance sheet or in the table above. Certain milestones are in advance of receipt of revenue from the sale of products and, therefore, we may require additional debt or equity capital to make such payments. These commitments include:

- Under an exclusive license agreement with Angiotech Pharmaceuticals (US), Inc. pursuant to which we license certain patents for our CT3 bioadhesive, we are required to make annual maintenance payments and payments based upon development, regulatory and commercial milestones for any products covered by the in-licensed intellectual property. The maximum aggregate milestone payments we may be obligated to make per product are \$3.0 million. We will also be required to pay a royalty on net sales of products covered by the in-licensed intellectual property in the single digits.
- Under an exclusive sub-license agreement with Brigham and Women's Hospital, Inc. pursuant to which we license certain patents relating to our exogenous tissue processor, we are required to make annual maintenance payments and payments based upon development, regulatory and commercial milestones for any products covered by the in-licensed intellectual property. The maximum aggregate milestone payments we may be obligated to make are \$200,000. We will also be required to pay a royalty on net sales of products covered by the in-licensed intellectual property in the low single digits.
- Under an exclusive license agreement with Board of Trustees of The Leland Stanford Junior University pursuant to which we license certain
  patents relating to the use of exogenous tissue processor, we are required to make annual maintenance payments and payments based upon
  development, regulatory and commercial milestones for any products covered by the in-licensed intellectual property. The maximum aggregate
  milestone payments we may be obligated to make per product are \$300,000. We will also be required to pay a royalty on net sales of products
  covered by the in-licensed intellectual property in the low single digits.
- Under an exclusive license agreement with Yeda Research and Development Co. Ltd. pursuant to which we license certain rights relating to high level expression of heterologous proteins and plasmid p80 BS. We are required to make a yearly, non-refundable license fee payment of \$2,000. We will also be required to pay a royalty fee of a low single digit percentage rate of net sales of the licensed products, a low single digit percentage rate of net sales for combination products (meaning the combination of the licensed product with at least one other active ingredient, material or medical device that would have a clinical effect if administered independently) and a low double digit percentage rate of all of our sublicensing receipts.

We enter into contracts in the normal course of business with clinical sites for the conduct of clinical trials, contract research service providers for preclinical research studies, professional consultants for expert advice and other vendors for laboratory and research supplies and services. These contracts generally provide for termination on notice, and therefore are cancelable contracts and not included in the table of contractual obligations and commitments.

Obligations related to grants received represent consideration agreed to be paid in royalties of a low single digit percentage rate of sales of sponsored products developed using the grant money.

Severance contract obligations represent the remaining payments due to a former executive whose employment ended in February 2014.

Engineering contract obligations represent the future minimum payments due to ST3 Development Corporation for the in-process production of a multi-unit bioreactor system expected to be completed in June 2014. Upon completion of the delivery of the system the remaining payments will be made.

#### **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. Any amounts drawn under the equipment line of credit will be amortized and 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 on the credit line 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, we issued a warrant to Silicon Valley Bank in July 2014 to purchase 70,946 shares of our common stock at an exercise price per share of \$0.74.

The equipment line of credit includes customary operating but non-financial covenants, including limitations on our ability to incur additional indebtedness, issue dividends, sell assets, engage in any business other than our current business, merge or consolidate with other entities, create liens on our assets, make investments, repurchase our stock in certain instances, enter into transactions with affiliates, make payments on subordinated indebtedness and transfer or encumber any collateral securing the debt. As of July 10, 2014, no borrowings were outstanding under the line of credit and we were in compliance with all required covenants.

#### **Off-Balance Sheet Arrangements**

We did not have 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.

#### **Quantitative and Qualitative Disclosures about Market Risks**

We are exposed to market risk related to changes in interest rates. As of March 31, 2014, we had cash and cash equivalents of \$3.4 million. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates, particularly because our investments are in short-term

securities backed by U.S. Treasuries. Our available for sale securities are subject to interest rate risk and will fall in value if market interest rates increase. Due to the short-term duration of our investment portfolio and the low risk profile of our investments, an immediate 10% change in interest rates would not have a material effect on the fair market value of our portfolio.

#### BUSINESS

#### Overview

We are a regenerative medicine company focused on developing and commercializing products in the musculoskeletal segment of the marketplace. Our first product candidate, NeoCart, is being investigated in a Phase 3 clinical trial. NeoCart utilizes various aspects of our regenerative medicine platform to develop an innovative tissue implant intended to treat tissue injury in the field of orthopedics, specifically cartilage damage in the knee. NeoCart is an investigational product and has not been approved for sale in any jurisdiction, including the United States. We we have no other products that are approved for sale in the United States and currently we are not selling any other products that may be approved for sale in other jurisdictions.

Our regenerative medicine platform provides the tools to develop NeoCart. Our regenerative medicine platform combines expertise in the following areas:

- Cell processing: the handling of a tissue biopsy, extraction of cells, and expansion of the cells;
- Scaffold: three-dimensional structures that enable the proper distribution of cells and organize cells in their natural environment to support tissue formation;
- Tissue engineering: the use of a combination of cells, engineering and materials to improve or replace biological functions;
- Bioadhesives: natural, biocompatible materials that act as adhesives for biological tissue; and
- Growth factors: naturally occurring substances capable of stimulating cellular growth, proliferation and differentiation.

NeoCart is a cartilage-like implant created using patient's own cartilage cells through a series of tissue engineering processes. First, the patient's cells are separated from a tissue biopsy specimen extracted from the patient by a surgeon and multiplied in our laboratory. The cells are then infused into our proprietary scaffold that provides structure for the developing implant. Before NeoCart is implanted in a patient, the cell- and scaffold construct undergoes a bioengineering process in our Tissue Engineering Processor (TEP). Our TEP is designed to mimic the conditions found in a joint so that the implant is prepared to begin functioning like normal healthy cartilage prior to implantation. When the NeoCart implant is implanted, a bioadhesive is used to anchor the NeoCart implant in the cartilage injury and seal the implant to the surrounding native cartilage interface. The use of the bioadhesive eliminates the need for complicated suturing. We believe that the Phase 1 and Phase 2 clinical trials provide preliminary evidence for the safety of the NeoCart implant and improvement in pain and function in patients treated with NeoCart.

We are currently enrolling a Phase 3 clinical trial for NeoCart in the United States to provide evidence of the safety and effectiveness of NeoCart, studying cartilage defects in the knees of 245 patients under a Special Protocol Assessment (SPA) with the U.S. Food and Drug Administration (FDA). Pursuant to the SPA, we formally and prospectively reached agreement with the FDA on key elements of the Phase 3 clinical trial protocol, including design, endpoints and statistical analyses of the resulting study data. The SPA is binding on the FDA review division with limited exceptions. If the clinical trial is successful, the data may be used to support efficacy claims for NeoCart approval and demonstrate clinical superiority over the current standard of care, microfracture. Microfracture consists of the creation of tiny holes or "fractures" in the bone underneath the injured cartilage leading to formation of a blood clot in the affected area. The blood and bone marrow that form the clot contain stem cells, which are thought to grow into cartilage-building cells. If we are successful in demonstrating superiority to microfracture in improvement in pain and function at 12 months postoperative in our Phase 3 clinical trial and NeoCart is approved for sale in the United States, we believe it would be the first product approved for the first-line treatment of severe cartilage damage to demonstrate clinical superiority over microfracture.

Musculoskeletal-related conditions, including cartilage damage, are one of the most prevalent health problems in the United States. Based on recent publications, we estimate that 1,000,000 knee arthroscopies are performed

each year in the United States and we believe cartilage damage is likely to be identified in over 60% of those knee arthroscopies. Cartilage damage is a leading cause of osteoarthritis, a chronic condition in which cartilage breaks down, and the condition most responsible for the estimated 750,000 knee replacements performed in the United States annually. We believe the current alternatives available to treat cartilage damage in the knee, including microfracture, the most frequently used procedure for severe cartilage damage, inadequately address this condition. We believe NeoCart would represent a superior solution to treat cartilage damage in the knee because it has the potential to solve for the limitations of the current treatment alternatives and has the potential to provide improved efficacy, long-term patient benefits, accelerated patient recovery and predictable patient outcomes through a technically straightforward surgical procedure. To date, we have completed two FDA-regulated human clinical trials in the United States. Specifically, we conducted a Phase 1 safety study of eight patients and a Phase 2 randomized controlled exploratory study of 30 patients. The objective of the Phase 1 clinical trial was to demonstrate the safety of NeoCart for use when implanted into cartilage defects in the knee. The objective of the Phase 2 clinical trial was to continue the safety evaluation of NeoCart, gather additional efficacy data compared to microfracture, identify endpoints that are meaningful to patients and physicians, identify appropriate patient populations to receive NeoCart and obtain additional data to be used in design of future clinical studies. NeoCart demonstrated improvement in clinical efficacy based on pain and function measures as compared to microfracture in our Phase 2 clinical trial. We believe our Phase 3 study will confirm the positive Phase 1 and Phase 2 clinical data generated by NeoCart, which we believe are a direct result of our regenerative medicine platform and the elements comprisi

The goal of our Phase 3 clinical trial, which we are currently enrolling, is to demonstrate advantages of NeoCart over microfracture with respect to efficacy, accelerated patient recovery, technically straightforward surgery, long-term patient benefits and positive safety profile. We believe the advantages will allow us to secure approval to sell NeoCart in the United States and will enable us to potentially become a market leader in cartilage repair. We expect to complete enrollment of our NeoCart Phase 3 clinical trial by the first half of 2016, but we may encounter difficulties enrolling patients in our clinical trials, which could delay or otherwise adversely affect our clinical development activities. We have over 20 sites eligible to enroll patients and have randomized 41 patients into the Phase 3 clinical trial as of July 1, 2014. We are enrolling the Phase 3 clinical trial using surgeon-investigators who screen patients with knee pain against a pre-specified set of eligibility criteria after obtaining their consent to participate in the trial. Once randomized into the trial based on eligibility, the patients undergo their surgical treatment and return for evaluation and data collection by the investigators at regular intervals for three years as set forth in the study protocol. We are financing the Phase 3 clinical trial with funds raised from our private financing activities and intend to use the proceeds from this offering to finance the trial through the expected completion of enrollment in the first half of 2016.

In anticipation of potential approval of NeoCart, we have begun to scale our internal current Good Manufacturing Practices manufacturing capabilities and transition the manufacture of all our products in-house at our facilities located in the greater Boston area. The transition commenced in March 2014 with the intent of having the ability to manufacture NeoCart and the critical components of NeoCart with minimal reliance on third parties prior to the commercialization of NeoCart in the event NeoCart is approved. Following this transition, we will be required to obtain FDA approval of the comparability of the critical NeoCart raw materials moved in-house, and if we fail to obtain, or if we experience a delay in obtaining such approval, our business, operating results and prospects will be adversely affected.

We believe our regenerative medicine platform may provide us with the ability to develop a strong pipeline and that the positive clinical data we have seen in treating cartilage damage of the knee with NeoCart will be applicable to other joints such as the ankle, hip and shoulder. We also believe our regenerative medicine platform has the ability to translate the fundamental science to allow us to develop additional product candidates to treat other soft tissue damage throughout the body such as tendon, ligament and meniscus tears and complex joint degeneration. Although not utilized in connection with our current NeoCart development, our portfolio of proprietary fibroblast growth factors may be explored for their use in optimizing manufacturing yields and we believe they could also have various therapeutic applications including wound healing and fracture healing. We

plan to continue investing in our intellectual property portfolio in order to expand and protect our regenerative medicine platform and future product candidates.

#### **Regenerative Medicine**

Regenerative medicine is a rapidly developing, interdisciplinary field that is transforming healthcare by translating fundamental science into a variety of products and solutions aimed at repairing, regenerating or replacing function loss caused by injury, disease or aging. Regenerative medicine technologies encompass a variety of therapeutic approaches, including tissue engineering, cell-based therapies, gene therapy, small molecules and biologics, stem cells and biobanking. Any combination of these technologies may be used to harness or stimulate the body's innate healing ability in order to treat a wide range of ailments, including musculoskeletal-related conditions, cardio- and peripheral vascular diseases, neurological disorders, stroke, non-healing wounds and ocular diseases.

Musculoskeletal conditions, comprised of injuries to or diseases of bones, cartilage, joints, ligaments, muscles, nerves, skin or tendons, are the most common health problem in the United States and are a leading cause of disability and healthcare expenditure according to *The Burden of Musculoskeletal Diseases in the United States*, a 2011 publication of a coalition of professional organizations including the American Academy of Orthopaedic Surgeons. Based on the commercial introduction of new products and expanded applications of approved products, the musculoskeletal, orthopedics and spine segment of the regenerative medicine market is projected to reach approximately \$13 billion worldwide by 2015 according to a 2010 report issued by MedMarket Diligence.

Our initial product candidate, NeoCart, leverages our regenerative medicine platform and, upon approval, if any, we believe will compete in the musculoskeletal segment of the regenerative medicine marketplace with an initial focus on treating cartilage damage in the knee.

#### Cartilage Damage

Joint, or articular, cartilage covers the ends of bones and allows for joints to glide smoothly with minimal friction. Cartilage damage, or chondral defects, can be caused by acute trauma, such as a bad fall or sports-related injury, or by repetitive trauma, such as general wear over time. Unlike other tissues in the body, joint cartilage has no innate ability to repair itself, making any injury permanent. Left untreated, even a small chondral defect can expand in size and progress to debilitating arthritis, ultimately necessitating a joint replacement procedure.

We estimate that, based in part on historical growth rates reflected in a 2011 article in the *Journal of Bone and Joint Surgery*, over 1,000,000 knee arthroscopies are performed on an annual basis in the United States in skeletally mature adults and, based on a 2007 article published in *The Knee*, more than 60% of those arthroscopies may reveal cartilage damage. To standardize the reporting of the severity of chondral defects, the International Cartilage Repair Society established a universal classification system that grades the damage using a scale of 1 to 4, with 4 considered the worst. Grade 3 and 4 chondral defects, also referred to as full-thickness defects, are considered severe. Based on the projected growth in the number of annual arthroscopies in the United States, we believe that by 2015 at least 750,000 patients in the United States will be diagnosed with full-thickness chondral defects and over 1,000,000 Americans annually will undergo a primary total knee replacement resulting from disabling arthritis.

#### Limitations of Current Alternatives for Treating Cartilage Damage

We estimate, based on internal research, that over 500,000 knee cartilage procedures are performed annually in the United States, primarily in the form of debridement, microfracture, conventional autologous chondrocyte implantation (ACI) and osteochondral grafting.

Debridement and microfracture procedures are the most frequently performed surgical procedures for treatment for cartilage damage, accounting for an estimated 90% of all such procedures according to materials from a 2009

meeting of the Cellular Tissue and Gene Therapies Advisory Committee of the FDA. Debridement is an arthroscopic procedure that involves removal of injured or loose tissue debris by shaving, cutting or scraping it. Debridement does not attempt to repair cartilage damage. The surgeon's only goal when performing debridement is to improve a patient's symptoms.

Microfracture is considered the current standard of care for severe chondral defects due to its short-term success in improving symptoms in many patients, its simplicity, its safety profile and the lack of other viable alternatives. The procedure consists of perforations, or microfractures, made to the bone plate at the location of cartilage damage in order to allow bone marrow stem cells access to the injured area. Microfracture surgery, a procedure pioneered in the 1980s, was developed to exploit the ability of stem cells to differentiate into mature cells and tissue types. If bone marrow stem cells are able to access the injured area and stay in place by forming a blood clot, then they may differentiate into cartilage cells, or chondrocytes, that would potentially go on to form cartilage. However, microfracture has been unsuccessful in reliably solving the underlying problem of cartilage damage because the repair tissue formed by the procedure, which has been found to usually be a mix of tissue types, is incapable of withstanding the normal shock and shear forces that joint cartilage sustains.

In addition to its inability to solve the underlying problem—damage to the articular cartilage—microfracture is associated with numerous other drawbacks and limitations, including the following:

- Modest Efficacy: The results of microfracture vary based on patient-specific characteristics and individual healing responses. Studies have shown the benefits of microfracture are negatively influenced by advanced age, higher body weight, larger chondral defect size and limited amount of repair tissue formed.
- **Limited Long-Term Patient Benefits:** Positive clinical response to microfracture has been shown to wane over time. A systematic review summarizing multiple articles on microfracture and published in the *American Journal of Sports Medicine* in 2009 revealed that up to 80% of microfracture patients report deterioration in their postoperative functional improvement after two years. Based on our interpretation of a 2013 article in *Cartilage* and the 2009 systematic review in the *American Journal of Sports Medicine*, we believe over 30% of microfracture patients require subsequent additional cartilage procedures after two years and up to 50% of all microfracture patients eventually require unplanned knee procedures due to persistent or recurrent symptoms.
- Extended Patient Recovery: Microfracture patients are typically not allowed to resume any vigorous activities for six months after their surgeries. During this time, patients must avoid weight-bearing activities for the first six weeks and use continuous passive motion machines for several hours per day. Prolonged physical therapy is often recommended. Such requirements and restrictions are believed necessary to optimize the anatomic and clinical results of microfracture, but come at the cost of muscle weakening and delayed resumption of activities.

ACI and osteochondral grafting are procedures generally reserved for failed cartilage procedures or very large cartilage defects. While studies indicate beneficial outcomes for patients receiving these treatments, both have drawbacks and limitations similar to those affecting debridement and microfracture, and also are associated with the following:

- **Technically Demanding Surgeries:** ACI is a slurry of autologous cartilage cells formed from a biopsy of a patient's cartilage and grown over six to eight weeks. A patch or cover must be sutured into the surrounding healthy cartilage to hold the slurry in place. Osteochondral grafting, whether using the patient's own cells or using another person's tissue, consists of a circular plug of bone and cartilage press-fit into the defect and can be challenging to perform because of the difficulty of achieving an exact match, fit and placement of the graft.
- *Negative Safety Profile:* ACI techniques are associated with graft failure, delamination (loss of cartilage layering), tissue overgrowth and knee stiffness. According to a 2006 report in the *Journal*

of Bone and Joint Surgery, 48% of ACI patients underwent reoperation as a result of problems directly related to the graft. Osteochondral grafting, if performed with the patient's own cells, is associated with limitations in treatable defect sizes because of associated donor site morbidity and, if performed using another person's tissue, is associated with the potential of disease transmission and nonunion.

#### **Our Regenerative Medicine Platform and Initial Product Candidate**

#### **Our Regenerative Medicine Platform**

Our regenerative medicine platform is comprised of innovative bioengineering, advanced proprietary materials sciences as well as molecular and cellular biology technologies that can be utilized individually or in a variety of combinations to treat musculoskeletal-related conditions:

- *Cell Processing:* As part of our process of implant production, our cell processing technologies involve the handling of a biopsy specimen in our own cGMP facilities, cell extraction from the biopsy and the expansion of cells in our segregated cell culture facility. Our proprietary process is currently optimized for, but not limited to, cartilage cell culturing.
- Scaffolds: Scaffolds are structures capable of supporting three-dimensional tissue formation and providing an environment for the cells that are needed to form the tissue. Our three-dimensional scaffold structures, including our honeycomb collagen scaffolds, are designed to produce a cartilage-like implant. The term "honeycomb" describes the shape of the pores inside of the scaffold as they are shaped like a honeycomb. The scaffold for NeoCart is shaped like a disk, with diameter of 34 mm and thickness of 1.5 mm. Our scaffold structures enable the distribution of cells throughout the scaffold. The honeycomb structure is important because it allows cartilage cells to line up vertically throughout the scaffold so that they organize as they normally would in native cartilage. Competing scaffolds only accommodate cells on their surface or in layers. Our proprietary three-dimensional scaffolds are biocompatible, biodegradable and non-toxic. These scaffolds can support and deliver a variety of cell types.
- *Tissue Engineering:* Tissue engineering refers to applications that repair or replace portions of or whole tissues such as cartilage, bone, blood vessels and skin. We use a combination of cells, engineering and materials methods to produce our tissue implant for the purpose of repairing cartilage tissue. Our proprietary TEPs incubate our cell- and scaffold-based implants under conditions designed to mimic the conditions found in the knee, including pressure changes and low oxygen levels. We believe our proprietary TEP technology is unique to the tissue repair market and is one of the reasons patients receiving a NeoCart implant in our Phase 1 and Phase 2 clinical trials recovered more quickly and realized positive long-term outcomes as compared to patients receiving microfracture surgery.
- **Bioadhesive:** Our proprietary bioadhesive, CT3, secures the NeoCart implant in the defect and eliminates the need for complicated suturing required during certain other cartilage repair treatments. Our internal studies demonstrate that CT3 is stronger than the fibrin glue used in other surgical procedures, including other current cartilage repair treatments. CT3 is comprised of three components: methylated collagen, activated polyethylene glycol (PEG) and a simple salt buffering solution that acts as a curing component. CT3 is biodegradable and nontoxic. We believe CT3 contributes to the quick recovery and the positive long-term outcomes seen in our Phase 1 and Phase 2 clinical trials.
- *Growth Factors:* Our proprietary growth factors include a number of variants that are key elements in the processes of proliferation and differentiation of a wide variety of cells and tissues. We intend to explore the use of these growth factor variants to speed the expansion of biopsy specimens in the laboratory and may eventually implement this technology into our manufacturing process. We also believe they could have therapeutic applications for, among other ailments wound and fracture healing.

#### NeoCart: Our Initial Product Candidate

NeoCart, our Phase 3 product candidate, utilizes many aspects of our regenerative medicine platform to repair knee cartilage damage. We believe NeoCart has the potential to provide several benefits not provided by current treatment alternatives for knee cartilage damage, including:

- *Improved Efficacy:* In our Phase 2 clinical trial of 30 patients, NeoCart showed better clinical outcomes when compared directly to microfracture on measures of pain and function. The difference in improvement between the two groups was apparent as early as three months following surgery and was statistically significant at six months, one year, two years and three years. We believe efficacy seen in our trials to date is a result of NeoCart's ability to function like cartilage upon implantation and integrate with the surrounding native tissue, features that distinguish it from current treatment alternatives.
- Long-Term Patient Benefits: In contrast to microfracture's well-documented deterioration of results after two years, NeoCart's positive outcomes have been sustained for three or more years in our Phase 1 and 2 clinical trials. We believe that all of the biologic and mechanical attributes of NeoCart provide the potential for a durable clinical response and give it the potential to prevent the evolution of osteoarthritis and subsequent need for knee replacement surgery.
- Accelerated Patient Recovery: Our CT3 bioadhesive anchors NeoCart in the defect bed and seals it to the surrounding native cartilage. The cartilage-like NeoCart implant coupled with the secure CT3 fixation may allow for earlier weight-bearing and accelerated recovery of function than is typical with current therapies, which would be distinctly advantageous for any cartilage repair solution. In our Phase 3 clinical trial, patients may be allowed to begin weight-bearing activities as soon as two weeks following implantation versus six weeks for the current standard of care, microfracture.
- *Technically Straightforward Surgery:* The use of our CT3 bioadhesive eliminates the need for complicated suturing associated with ACI techniques. Unlike osteochondral grafting procedures, the NeoCart implant is tailored to the shape of the defect so that all normal host tissue is left in place.
- **Positive Safety Profile:** To date, NeoCart has shown no evidence of tissue overgrowth or knee stiffness often associated with ACI techniques. Reoperation rates to address problems directly related to the cartilage procedure or other persistent general knee symptoms, associated with all cartilage techniques and particularly high with ACI techniques, have been very low in NeoCart patients followed for five years in our Phase 1 and Phase 2 clinical trials.

#### **Our Business Strategy**

Our goal is to leverage our regenerative medicine platform to develop and commercialize innovative, next generation products to treat patients suffering from musculoskeletal-related conditions. To achieve our goal, we initially plan to focus on completing the enrollment of our Phase 3 clinical trial for NeoCart by the end of the first half of 2016 with the intent of applying for regulatory approval in the United States from the FDA after the clinical data is available. In parallel, we plan to continue to develop our manufacturing capabilities that support the clinical development and eventual commercial development of NeoCart, if approved. We plan to build our commercial infrastructure during our Phase 3 clinical trial for NeoCart to support a successful launch and commercialization of NeoCart in the event it receives FDA approval. The overarching strategies that support these goals are as follows:

• Complete Phase 3 Clinical Trial and Apply for Regulatory Approval of NeoCart in the United States. We are currently enrolling our Phase 3 clinical trial. As part of the clinical trial, 245 patients will be randomly selected to receive either a NeoCart implant or microfracture surgery on a two-to-one basis. As of July 1, 2014, we had over 20 sites eligible to enroll patients across the United States, with an additional nine sites identified that we may elect to activate. We have the ability, if we choose to, to activate up to an aggregate of 40 sites for the completion of the clinical

trial. Assuming positive results of the clinical trial, we plan to submit a Biologics License Application (BLA) to the FDA for approval in the United States when the 12 month data is available, which we expect to be in the second half of 2017. Upon receiving approval from the FDA, if at all, which we anticipate would be in 2018 if a BLA is submitted in the second half of 2017, we then intend to launch and commercially market NeoCart for the treatment of cartilage defects in the knee.

- Continue to Develop Our Manufacturing Capabilities. We own and operate our own cGMP manufacturing operations for NeoCart and we plan to transfer production of critical raw materials and components used in the NeoCart production process to a new manufacturing facility that we are in the process of developing. For our clinical trials of NeoCart, the raw materials and components were supplied to us by external vendors. We are transferring production to our own facilities in order to gain full control over quality, process, supply and costs. This transition to our own manufacturing facilities will also enable us to expand production capacity for clinical and commercial supply of NeoCart in the future in the event we receive FDA approval, subject to comparability verification and confirmation by the FDA.
- Maximize Commercial Opportunity of NeoCart. We expect to invest strategically in a U.S. commercial infrastructure to support the successful launch, commercialization and post-marketing support for NeoCart in the event NeoCart should receive FDA approval. As part of this investment, we intend to build a highly experienced medical affairs, sales and marketing organization to target orthopedic surgeons in the United States as the primary point of contact. The commercial organization is also expected to include internal infrastructure to support the high-touch, on-demand communication and processes associated with the manufacturing, specialized distribution and final delivery of NeoCart to the orthopedic surgeons who perform the NeoCart implantation.
- Leverage Our Core Technology Platform to Expand into Additional Therapeutic Applications. We believe a significant unmet market need and commercial opportunity exist for NeoCart to treat cartilage defects in other joints such as ankles, shoulders and hips. Further, we plan to exploit our regenerative medicine platform to develop products that treat additional soft tissue and musculoskeletal-related disorders.
- Selectively Evaluate Business Development Opportunities. We plan to evaluate business development opportunities, which may include inlicensing and out-licensing of products or technologies, in order to strengthen our revenue prospects and improve our manufacturing capabilities.
- Continue to Invest in Building and Protecting Our Intellectual Property. We intend to continue to expand our strong existing intellectual property portfolio and protect our regenerative medicine platform for both NeoCart and future product candidates by filing patent applications in the United States, the European Economic Area (EEA, which is comprised of the 28 Member States of the European Union, Iceland, Liechtenstein and Norway) and other jurisdictions with the goal of extending the degree and level of protection as well as the duration of protection across our core technologies and products.

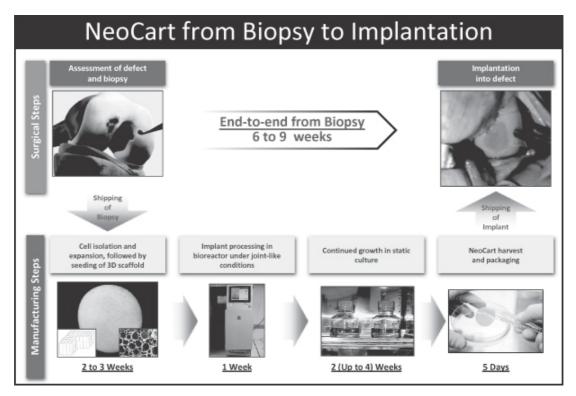
#### Our Phase 3 Product Candidate: NeoCart

NeoCart is our lead product candidate and is currently being evaluated in a U.S. Phase 3 clinical trial as a first-line therapy for full thickness knee chondral lesions in skeletally mature adults age 18 to 55. NeoCart is a cartilage-like implant created from a patient's own cartilage cells. The patient's cells are multiplied in our laboratory and then infused into a proprietary scaffold to allow them to organize and function like cartilage cells. Before NeoCart is shipped to the surgeon for implantation, the cell- and scaffold construct undergoes a bioengineering process that is designed to mimic a joint so that the implant, upon placement in the knee with our proprietary CT3 bioadhesive, is primed to begin functioning like healthy cartilage.

NeoCart data produced to date in the Phase 1 and 2 clinical trials has demonstrated very favorable safety and the potential for durable efficacy and has been published in journals such as the *Journal of Bone and Joint Surgery*, which

accepted the Phase 2 data as resulting from a study that was designed, conducted, analyzed and reported with the highest degree of rigor possible. Please see the sections below entitled "Phase 2 Clinical Trial" and "Phase 1 Clinical Trial" for a discussion of the data from our Phase 1 and Phase 2 clinical trials. We consider the data observed thus far to be a direct result of NeoCart's distinct attributes, derived from our regenerative medicine platform, that combine to form a sophisticated and unique biologic implant capable of functioning like normal cartilage upon implantation. Further, we believe the data reflects that, after implantation, NeoCart continues to mature and integrate with the native cartilage as it experiences the natural environment of the joint. We believe these attributes and the clinical data we have accumulated to date differentiate NeoCart from other treatment alternatives, including microfracture. A pictorial representation of the entire NeoCart creation process from biopsy to implantation is displayed below.

# THE NEOCART PROCESS



### Phase 3 Clinical Trial

We are pursuing FDA approval via a BLA pathway with a clinical trial designed to show superiority against the current standard of care, microfracture. Our NeoCart Phase 3 clinical trial is being performed under an SPA with the FDA and was initiated as a confirmatory study based on the promising safety and efficacy findings from our Phase 2 clinical trial. The Phase 3 clinical trial design, based on our Phase 2 clinical trial, is a prospective, controlled, multi-center trial of 245 adults between the ages of 18 and 55 years who have symptomatic focal full-thickness chondral knee defects randomized between NeoCart and microfracture on a two-to-one basis. Randomization is done at arthroscopy, at which time final patient eligibility is determined.

As agreed to with the FDA under our SPA, the primary endpoint for approval is superiority at one year in the proportion of responders in the NeoCart patient group compared to the proportion of responders in the microfracture patient group in a dual-threshold responder analysis utilizing the Knee Injury and Osteoarthritis

Outcome Score (KOOS) pain subscale and International Knee Documentation Committee Subjective (IKDC Subjective) assessments. Both the KOOS pain and the IKDC Subjective assessments are validated, patient-centered and self-administered outcome instruments intended to assess patient-relevant outcomes. The KOOS separately assesses and scores five dimensions of outcomes from the patient's perspective: pain, symptoms, activities of daily living, sport and recreation function and knee-related quality of life. Similarly, the IKDC Subjective assesses and scores three dimensions of outcomes from the patient's perspective: symptoms, function during activities of daily living and sports.

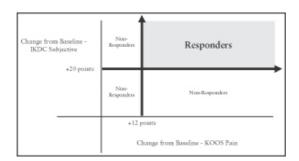
The scores are tabulated and transformed to a 100-point scale, where 100 represents the best outcome for either pain or function and zero represents the worst outcome. A one-year superiority endpoint was deemed appropriate for our Phase 3 clinical under our SPA trial based on the magnitude of difference between the responder rates at one year for patients receiving NeoCart implants and patients receiving microfracture surgery in our Phase 2 clinical trial, a magnitude of difference that continued to be present at the second and third years. We believe that, should our Phase 3 clinical trial show a comparable magnitude of difference in responder rates between NeoCart and microfracture, NeoCart's ability to function like cartilage upon implantation and integrate with the surrounding native tissue, attributes of NeoCart we believe are responsible for our Phase 2 clinical trial results, will be a principal reason for the one-year Phase 3 clinical trial outcome and the presumed resultant durability. However, there is no guarantee that our Phase 3 clinical trial results will demonstrate the same results as our Phase 2 or Phase 1 clinical trials and NeoCart may not be approved for sale in the United States by the FDA after the FDA reviews the results of the Phase 3 clinical trial.

Similar to our Phase 2 clinical trial, discussed below in "Phase 2 Clinical Trial," in the Phase 3 clinical trial, a patient is considered a responder if he or she achieves both of the following patient-reported outcomes:

- improvement of at least 12 points compared to the patient's baseline score in KOOS pain subscore assessment; and
- improvement of at least 20 points compared to the patient's baseline score on the IKDC Subjective assessment.

In the schematic below, the area in the upper right-hand quadrant of the graph, shaded in gray, is the zone reflecting those patients who achieved improvement of both at least 12 points on the KOOS pain scale and at least 20 points on the IKDC Subjective. The horizontal axis, or x-axis, is the KOOS pain scale and the vertical axis, or y-axis, is the IKDC Subjective.

### SCHEMATIC REPRESENTATION OF RESPONDER RATE ANALYSIS



The following additional endpoints will be evaluated in secondary superiority testing at one year comparing the NeoCart patient group to the microfracture patient group:

time to full weight-bearing;

- "treatment failure," defined as a greater than an 8-point deterioration in KOOS pain score at one year compared to baseline; and
- presence of mature collagen layering as assessed by magnetic resonance imaging cartilage mapping at one year.

Patients will be followed for a total of three years for safety and additional efficacy data.

#### Phase 3 Status

In late 2009, pursuant to our SPA, we initiated our Phase 3 clinical trial and our first patient was randomized in June 2010. In September 2010, after nine patients had been randomized, active enrollment was postponed until the completion of a convertible debt financing in late 2011.

In November 2012, we voluntarily suspended manufacturing operations and paused enrollment of the NeoCart Phase 3 clinical trial upon discovery of discrepancies in the testing procedures used to assess one of the raw materials (bovine-derived type I collagen) utilized in the manufacture of NeoCart implants. All participating clinical trial sites, including Institutional Review Boards (IRB), and the FDA were notified of our decision. After an in-depth review of all available information, we concluded that the observed discrepancies did not impact product quality or patient safety, but we chose to continue our self-imposed pause to improve and upgrade our existing manufacturing and quality control systems processes to meet or exceed cGMP standards. This transition was completed in December 2013.

Prior to our November 2012 voluntary election to pause enrollment, 30 patients had been randomized into the NeoCart Phase 3 clinical trial. Twenty-one of these patients were randomized to receive a NeoCart implant and nine were randomized to undergo a microfracture procedure. Upon completion of the manufacturing transition in December 2013, we resumed enrollment at over 20 active sites, specifically chosen based on appropriate case volume, investigator interest in the science of cartilage and clinical research capabilities. Under the SPA, we have the ability to expand the clinical trial to 40 U.S. sites. Based on certain assumptions, including estimates of patient recruitment at 25 fully qualified sites and timely completion of the technology transfer discussed below in "Manufacturing – NeoCart Technology and Materials Transfer," we anticipate enrolling the remaining 204 patients by the first half of 2016.

#### Phase 2 Clinical Trial

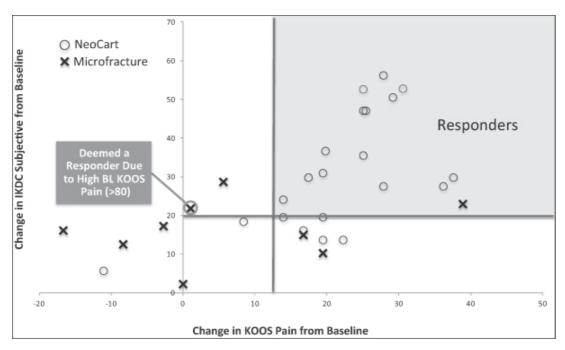
Our NeoCart Phase 2 clinical trial was initiated in 2007 to evaluate further the positive safety and early efficacy signals demonstrated in our Phase 1 clinical trial of NeoCart for articular cartilage damage in the knee. We also sought to identify clinically meaningful endpoints and identify appropriate patient populations to be studied in the design of future clinical studies. The trial was a five-year prospective, controlled, randomized, clinical study of 30 patients conducted at six U.S. centers and completed its enrollment in 2008. Twenty-one patients were randomized to receive a NeoCart implant and nine patients were randomized to undergo a microfracture procedure. The trial was completed in 2013 and final data collection was completed in 2014.

In the Phase 2 clinical trial, baseline (preoperative) pain and function assessments were obtained and included, among other measurement instruments, the KOOS pain and symptoms subscales, the IKDC Subjective assessment and a visual analog pain scale. At every measurement interval between three months and three years, the same pain and function assessments were measured. The data were analyzed using descriptive statistics (mean and standard deviation), paired t testing and analysis of covariance with significance levels (p-values) set at less than 0.05 (two-sided). According to the results of the analysis, those patients receiving a NeoCart implant achieved statistically significant improvement (all p-values <0.05) compared to their baseline assessments on the KOOS pain and symptoms subscales, the IKDC Subjective assessment and a visual analog pain scale, meaning that sufficient data exist to indicate the improvement on each measure is unlikely to have occurred by chance. Furthermore, when this improvement from baseline was compared to the improvement of microfracture from baseline, NeoCart's improvement was statistically significantly better (all p-values <0.05) than microfracture's improvement on over half of the measurements.

Additional comparison of the two groups was performed with the previously described dual-threshold responder analysis we are utilizing in our Phase 3 clinical trial. To be considered a responder in the Phase 2 clinical trial, a patient must have achieved a minimum improvement on the KOOS pain subscale and the IKDC Subjective assessment compared to his or her baseline scores. The minimum required improvement for pain was 12 points and the minimum required improvement for function was 20 points.

The selected thresholds have been validated in the literature as clinically meaningful to patients. In some cases, patients entered the Phase 2 clinical trial with pain scores at a level such that they could not have improved a great deal (for example, a baseline of 91 points on a scale of 100). In those cases, patients were considered responders if their function scores improved a minimum of 20 points even if their pain scores did not improve the required 12 points. Compared to the microfracture group, significantly more NeoCart-treated patients responded to treatment at six months, one year and two years. In addition, a majority of Year 1 responders with a NeoCart implant remained responders at Year 3 compared to none of the microfracture responders at Year 1. The difference in responder rates between the groups favored NeoCart as early as three months post-surgery.

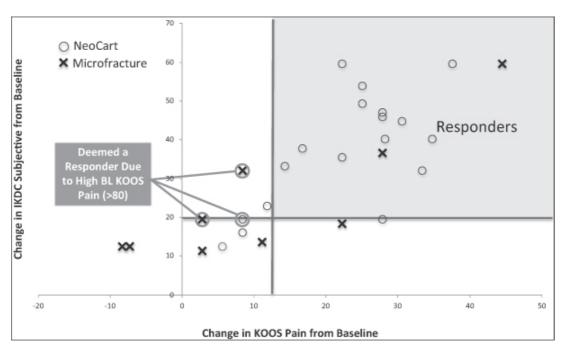
#### **RESPONDER RATE ANALYSIS AT YEAR 1**



As shown in the graphic above, at Year 1, the number of NeoCart patients (represented by an "O") who achieved responder status was greater than the number of microfracture patients (represented by an "X") who achieved responder status. Many patients far exceeded the minimum dual thresholds required to be considered a responder.

As explained more fully above, some patients entered the Phase 2 clinical trial with minimal pain indicated by a high baseline KOOS pain score. A score of 100 on the KOOS pain scale indicates the patient is reporting no pain. In those few cases, only the change in IKDC Subjective score was used to determine if the patients responded to therapy. In those cases, patients were deemed responders if their function scores improved a minimum of 20 points even if their pain scores did not improve the required 12 points.

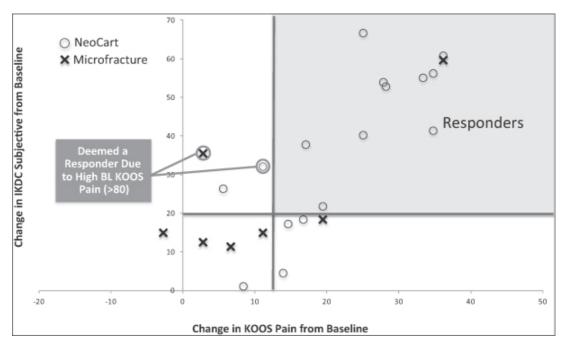
#### **RESPONDER RATE ANALYSIS AT YEAR 2**



As shown in the graphic above, at Year 2, the number of NeoCart patients (represented by an "O") who achieved responder status was greater than the number of microfracture patients (represented by an "X") who achieved responder status. Many patients far exceeded the minimum dual thresholds required to be considered a responder. Some NeoCart patients continued to improve compared to their Year 1 results, indicative of durability of response.

As explained more fully above, some patients entered the Phase 2 clinical trial with minimal pain indicated by a high baseline KOOS pain score. A score of 100 on the KOOS pain scale indicates the patient is reporting no pain. In those few cases, only the change in IKDC Subjective score was used to determine if the patients responded to therapy. In those cases, patients were deemed responders if their function scores improved a minimum of 20 points even if their pain scores did not improve the required 12 points.

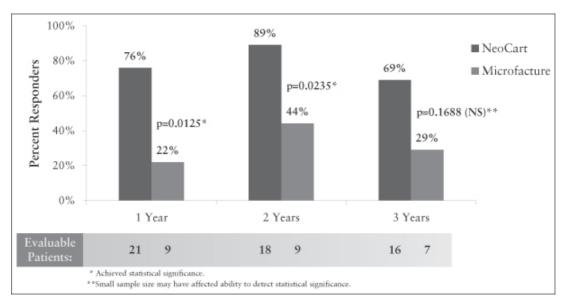
#### **RESPONDER RATE ANALYSIS AT YEAR 3**



As shown in the graphic above, at Year 3, the number of NeoCart patients (represented by an "O") who achieved responder status was greater than the number of microfracture patients (represented by an "X") who achieved responder status. Many patients far exceeded the minimum dual thresholds required to be considered a responder. Some NeoCart patients continued to improve compared to their Year 1 and Year 2 results, indicative of durability of response. A microfracture patient also far exceeded the minimum dual thresholds to be considered a responder. This patient had not been in the responder group prior to Year 3.

As explained more fully above, some patients entered the Phase 2 clinical trial with minimal pain indicated by a high baseline KOOS pain score. A score of 100 on the KOOS pain scale indicates the patient is reporting no pain. In those few cases, only the change in IKDC Subjective score was used to determine if the patients responded to therapy. In those cases, patients were deemed responders if their function scores improved a minimum of 20 points even if their pain scores did not improve the required 12 points.

#### RESPONDER RATE ANALYSIS AT YEARS 1, 2 AND 3



In November 2013, the Phase 2 trial concluded its five-year observation period and we anticipate submitting final results in late 2014. During the course of the trial, no serious adverse events (expected or unexpected) were considered to be product- or implant-related. Two-year results of this trial were published in the *Journal of Bone and Joint Surgery* in 2012.

# Phase 1 Clinical Trial

A Phase 1 clinical trial was conducted to demonstrate the safety of NeoCart for use when implanted into cartilage defects in the knee with the intention of repairing the articular cartilage defects. The two-year results of our Phase 1 clinical trial were published in the *American Journal of Sports Medicine* in 2009. Among the eight patients studied, all of whom enrolled in 2005 and completed five years of observation, a highly favorable safety profile of NeoCart was documented. The trial was completed in 2010 and final data collection was completed in 2011. Specifically, few reported complications occurred and no serious adverse events (expected or unexpected) were deemed treatment-related. No cases of infection, implant rejection or immune reaction were documented. Additionally, joint stiffness and implant overgrowth did not occur in any patient. Efficacy signals in the form of significant improvement in pain and function, measured with patient-reported outcome surveys such as the visual analog pain scale and the IKDC Subjective score, compared to each patient's baseline scores were also noted.

# Pipeline and NeoCart Indication Expansion

We expect to build a robust development pipeline by leveraging our regenerative medicine platform and intellectual property portfolio as well as expanding the applications of NeoCart into additional indications.

Although our initial focus for NeoCart is for the treatment of knee cartilage damage, we plan to leverage our regenerative medicine platform to explore the treatment of chondral defects in other joints, such as the ankle, hip and shoulder. Furthermore, we believe our platform can be utilized to address more extensive cartilage damage associated with significant bone loss and generalized arthritis as well.

Our acellular scaffolds are capable of hosting cells of any type, which allows us the flexibility to tailor their use for other regenerative medicine opportunities beyond cartilage repair, including ligament, tendon and meniscus repair.

In addition to the potential use of our growth factor variants in optimizing our manufacturing process, our proprietary growth factor variants may be capable of being used in therapeutic applications such as fracture healing, osteoporosis, generalized osteoarthritis, orphan diseases involving genetically-based bone growth disruption (applicable to our specific variants) and wound healing.

#### Commercialization

Assuming NeoCart is approved by the FDA, we plan to build our own commercial organization in the United States to support the launch and commercialization of NeoCart. The organization will be designed for scalability to support other potential future products as well. For NeoCart, we initially plan to scale up to approximately 30 sales representatives and management after FDA approval. The NeoCart sales force will target the estimated 4,000 to 5,000 orthopedic surgeons in the United States who may use NeoCart, including a core group of physicians focused on the care of cartilage injuries. We expect this core commercial team to be comprised of experienced sales representatives with relevant industry experience in the areas of orthopedic surgery and biologics sales. The commercial organization is anticipated to include hospital-based and physician-based sales, medical affairs, strategic and product marketing, access reimbursement specialists and distribution specialists. We may also selectively evaluate commercialization strategies, including partnering, for NeoCart outside of the United States.

#### **Manufacturing**

We operate our own cGMP manufacturing facility in Waltham, Massachusetts for the end-to-end production of NeoCart. We currently have adequate capacity in our Waltham, Massachusetts facility to meet NeoCart clinical demand and initial commercial demand if we are successful in receiving regulatory approval for NeoCart in the United States. Our manufacturing strategy is to own and operate fully integrated cGMP manufacturing operations for commercial production of NeoCart in the event NeoCart receives FDA approval. We expect that the exclusive ownership of our cGMP operations will afford us the potential for greater optimization, scalability, lower cost of goods and greater control over our supply chain as compared to utilizing one or more third-party manufacturers.

We are in the process of locating and developing our own cGMP manufacturing facility in Waltham, Massachusetts for production of key raw material and components used in the NeoCart production process and during implantation of NeoCart. Our scaffolds and CT3 bioadhesive will be manufactured at the facility. We also plan to manufacture the collagen raw material used in the production of the scaffold, CT3 bioadhesive and sterile collagen solution.

# **NeoCart Manufacturing Process**

Our manufacturing process for NeoCart is systematic and organized with specific steps that are tightly controlled. The first step includes receiving a biopsy from the patient's own cartilage from which cartilage cells can be isolated and expanded in number using segregated cell culture technology at our cGMP manufacturing facility in Waltham, Massachusetts. Once we have achieved an adequate number of cartilage cells, these cartilage cells are placed into a sterile collagen solution provided to us in vials after sterile filtration by a third party contract manufacturer, and then applied to the three-dimensional collagen scaffold. The scaffold provides a support for the NeoCart implant to grow and develop into the form ultimately implanted. The scaffold is currently provided to us by a third-party supplier. The development of the NeoCart implant occurs under controlled conditions in our in our TEP system which exposes the implant to pressure cycles designed to simulate the pressure cycles that cartilage is exposed to in the knee. After development in the TEP system, the implant is placed into a solution that allows further maturation prior to implantation. Once the implant is mature, it is shipped by a third-party to the clinical site for implantation in the patient, which typically occurs within three to five days after the completion of the manufacturing process. The manufacturing cycle time, from receipt of biopsy to delivery of the implant, is approximately six to 12 weeks. The range in cycle time is dependent upon the variability in growth rate of the cells obtained from individual patients.

The quality control laboratory, located within our main Waltham, Massachusetts facility, handles cGMP release testing for the raw materials, CT3 components and adhesive, the collagen scaffold and final NeoCart implant. Further, our quality control group handles all in-process and finished product environmental monitoring related

to the manufacturing process. Testing is performed pursuant to validated test methods using qualified equipment. The quality control group also maintains a stability testing program for the collagen raw material and finished products.

# NeoCart Technology and Materials Transfer

Manufacturing of raw materials and components used in the NeoCart supply chain is undergoing a technology transfer from outsourced contract manufacturers, which we used for clinical manufacturing, to our anticipated new manufacturing facility in the Waltham, Massachusetts area, which we will use for commercial manufacturing in the event NeoCart is approved by the FDA. This technology transfer extends to the three components of the CT3 bioadhesive—methylated collagen, curing solution and activated PEG—and collagen honeycomb scaffold, which is used in the production of NeoCart. We also plan to transfer production of the collagen raw material used in some of the NeoCart components to our new facility. Sterile filtration and aseptic filling of our sterile collagen solution used in NeoCart production will continue to be performed by a third-party contract manufacturer. We do not anticipate changes to raw materials, components, formulations or properties, nor do we anticipate changes to the NeoCart manufacturing process or finished product specifications as a result of the transfer.

Because we are transitioning production of critical raw material and components to our own manufacturing facility for future commercial production, we will be required to demonstrate to the FDA that the raw collagen material and the components manufactured in the new facility are comparable to those that were used previously in clinical studies. In order to implement the technology transfer prior to submission of the BLA, we intend to submit an amendment to the existing Investigational New Drug (IND) application file for FDA pre-approval. Prior to submission of this amendment, we plan to obtain FDA input and agreement with our plans via a formal FDA-Sponsor Type C meeting. We are targeting the second half of 2014 to present technology transfer and comparability plans that include our cGMP compliant facilities, our processes as well as comparability data that we will have generated from materials produced from pilot scale runs. The presentation will also include a proposed analytical comparability protocol for materials produced from full scale production runs. Demonstrating comparability requires evidence that the product is consistent with that produced for the clinical trial to assure that the technology transfer does not affect safety, identity, purity, or potency (efficacy) during the expansion from pilot scale to full scale production. This demonstration is based on various methods, as recommended in the FDA and International Conference on Harmonization regulatory guidelines. At the Type C meeting, we will seek FDA feedback and agreement that our initial pilot scale analytical comparability data and proposed comparability protocol are sufficient. Based on internal review and guidance, we believe our current plan to provide analytical comparability data to the FDA for review may be sufficient. Should the FDA determine that additional clinical data is required to confirm comparability, we would collaborate with FDA to develop a mutually agreeable plan to be executed prior to submitting the BLA.

#### **Intellectual Property**

Patent and trade secret protection is critical to our business. Our success will depend in large part on our ability to continue to 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 22 issued patents and 12 patent applications in the United States that we own, and 23 issued patents and three patent applications in the United States that we license from academic institutions and business entities. We also have over 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 2014 and 2030.

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 18 issued patents and 11 pending patent applications relating to an exogenous tissue processor. Through this agreement, we have a sublicense to three issued U.S. patents and six issued foreign patents owned by Brigham and Women's Hospital, Inc. (BWH) and Purpose that relate to compositions and methods for preparing multi-layered tissue constructs that include a cellular support matrix seeded with living cells derived from a native tissue and tissue culture protocols to promote the in vitro growth of tissues and tissue constructs. 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 2021 and 2030.

We have an exclusive license to a portfolio consisting of four families of issued patents and pending patent applications owned by Angiotech Pharmaceuticals (US), Inc. and Angiodevice International GmbH. This exclusivity is for CT3 for use in combination with intellectual property for the repair of articular cartilage, ligament, meniscus or tendon damage. The patents relate to a method of introducing rapidly gelling biodegradable collagen-PEG hydrogel to the site of injury, methods of inducing meniscal regeneration by introducing a strong adhesive to a site of injury and methods for in situ repair in which the meniscal injury is filled with an adhesive hydrogel complex consisting of methylated PEG and in which the injury is filled with the adhesive hydrogel complex and a collagen matrix. Any patents within this portfolio that have issued or may yet issue will have statutory expiration dates between 2014 and 2019.

We have an exclusive license to a portfolio of three patent families 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 2016 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**

### Purpose Co., Ltd.

In June 2012, we amended and restated a license agreement with Purpose. Under the amended and restated agreement, Purpose granted us an exclusive, perpetual, paid-up, worldwide and sublicensable license 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. Under the agreement, we grant Purpose an exclusive, perpetual, paid-up, sublicensable right solely in Japan under our patents and technology relating to the biotechnology and biomaterials of NeoCart and two other products in development to (1) make,

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

We paid Purpose JP¥19,572,000 (approximately \$250,000 based on an exchange rate of JP¥0.0128/dollar as of September 30, 2012) for costs Purpose incurred in developing a multi-unit exogenous tissue processor machine. As described below, we are obligated to pay royalties and milestone payments due on the Brigham and Women's Hospital, Inc. (BWH)-Purpose license. Our obligation to pay royalties due on the BWH-Purpose license is limited to such royalties measured by our revenue. Upon written notice to Purpose of our intent to stop using the technology in the BWH-Purpose license sublicensed to us, Purpose will reassume all responsibility under the BWH-Purpose license. Concurrent with our entering into the amended and restated license agreement with Purpose, we agreed, in the case of an initial public offering that we or our stockholders that are parties to the second amended and restated stockholders' agreement will issue to Purpose immediately upon the effectiveness of this offering a number of shares equal to 7.8125% of our equity value at the time of the offering, less our costs in connection with such offering, the amount of any of our debt and the amount of the liquidation preference of the Series A Preferred and Series A-1 Preferred per share, the midpoint of the initial public offering price shares issued to certain of our stockholders. Based on an assumed initial public offering price of \$ range on the cover of this prospectus, and our estimated offering expenses, we or our stockholders, pursuant to the Purpose Agreement, would be required to issue shares to Purpose upon the closing of this offering, subject to adjustment. Pursuant to the second amended and restated stockholders' agreement, the number of shares to be issued to Purpose upon an initial public offering will be reallocated from the investors that are parties to that agreement to Purpose rather than issued by us. As part of the Series A-1 Financing, described elsewhere in this prospectus, we entered into certain escrow agreements with the holders of our Series A and Series A-1 Preferred stock and holders of certain warrants who are obligated to reallocate shares under our second amended and restated stockholders' agreement. Pursuant to these escrow agreements, we hold in escrow shares of our preferred stock and warrants exercisable for common stock representing an aggregate of 4,000,000 shares of our common stock which shares are to be issued to Purpose in order to satisfy the obligations to Purpose immediately upon the effectiveness of this offering. We believe this number of shares, based on the required calculations in the Purpose agreement, would allow us to reallocate the number of shares necessary to satisfy our obligation to Purpose for an offering up to approximately \$ , which we do not expect to exceed the proposed maximum offering price under this prospectus. For more information, see "Certain Relationships and Related Party Transactions—The Series A-1 Financing" and "Principal Stockholders—Footnote 11" below.

Under the amended and restated agreement, Purpose agreed to continue to manufacture and sell single unit exogenous tissue processor machines to us. We are obligated to cooperate with Purpose, at Purpose's expense, in its efforts to commercialize all or any portion of NeoCart and two other products in development in connection with articular cartilage, ligaments, tendons and meniscus and obtain governmental approvals required for the manufacture and sale in Japan of NeoCart and two other products in development. In addition, we are required to supply Purpose with collagen scaffold and CT3.

Purpose exclusively sublicensed to us its rights and obligations under the BWH-Purpose license. 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, 2015, subject to a one-year extension upon Purpose paying BWH \$10,000.

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 \$160,000 and sublicense payments of \$100,000 through March 31, 2014. 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 after we paid \$1.0 million to Angiotech. 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.

As a license fee, we issued to Angiotech certain warrants to purchase from us shares of common stock, subject to certain anti-dilution protections. These warrants are no longer outstanding. We paid \$1.0 million to Angiotech to make the license grant under the agreement exclusive. In addition, we paid three annual patent fees of \$50,000 each as of March 31, 2014. We are also obligated to pay an additional annual patent fee of \$50,000 and 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.

#### Koken Co., Ltd.

In March 2013, we entered into a license agreement with Koken Co., Ltd. (Koken) for a non-exclusive, non-transferable and non-sublicensable right to use its know-how related to the process for manufacturing atelocollagen honeycomb sponge materials, which we use in our scaffolds. Pursuant to the agreement, we paid Koken a fee in March 2013 for such right. Koken may terminate this agreement if we fail to perform any obligation under the agreement and such failure remains uncured for more than 30 days, if we become insolvent, bankrupt, go into liquidation or receivership, or if we file for bankruptcy or a petition in bankruptcy is filed against us.

### The Board of Trustees of The Leland Stanford Junior University

In April 2001, we entered into a license agreement with The Board of Trustees of The Leland Stanford Junior University (Stanford) for patent rights relating to the restoration of articular cartilage scaffold. Our agreement with Stanford provides us with a worldwide license to make and sell products covered by claims of the licensed patents for growth, ontogenesis, and regeneration of cartilaginous tissues and collagen. Under the agreement, Stanford agreed not to grant further licenses to such rights in such field.

We paid Stanford \$30,000 upon execution of the agreement and, as of March 31, 2014, \$375,000 as reimbursement for patent-related costs incurred by Stanford. We are required to pay Stanford a yearly royalty fee of \$10,000, which is creditable against earned royalty payments due on net sales of that year. We have paid \$120,000 in yearly royalty fees through March 31, 2014. Stanford is also entitled to a low single digit percentage rate of our net sales in royalties. We paid Stanford milestone payments of \$35,000 upon issuance of the first licensed patent and \$50,000 upon initiation of Phase 1 clinical trials of the licensed product in the first field that requires separate regulatory authority clinical approval. We have paid Stanford a milestone payment of \$50,000 upon initiation of Phase 1 clinical trials of the licensed product in other fields that requires separate regulatory authority clinical approval, and are obligated to pay an additional milestone payment of \$300,000 upon FDA marketing approval of the first licensed product.

The agreement terminates on the date that the last of the licensed patents expire, expected to be January 25, 2021. We may terminate the agreement by giving Stanford notice in writing at least 30 days in advance of the date of termination. Stanford has the right to terminate the agreement if we are in default in payment of royalty or providing of reports, if we are in breach of any other provisions of the agreement, or if we provide a false report to Stanford, and in each case, we fail to remedy such default, breach or false report within 30 days after written notice thereof. We are obligated to have licensed products relating to growth, ontogenesis and regeneration of cartilaginous tissue available for commercial sale by December 31, 2015. If we fail to fulfill such obligation, Stanford may terminate our rights with respect to the applicable part of the field of use. Stanford may also terminate the agreement if we or our sublicensees have not sold licensed products for a continuous period of one year after the first commercial sale of licensed products.

# Yeda Research and Development Co., Ltd.

In January 2008, we entered into an exclusive license agreement with Yeda Research and Development Co., Ltd. (Yeda) for rights relating to high level expression of heterologous proteins and plasmid p80 BS, which rights are jointly owned by Yeda and us. Under our agreement, Yeda granted us an exclusive worldwide license under its rights for the manufacture, use and sale of heterologous proteins and plasmid p80 BS.

We are required to pay Yeda a yearly license fee of \$2,000 for the life of the license, which is creditable against royalties payable by us to Yeda during the one-year period in respect of which such fee was paid. Yeda is entitled a royalty fee of a low single digit percentage rate of our net sales of the licensed products, a low single digit percentage rate of our net sales for combination products (meaning the combination of the licensed product with at least one other active ingredient, material or medical device that would have a clinical effect if administered independently) and a low double digit percentage rate of all of our sublicensing receipts.

The agreement terminates on a country-by-country, licensed product-by-licensed product basis on the later of (a) the date of expiration in such country of the last licensed patent covering the applicable licensed product and (b) ten years from the date of the first commercial sale of the first licensed product in that country, or, if there have not been any sales in such country, ten years from the date of the first commercial sale of the licensed product worldwide. Either party may terminate the agreement by written notice if there is an uncurable material breach or a material breach that is not cured within 30 days (14 days in the case of non-payment).

#### Advanced BioMatrix, Inc.

In April 2014, we entered into an agreement with Advanced BioMatrix, Inc. (ABM) for a nonexclusive, nontransferable (except as expressly provided in the agreement), non-sublicensable (except as provided in the agreement), perpetual, irrevocable, worldwide, royalty-free right and license to use its technology related to certain collagen solutions and to make, use, sell and otherwise exploit collagen solutions produced using such technology, solely for the development and commercialization, including generation, implantation and use, of engineered tissue and biomaterials in the field of orthopedics. Pursuant to the agreement, we paid a fee in April 2014 and will pay additional fees plus reimburse ABM for mutually agreed upon expenses for such rights and services to be performed by ABM for us in connection with such technology. This agreement will remain in effect until we or ABM provides written notice to terminate the agreement. Either party may terminate the agreement if the other party materially breaches any material term of the agreement and fails to cure such breach within 45 days after receiving notice of such breach.

# Competition

The regenerative medicine industry 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 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; (2) uncultured cell-based (with or without scaffold), such as Zimmer's DeNovo NT, Arthrex's BioCartilage and Osiris' Cartiform; (3) cultured cell-based (without scaffold), such as Genzyme's Carticel and ISTO's RevaFlex; (4) cultured cell- and scaffold-based, such as Sanofi'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.

For knee cartilage repair and regeneration, the market is large and growing, driven by more knee injuries in an increasingly active population. Worldwide, many products are commercially available, but the majority of these products are currently only available in the EEA, with Carticel, which was approved by the FDA in 1997, whose label restricts it for use in salvage cases, being the only cartilage repair product to gain U.S. approval through a regulated path to market. RevaFlex and NovoCart 3D are in U.S. clinical development, which, based on our internal analysis of publicly available information, we believe may be approved in 2020 and 2023, respectively, but their early clinical data has not been published in highly regarded peer-reviewed journals. Although minimally-modified cells such as DeNovo NT, which launched in the United States in 2007, and acellular

cartilage matrix products such as Cartiform and Arthrex's BioCartilage and are available in the United States, their path to market did not require a rigorous regulatory path and their clinical data to date has been sparse and commercial uptake limited. Product-less procedures such as debridement and microfracture continue to dominate the U.S. market.

Any product candidates that we successfully develop and commercialize will compete with existing therapies and new therapies that may become available in the future. Our competitors may have substantially greater financial, technical and human resources that could put them at an advantage in the development of safe and efficacious products and may help them obtain regulatory approval for their products more rapidly, as well as achieve more widespread market acceptance. We believe, however, the competitive benefits of NeoCart will allow us to position NeoCart effectively as a strong contender in the tissue repair market.

Outside the United States, many procedures and products for cartilage repair are available. However, we anticipate that many of these are unlikely to seek approval in the United States because of the rigorous and lengthy regulatory path a sponsor must pursue in order to access the market and the high-quality superiority data that must be produced. Additionally, other than the few currently approved U.S. products, to our knowledge no other known European cartilage product to date has any clinical experience or data in U.S. patients.

# **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 BLA filing 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. The FDA now requires evidence of clinical efficacy against approved 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 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

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.

### Anticipated FDA Regulatory and Approval Process for NeoCart

We anticipate NeoCart, if approved, to be the first autologous cell- and scaffold-based product in the U.S. market to have been studied in a randomized controlled trial with a rigorous responder analysis under an approved SPA.

The FDA approved the NeoCart Phase 3 study design under the SPA process and concluded that the trial "design and planned analyses ... sufficiently address the studies' objectives ... these studies are adequately designed to provide the necessary data that ... could support a license application submission." We anticipate the SPA to be binding on the FDA review division, with limited exceptions provided by FDA guidance, such as the FDA "determines that a substantial issue essential to determining the safety or efficacy of the [product] has been identified after the testing has begun," or if we fail to follow the agreed-upon protocol.

#### 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. We plan to provide objective clinical data, patient-reported quality of life data and health economic data demonstrating NeoCart's value to assist in optimizing payment decisions for NeoCart.

# 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 IND application 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 application. Some nonclinical testing may continue even after the IND application is submitted. The IND application 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 application sponsor must resolve any outstanding concerns with the FDA before the clinical trial may begin. Further, an 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 application 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 application 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 user fee. The FDA adjusts the PDUFA user fees on an annual basis. According to the FDA's fee schedule, effective beginning on October 1, 2013 and in effect through September 30, 2014, the user fee for an application requiring clinical data, such as a BLA, will be \$2.2 million for 2014. PDUFA also imposes an annual product fee for biologics (\$104,060 for 2014), and an annual establishment fee (\$554,600 for 2014) on facilities used to manufacture prescription biologics. 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 submission 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 application 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, not

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 submission. 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 cellbased 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.

# **Facilities**

Our corporate headquarters are currently located in Waltham, Massachusetts, for which we have a lease until December 2017, renewable for two additional five-year terms. 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 NeoCart manufacturing. We have subleased approximately 7,310 square feet of our facility to a tenant through March 2015, at which time this space will be returned for our use. The Waltham facility is expected to be adequate for a potential initial commercial launch of NeoCart in 2017.

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 October 1, 2022 and can be extended for one additional five year period thereafter. This facility includes clean room space that will 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, once the build-out of the space is completed. This facility also includes necessary space for quality operations, including necessary quality control testing.

## **Employees**

As of July 10, 2014, we employed 36 full-time employees, including two in research and development, seven in clinical development, two in regulatory, 20 in manufacturing and quality control and assurance, and five in executive, general and administrative. We also employed three part-time employees, including one in clinical development and two in executive, general and administrative. We have never had a work stoppage, and none of our employees is represented by a labor organization or under any collective bargaining arrangements.

# **Legal Proceedings**

We are not a party to any material legal proceedings at this time. From time to time, we may be subject to various legal proceedings and claims that arise in the ordinary course of our business activities. Although the results of litigation and claims cannot be predicted with certainty, as of the date of this prospectus, we do not believe we are party to any claim or litigation the outcome of which, if determined adversely to us, would individually or in the aggregate be reasonably expected to have a material adverse effect on our business. 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.

#### MANAGEMENT

# **Executive Officers, Key Employees and Directors**

Our executive officers, key employees, directors and their ages and positions as of July 10, 2014, are set forth below:

<u>Name</u>	Age	Position
Executive officers:		
Adam Gridley <sup>(1)</sup>	41	Chief Executive Officer, President and Director
Kevin McArdle	42	Chief Financial Officer
Nancy Lynch, M.D.	50	Chief Medical Officer
Stephen Kennedy	57	Senior Vice President of Manufacturing, Operations and Supply Chain
Other key employees:		
Elissa Cote	39	Vice President of Marketing and External Relations
Peter Hamilton	50	Vice President of Manufacturing and Production
Kathleen Large	54	Vice President of Clinical Development
Laura Mondano	53	Vice President of Regulatory and Quality
Non-employee directors:		
Joshua Baltzell <sup>(2)(3)</sup>	45	Director
John H. Johnson <sup>(2)(4)</sup>	56	Director
Garheng Kong, M.D., Ph.D.(3)	39	Director, Chairman of the Board
Michael Lewis(3)	55	Director
Kevin Rakin <sup>(3)(4)</sup>	53	Director

<sup>(1)</sup> Mr. Gridley was appointed as our chief executive officer, president and a director and began employment with us in May 2014.

Each executive officer serves at the discretion of our board of directors and holds office until his successor is duly elected and qualified or until his earlier resignation or removal. There are no family relationships among any of our directors or executive officers.

# **Executive Officers**

Adam Gridley has served as our Chief Executive Officer and President since May 2014. 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. From 2005 to 2008 Mr. Gridley held the position of Vice President, Corporate Development for BioForm Medical, Inc., and from 2003 to 2005, he held various marketing and corporate development positions. From 1996 to 2003, Mr. Gridley held a variety of financial, strategic planning, investor relations and business development roles of increasing responsibility at Gliatech, Inc., a public medical device and biotechnology company. From 1990 to 1996, Mr. Gridley was General Manager of Pintail Systems, Inc., a start-up environmental bioremediation firm. 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 our 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.

*Kevin McArdle* has served as our Chief Financial Officer since May 2011. From January 2009 to May 2011, Mr. McArdle was the Chief Financial Officer of ProChon Biotech Ltd., an Israeli-based company focused on the

<sup>(2)</sup> Member of Compensation Committee.

<sup>(3)</sup> Member of Nominating and Corporate Governance Committee.

<sup>(4)</sup> Member of Audit Committee.

treatment of cartilage defects that we acquired in May 2011. Mr. McArdle was contract Chief Financial Officer for two life science companies, Avedro, Inc. and INVO Bioscience, Inc., from January 2007 to January 2009. During this time, Mr. McArdle also started two seed-stage technologies of his own in the fields of cardiac resynchronization therapy (Oxus Medical) and orthopedics (Tesa Medical). Mr. McArdle was Vice President of Worldwide Finance for Microsulis, an international, commercial stage company focused on ablation of unhealthy tissue for endometriosis, liver cancer and venous malformations from 2004 to 2007. From 1998 to 2004 Mr. McArdle was employed by BioSphere Medical. Mr. McArdle received his B.S. and M.B.A. from Boston College.

*Nancy Lynch, M.D.* has served as our Chief Medical Officer since September 2013. Dr. Lynch is also the President of Advisorthopædics, a consulting company focused on the orthopedics industry, which she founded in May 2010. Previously, Dr. Lynch was employed with Scale Venture Partners, a venture capital company, as a Principal and Associate from 2006 to April 2010. Dr. Lynch earned her M.D. from the Washington University School of Medicine in St. Louis and her M.B.A. from Duke University. Dr. Lynch completed her residency in orthopaedic surgery with the Mayo Graduate School of Medicine in 1995. Dr. Lynch is a Fellow of the American Academy of Orthopaedic Surgeons and is a board-certified orthopedic surgeon.

Stephen Kennedy has served as our Senior Vice President of Manufacturing, Operations and Supply Chain since August 2013. 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.

# Other Key Employees

*Elissa Cote* has served as our Vice President of Marketing and External Relations since September 2013. Prior to joining us, Ms. Cote worked as Director, Global Strategic Marketing, Emerging Brands for MedImmune, LLC, the biologics division of AstraZeneca PLC from June 2009 to July 2013. From March 2007 to June 2009, Ms. Cote was a strategic management consultant at The North Highland Company. From September 1996 to March 2007, Ms. Cote was a strategic management consultant at Accenture LLP. Ms. Cote has a B.A. from Union College.

**Peter Hamilton** has served as our Vice President of Manufacturing and Production since July 2011. From July 2007 to July 2011, Mr. Hamilton served as Vice President Operations for Choice Therapeutics, Inc., a start-up wound care company specializing in antimicrobial dressings using silver nylon. Mr. Hamilton served as the Operations Manager at BioSphere Medical, Inc. from February 2000 until June 2007. Mr. Hamilton was a Senior Development Engineer at Boston Scientific, from 1991 through 2000. Mr. Hamilton served as a Design Engineer at Deknatel from 1988 until 1991. Mr. Hamilton has a B.S. from Wentworth Institute of Technology and an M.B.A. from Anna Maria College.

Kathleen Large has served as our Vice President of Clinical Development since July 2014. Prior to joining us, Ms. Large worked as Director, Early Development and Strategic Site Alliances at Takeda Pharmaceuticals International GmbH, which was previously Millennium Pharmaceuticals, Inc. prior to a reorganization where her title was Director, Clinical Development Operations, Early Phase, since January 2012. From October 2000 through July 2011, Ms. Large held several positions within the Medical and Program Management organizations at Eli Lilly and Co., with her most recent role as Director, Oncology Clinical Planning and Execution. From January 1998 through September 2000, Ms. Large worked for Quintiles Inc. as Associate Director of Project Management within the Accelerated Clinical Research division. Ms. Large has a B.S. from Boston College and an M.S. from the University of California, San Francisco.

*Laura Mondano* has served as our Vice President of Regulatory and Quality since July 2012. Prior to joining us, Ms. Mondano worked as a regulatory consultant from January 2011 to June 2012. From 2002 to November 2010, Ms. Mondano was with Genzyme Corporation serving most recently as Director of Global Regulatory Affairs. Prior to this, Ms. Mondano was the Director of Regulatory and Clinical Affairs at Anika Therapeutics from 2000 to 2002 and she held several positions in regulatory affairs at Boston Scientific from 1992 to 2000. Ms. Mondano has a B.S. from the University of New Hampshire and is Regulatory Affairs Certified.

## Non-employee Directors

Joshua Baltzell has served as a member of our board of directors since July 2012. Mr. Baltzell joined Split Rock Partners at the firm's inception in 2004 as a Principal with the healthcare investment team and has served as a Managing Director since January 2009. From January 2009 to January 2010, Mr. Baltzell served as the Chief Executive Officer and President of Tarsus Medical, a developer of solutions and devices for unsolved problems within the field of podiatry. From 2005 to January 2009, Mr. Baltzell served as a Principal with St. Paul Venture Capital's healthcare team. Mr. Baltzell graduated from St. Olaf College and has an M.B.A. from the University of Minnesota's Carlson School of Management. We believe Mr. Baltzell's qualifications to serve as a director of our company include his extensive experience in the venture capital industry, his investment banking experience in the healthcare and medical devise industries with both public and privately held companies and his significant prior board experience.

John H. Johnson has served as a member of our board of directors since November 2013. Mr. Johnson has served as President and Chief Executive Officer of Dendreon Corporation since January 2012. Mr. Johnson previously served as the Chief Executive Officer and a director of Savient Pharmaceuticals, Inc., a pharmaceutical company, from January 2011 until January 2012, and prior to that time, served as Senior Vice President and President of Eli Lilly and Company's oncology unit from November 2009 until January 2011. He was also Chief Executive Officer of ImClone Systems Incorporated from 2007 until November 2009, and served on ImClone's board of directors until it was acquired by Eli Lilly in 2008. Prior to joining ImClone, Mr. Johnson served as Company Group Chairman of Johnson & Johnson's Worldwide Biopharmaceuticals unit from 2005 until 2007, President of its Ortho Biotech Products LP and Ortho Biotech Canada units from 2003 until 2005, and Worldwide Vice President of its CNS, Pharmaceuticals Group Strategic unit from 2001 until 2003. Mr. Johnson currently serves as chairman of the board of directors of Tranzyme, Inc. and Dendreon Corporation, and as a director of Cempra, Inc., a clinical stage pharmaceutical company. He also serves as a member of the board of directors for the Pharmaceutical Research and Manufacturers of America and as a member of the Health Section Governing Board of Biotechnology Industry Organization. He earned his B.S. from the East Stroudsburg University of Pennsylvania. We believe that Mr. Johnson's qualifications to serve as a director of our company include his extensive experience as an executive in the biotechnology industry and his prior service as a senior-level executive in mature biotechnology companies.

Garheng Kong, M.D., Ph.D. has served as a member of our board of directors since July 2012. Dr. Kong has been the Managing Partner of Sofinnova HealthQuest, a healthcare investment firm, since July 2013. He was a general partner at Sofinnova Ventures, a venture capital firm focused on life sciences, from September 2010 to December 2013. From 2000 to September 2010, he was at Intersouth Partners, a venture capital firm, most recently as a general partner. Dr. Kong has served on the board of directors of Cempra, Inc., a NASDAQ-listed clinical-stage pharmaceutical company, since 2006 and as chairman of its board since 2008. Dr. Kong has also served on the board of directors of Alimera Sciences, Inc., a NASDAQ-listed biopharmaceutical company, since October 2012 and served on the board of Laboratory Corporation of America Holdings, a NYSE-listed healthcare company, since December 2013. Dr. Kong holds a B.S. from Stanford University. He holds an M.D., Ph.D. and an M.B.A. from Duke University. Among other experience, qualifications, attributes and skills, Dr. Kong's knowledge and experience in the venture capital industry and his medical training led to the conclusion of our board of directors that he should serve as a director of us in light of our business and structure.

Michael Lewis has served as a member of our board of directors 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, and is also a Partner of Oceana Investment Partners LLP, a U.K. investment advisor. Mr. Lewis currently serves as Chairman of Strandbags Holdings Pty Limited, an Australian retail company comprising some 450 stores and a Non-Executive Director of The Foschini Group Limited, a South African retail company with some 2,000 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's qualifications to serve as a director 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 our board of directors 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. Prior to joining Shire, Mr. Rakin served as the Chairman and Chief Executive Officer of Advanced BioHealing from 2007 until its acquisition by Shire for \$750 million in June 2011. Mr. Rakin currently serves on the executive committee for Connecticut United for Research Excellence (CURE), Connecticut's bioscience cluster and as a board member of CyVek, Inc, Cheetah Medical Inc. and Tela Bio, Inc. He has previously served as a board member for Ipsogen SA, Vion Pharmaceuticals, Inc., OMRIX Biopharmaceuticals, Inc. and Clinical Data, 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 our 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.

#### **Board of Directors**

Our business and affairs are managed under the direction of our board of directors, which is currently composed of five members. Our current directors were elected pursuant to an amended and restated stockholder agreement among certain of our preferred and common stock holders. This agreement will terminate upon the closing of this offering, at which time there will be no further contractual obligations regarding the election of our directors.

# **Independent Directors**

We have applied to list our common stock on the NASDAQ Global Market. Under NASDAQ rules, independent directors must comprise a majority of a listed company's board of directors within 12 months from the date of listing. In addition, NASDAQ rules require that, subject to specified exceptions, each member of a listed company's audit, compensation and nominating and governance committees be independent within 12 months from the date of listing. Audit committee members must also satisfy additional independence criteria, including those set forth in Rule 10A-3 under the Securities Exchange Act, and compensation committee members must also satisfy additional independence criteria, including those set forth in Rule 10C-1 of the Securities Exchange Act. Under NASDAQ rules, a director will qualify as an "independent director" only if, in the opinion of that company's board of directors, that person does not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director. In order to be considered independent for purposes of Rule 10A-3 under the Securities Exchange Act, a member of an audit committee of a listed company may not, other than in his or her capacity as a member of the audit committee, the board of directors or any other board committee: (1) accept, directly or indirectly, any consulting, advisory or other compensatory fee from the listed company or any of its subsidiaries, other than compensation for board service; or (2) be an affiliated person of the listed company or any of its subsidiaries independent for purposes of Rule 10C-1 under the Securities Exchange Act, each member of the compensation committee must be a member of the board of directors of the listed company, and must otherwise be independent. In determining independence

requirements for members of compensation committees, the national securities exchanges and national securities associations shall consider relevant factors, including: (1) the source of compensation of a member of the board of directors of a listed company, including any consulting, advisory or other compensatory fee paid by the listed company to such member of the board of directors; and (2) whether a member of the board of directors of a listed company is affiliated with the listed company, a subsidiary of the listed company or an affiliate of a subsidiary of the listed company.

In November 2013, our board of directors undertook a review of its composition and that of its committees, as well as the independence of each director who will serve following the consummation of this offering. Based upon information requested from and provided by each director concerning his background, employment and affiliations, including family relationships, our board of directors has determined that each of Joshua Baltzell, John H. Johnson, Garheng Kong, M.D., Ph.D., Michael Lewis and Kevin Rakin qualify as independent directors in accordance with the rules of NASDAQ, each of Joshua Baltzell, John H. Johnson, Garheng Kong, M.D., Ph.D., Michael Lewis and Kevin Rakin qualify as independent directors in accordance with Rule 10C-1 under the Securities Exchange Act and each of John H. Johnson and Kevin Rakin qualify as independent directors in accordance with Rule 10A-3 under the Securities Exchange Act. The independent members of our board of directors will hold separate regularly scheduled executive session meetings at which only independent directors are present.

# Classified Board

Immediately following this offering, in accordance with the terms of our certificate of incorporation and bylaws, our board of directors will be divided into three classes with staggered three-year terms. At each annual meeting of stockholders, the successors to directors whose terms then expire will be elected to serve from the time of election and qualification until the third annual meeting following election. Our current directors will be divided among the three classes as follows:

- The Class I directors will be Joshua Baltzell and Kevin Rakin, and their terms will expire at the annual meeting of stockholders to be held in 2015.
- The Class II directors will be Michael Lewis and Adam Gridley, and their terms will expire at the annual meeting of stockholders to be held in 2016.
- The Class III directors will be John H. Johnson and Garheng Kong, M.D., Ph.D., and their terms will expire at the annual meeting of stockholders to be held in 2017.

Each director's term will continue until the election and qualification of his successor, or his earlier death, resignation, retirement, disqualification or other removal. Any increase or decrease in the number of directors will be distributed among the three classes so that, as nearly as reasonably possible, each class will consist of one-third of our directors.

The authorized number of directors may be changed only by resolution of the board of directors. This classification of the board of directors into three classes with staggered three-year terms may have the effect of delaying or preventing changes in our control or management.

Our directors may be removed only for cause and by the affirmative vote of the holders of two-thirds of our outstanding voting stock.

# **Board Leadership Structure**

Our board of directors is currently led by its chairman, Garheng Kong, M.D., Ph.D. Our board of directors recognizes that it is important to determine an optimal board leadership structure to ensure the independent oversight of management as the company continues to grow. We separate the roles of chief executive officer and chairman of the board in recognition of the differences between the two roles. The chief executive officer is

responsible for setting the strategic direction for the company and the day-to-day leadership and performance of the company, while the chairman of the board of directors provides guidance to the chief executive officer and presides over meetings of the full board of directors. We believe that this separation of responsibilities provides a balanced approach to managing the board of directors and overseeing the company.

Our board of directors has concluded that our current leadership structure is appropriate at this time. However, our board of directors will continue to periodically review our leadership structure and may make such changes in the future as it deems appropriate.

# **Board Oversight of Risk**

Our board of directors 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 our board receiving regular reports from board committees and members of senior management to enable our 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 and reputational risk.

The audit committee of our board of directors 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 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 of our board of directors is responsible for assessing whether any of our compensation policies or programs has the potential to encourage excessive risk-taking. The nominating and corporate governance committee of our board of directors 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 our board as a whole.

#### **Code of Business Conduct**

Our board of directors 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 addresses various topics, including:

- compliance with applicable laws, rules and regulations;
- conflicts of interest;
- public disclosure of information;
- · insider trading;
- corporate opportunities;
- competition and fair dealing;
- gifts;
- discrimination, harassment and retaliation;
- health and safety;
- · record-keeping;
- confidentiality;
- protection and proper use of company assets;

- · payments to government personnel; and
- the reporting of illegal and unethical behavior.

Prior to the completion of this offering, the code of business conduct will be posted on the Investor Relations section of our website, which is located at www.histogenics.com. Any waiver of the code of business conduct for an executive officer or director may be granted only by our board of directors 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.

## **Board Committees**

Our board of directors has established an audit committee, a compensation committee and a nominating and corporate governance committee. Prior to the completion of this offering, the composition of these committees will meet the criteria for independence under, and the functioning of these committees will comply with, the applicable requirements of the rules of NASDAQ and SEC rules and regulations. We intend to comply with future requirements as they become applicable to us.

Each committee operates under a charter that has been approved by our board of directors. Prior to the completion of this offering, copies of each committee's charter will be posted on the Investor Relations section of our website, which is located at www.histogenics.com. Each committee has the composition and responsibilities described below. Our board of directors may from time to time establish other committees.

#### **Audit Committee**

In November 2013, our board of directors adopted a revised charter for the audit committee of the board, which is currently comprised of John H. Johnson and Kevin Rakin, each of whom is a non-employee member of the board of directors. Kevin Rakin serves as the chair of the audit committee. The audit committee's main function is to oversee our accounting and financial reporting processes, internal systems of control, independent registered public accounting firm relationships and the audits of our financial statements. Pursuant to the audit committee charter, the functions of the committee include, among other things:

- appointing, approving the compensation of, and assessing the independence of our registered public accounting firm;
- overseeing the work of our registered public accounting firm, including through the receipt and consideration of reports from such firm;
- reviewing and discussing with management and the registered public accounting firm our annual and quarterly financial statements and related disclosures;
- monitoring our internal control over financial reporting and our disclosure controls and procedures;
- meeting independently with our registered public accounting firm and management;
- furnishing the audit committee report required by SEC rules;
- · reviewing and approving or ratifying any related person transactions; and
- overseeing our risk assessment and risk management policies.

All members of our audit committee meet the requirements for financial literacy under the applicable rules and regulations of the SEC and NASDAQ. Our board of directors has determined that Kevin Rakin is an "audit committee financial expert" as defined by applicable SEC rules and has the requisite financial sophistication as defined under the applicable NASDAQ rules and regulations.

Our board of directors has determined that each of John H. Johnson and Kevin Rakin is independent under the applicable rules and regulations of NASDAQ, including Rule 10A-3 under the Securities Exchange Act. Prior to the completion of this offering, we expect to appoint an additional independent director to the audit committee.

# **Compensation Committee**

In November 2013, our board of directors established a compensation committee, which is currently comprised of Joshua Baltzell, John H. Johnson and Kevin Rakin. John H. Johnson serves as the chair of the compensation committee. Our compensation committee reviews and recommends policies relating to compensation and benefits of our officers and employees. Pursuant to the compensation committee charter, the functions of this committee include:

- 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;
- identifying the corporate and individual objectives governing the chief executive officer's compensation;
- approving the compensation of our other executive officers;
- making recommendations to our board with respect to director compensation;
- reviewing and approving the terms of material agreements between us and our executive officers;
- overseeing and administering our equity incentive plans and employee benefit plans;
- reviewing and approving policies and procedures relating to the perquisites and expense accounts of our executive officers;
- preparing the annual compensation committee report required by SEC rules; and
- conducting a review of executive officer succession planning, as necessary, reporting its findings and recommendations to our board of directors, and working with the Board in evaluating potential successors to executive officer positions.

In accordance with NASDAQ listing standards, our board of directors has granted our compensation committee the authority and responsibility required under Rules 10C-1(b)(2), (3) and (4) of the Securities Exchange Act, relating to the authority 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 Rules 10C-1(b) (4)(i) through (vi) and any additional factors the compensation committee deems relevant.

Our board of directors has determined that each of Joshua Baltzell, John H. Johnson and Kevin Rakin is independent under the applicable rules and regulations of NASDAQ, including Rule 10C-1 under the Securities Exchange Act, is a "non-employee director" as defined in Rule 16b-3 promulgated under the Securities Exchange Act and is an "outside director" as that term is defined in Section 162(m) of the Internal Revenue Code.

# Nominating and Corporate Governance Committee

In November 2013, our board of directors established a nominating and corporate governance committee of the board, which is currently comprised of Joshua Baltzell, Garheng Kong, M.D., Ph.D. and Michael Lewis. Dr. Kong serves as the chair of the nominating and corporate governance committee. Pursuant to the nominating and corporate governance committee charter, the functions of this committee include, among other things:

- identifying, evaluating, and making recommendations to our board of directors and our stockholders concerning nominees for election to our board, to each of the board's committees and as committee chairs;
- · annually reviewing the performance and effectiveness of our board and developing and overseeing a performance evaluation process;
- annually evaluating the performance of management, the board and each board committee against their duties and responsibilities relating to corporate governance;
- · annually evaluating adequacy of our corporate governance structure, policies, and procedures; and
- · providing reports to our board regarding the committee's nominations for election to the board and its committees.

# Compensation Committee Interlocks and Insider Participation

None of the members of our compensation committee is or has in the past served as an officer or employee of our company. None of our executive officers currently serves, or in the past year has served, as a member of the board of directors or compensation committee of any entity that has one or more executive officers serving on our board of directors or compensation committee.

## **Limitations on Liability and Indemnification Matters**

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to our directors, officers or controlling persons, we have been informed that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

## DIRECTOR COMPENSATION

# **Fiscal Year 2013 Director Compensation**

We do not have any established policy with regard to cash or equity-based compensation of non-employee members of our board of directors. However, under our 2013 equity incentive plan (2013 Plan), pursuant to which we intend to issue awards beginning with the effective date of this offering, the maximum number of shares subject to equity awards, and the maximum size of performance cash awards, that may be granted or paid to participants in any calendar year is limited, as set forth in more detail under "Executive Compensation—Equity Plans" below. During the year ended December 31, 2013, our non-employee directors did not receive any cash compensation or stock awards for their service on our board of directors or committees of our board of directors, except that Kevin Rakin was granted the right to purchase 81,623 shares of our common stock in April 2013 in connection with his service as a member of our board of directors, and John H. Johnson was granted an option to purchase 100,000 shares of our common stock in December 2013 in connection with his appointment to our board of directors.

The following table presents certain information with respect to the compensation of all of our non-employee directors:

Name	Stock Awards(\$) <sup>(2)(3)</sup>	Option Awards(\$) <sup>(2)(3)</sup>	Total(\$)
Joshua Baltzell		_	
John H. Johnson <sup>(1)</sup>	<del>_</del>	52,000(5)	52,000
Garheng Kong, M.D., Ph.D.	<del>_</del>	_	_
Michael Lewis	<del>_</del>	_	_
Kevin Rakin	8,979(4)	_	8,979

<sup>(1)</sup> Mr. Johnson was appointed to our board of directors effective November 13, 2013.

None of our executive officers who also served as a member of our board of directors during our fiscal year ended December 31, 2013, received any additional compensation for such service as a director.

We have a policy of reimbursing our directors for their reasonable out-of-pocket expenses incurred in attending board of directors and committee meetings.

<sup>(2)</sup> The amounts in these columns represent the aggregate grant date fair value of the option granted to Mr. Johnson on December 11, 2013, and the restricted shares sold to Mr. Rakin on April 23, 2013, computed in accordance with FASB ASC Topic 718. See Note 11 to our consolidated financial statements included elsewhere in this prospectus for a discussion of the assumptions made by us in determining the grant date fair value of our equity awards.

(3) As of December 31, 2013, Mr. Johnson held an outstanding option to purchase 100,000 shares of our common stock, and Mr. Rakin held an aggregate of 127,444 restricted shares of our common stock and a

As of December 31, 2013, Mr. Johnson held an outstanding option to purchase 100,000 shares of our common stock, and Mr. Rakin held an aggregate of 127,444 restricted shares of our common stock and a non-compensatory warrant to purchase 2,624 shares of our common stock. None of our other non-employee directors held stock awards or options as of December 31, 2013.
 Mr. Rakin purchased 81,623 shares of our common stock at a price of \$0.001 per share, subject to our repurchase right if his service terminates prior to his vesting in such shares. Such repurchase right lapses

Mr. Rakin purchased 81,623 shares of our common stock at a price of \$0.001 per share, subject to our repurchase right if his service terminates prior to his vesting in such shares. Such repurchase right lapses in equal annual installments upon the completion of each of four years of continuous service provided by Mr. Rakin as a director following April 23, 2013. Our repurchase right lapses in full if we are subject to a change in control (as defined under "Change in Control Benefits") prior to the termination of Mr. Rakin's director service.
 Mr. Johnson was granted an option to purchase 100,000 shares of our common stock at an exercise price of \$0.66 per share. The option vests in equal annual installments upon the completion of each of four

OMr. Johnson was granted an option to purchase 100,000 shares of our common stock at an exercise price of \$0.66 per share. The option vests in equal annual installments upon the completion of each of four years of continuous service provided by Mr. Johnson as a director following November 13, 2013. In addition, the option will vest in full if we are subject to a change in control (as defined under "Change in Control Benefits") prior to the termination of Mr. Johnson's director service.

## **EXECUTIVE COMPENSATION**

# Fiscal Year 2013 Summary Compensation Table

The following table provides information concerning the compensation paid to Peter Greenleaf, our former President and Chief Executive Officer, our next two most highly compensated executive officers during the year ended December 31, 2013, and Patrick O'Donnell, our former Chairman, President and Chief Executive Officer. We refer to these individuals as our named executive officers.

ar and the second		- · · · · · (E)		Option Awards	All Other Compensation	
Name and Principal Position	Year	Salary (\$) <sup>(5)</sup>	Bonus (\$)	(\$) <sup>(7)</sup>	(\$)	Total (\$)
Peter Greenleaf <sup>(1)</sup>	2013	196,575	_	230,967	28,957(9)	456,499
Former Director, President and Chief Executive Officer						
Nancy Lynch, M.D. <sup>(2)</sup>	2013	71,233	25,000(6)	156,000	_	252,233
Chief Medical Officer						
Stephen Kennedy <sup>(3)</sup>	2013	116,342	_	156,000	_	272,342
Senior Vice President of Manufacturing, Operations and Supply						
Chain						
Patrick O'Donnell <sup>(4)</sup>	2013	46,466		7,088(8)	235,851(10)	289,405
Former Chairman, President and Chief Executive Officer						

<sup>(1)</sup> Employment commenced on June 10, 2013. Mr. Greenleaf resigned his employment on February 28, 2014.

# 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.

Employment commenced on September 23, 2013.

<sup>(3)</sup> Employment commenced on August 5, 2013.

<sup>(4)</sup> Resigned his employment on March 5, 2013.

Represents prorated salary due to the commencement or termination of the officer's employment during the year ended December 31, 2013.

Represents a sign-on bonus paid to Dr. Lynch in connection with the commencement of her employment. A prorated portion of the bonus is repayable to us if Dr. Lynch resigns her employment prior to September 23, 2014.

Represents the aggregate grant date fair value of option awards granted to each of Messrs. Greenleaf and Kennedy and to Dr. Lynch, and the incremental fair value with respect to the modification of Mr. O'Donnell's option, during the year ended December 31, 2013, computed in accordance with FASB ASC Topic 718. See Note 11 to our consolidated financial statements included elsewhere in this prospectus for a discussion of the assumptions made by us in determining the fair value of our equity awards.

Represents incremental fair value related to the modification of the vesting schedule applicable to Mr. O'Donnell's option granted on August 5, 2012 in connection with his resignation of employment.

Represents incremental fair value related to the modification of the vesting schedule applicable to Mr. O'Donnell's option granted on August 5, 2012 in connection with his resignation of employment. Pursuant to his separation agreement, 354,395 shares subject to such option will vest in equal monthly installments during the 12-month period following March 19, 2013, provided that he continues to fulfill his obligations to us described in such separation agreement.

Represents \$24,000 paid to Mr. Greenleaf to cover estimated temporary housing and related expenses during his first six months of employment and \$4,957 paid to Mr. Greenleaf as a gross-up with respect to taxes incurred on such payment. A prorated portion of such payment was repayable to us upon Mr. Greenleaf's resignation on February 28, 2014, unless determined otherwise by our board of directors. Mr. Greenleaf repaid such amounts in accordance with his employment agreement prior to his resignation.

<sup>(10)</sup> Represents severance benefits paid to Mr. O'Donnell pursuant to his separation agreement with us, including \$218,534 in cash severance, \$13,113 for health insurance premiums and \$4,204 for accrued but unused vacation, in exchange for a release of claims.

#### **Base Salaries**

For the year ended December 31, 2013, the annual base salaries for our named executive officers were as follows: Peter Greenleaf—\$350,000; Nancy Lynch, M.D.—\$260,000; Stephen Kennedy—\$285,000; and Patrick O'Donnell—\$265,000. Except in connection with hiring new executive officers, neither our board of directors nor the compensation committee of our board of directors took any action during the year ended December 31, 2013, to increase or decrease the base salaries of our named executive officers.

# Performance-Based Bonuses

Pursuant to employment agreements with Messrs. Greenleaf and O'Donnell and offer letters with Dr. Lynch and Mr. Kennedy, each named executive officer is eligible (or was eligible in the case of Messrs. Greenleaf and O'Donnell) to earn an annual bonus equal to a specified percentage of his or her base salary (40% with respect to each of Mr. Greenleaf and Dr. Lynch and 35% with respect to each of Messrs. Kennedy and O'Donnell). The actual amount of bonus earned is determined by our board of directors based on our performance and the officer's achievement of objectives and goals determined by our chief executive officer (or, with respect to Messrs. Greenleaf and O'Donnell, our board of directors).

# 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 2013 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, 2013.

		Option Awards			
	Number of				
	Securities				
	Underlying	Number of Securities			
	Unexercised	Underlying	Option	Option	
	Options	Unexercised Options	Exercise Price	Expiration	
Name	Exercisable(#)	Unexercisable(#)	(\$)	Date	
Peter Greenleaf	<del>_</del>	2,099,704(1)	0.07	7/15/2023	
Nancy Lynch, M.D.	_	300,000(2)	0.66	12/10/2023	
Stephen Kennedy	<del>_</del>	300,000(3)	0.66	12/10/2023	
Patrick O'Donnell	265,796	88,599(4)	0.07	6/17/2014	

<sup>(1)</sup> Option vests over four years of service following June 10, 2013, with 25% vesting upon completion of 12 months of service and in 36 equal monthly installments thereafter. Mr. Greenleaf resigned his employment on February 28, 2014. As of February 28, 2014, Mr. Greenleaf was not vested in any of the options previously granted and such options lapsed per his separation agreement.

(2) Option vests over four years of service following September 23, 2013, with 25% vesting upon completion of 12 months of service and in 36 equal monthly installments thereafter.

<sup>(4)</sup> Pursuant to his separation agreement, 354,395 of the shares subject to Mr. O'Donnell's option granted on August 15, 2012, vest and become exercisable in 12 equal monthly installments following March 19, 2013, provided that he continues to fulfill his obligations to us described in his separation agreement. Mr. O'Donnell has 90 days from March 19, 2014 to exercise his vested options. The remaining 1,063,184 shares originally subject to Mr. O'Donnell's option expired in connection with his resignation on March 5, 2012.

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

# **Employment Agreements**

### Peter Greenleaf

In June 2013, we entered into an employment agreement with Peter Greenleaf in connection with his appointment as our president and chief executive officer. Under this agreement, Mr. Greenleaf's initial base salary was \$350,000 per year, and he was initially eligible to receive an annual cash bonus equal to 40% of his base salary, subject to satisfaction of objective or subjective criteria established by our board of directors or its compensation committee. For a period of 12 months after the termination of his employment, Mr. Greenleaf will be subject to certain restrictions on competition with us and on the solicitation of our employees and customers. Mr. Greenleaf had an at-will employment relationship with us.

In connection with the commencement of his employment, we paid Mr. Greenleaf \$28,957 to assist with estimated temporary housing and related expenses, which amount includes a tax gross-up with respect to such expenses. Such amount was subject to repayment to us upon Mr. Greenleaf's resignation on February 28, 2014, because he had not completed 12 months of employment. Mr. Greenleaf repaid such amounts in accordance with his employment agreement prior to his resignation.

Pursuant to his employment agreement, Mr. Greenleaf received an option to purchase up to 2,099,704 shares of our common stock, as described in more detail above under "Outstanding Equity Awards at 2013 Fiscal Year-End." In February 2014, we entered into a separation agreement and general release of all claims with Mr. Greenleaf in connection with his resignation of employment. Pursuant to such agreement, the option expired in its entirety on his resignation date. For information regarding the vesting acceleration provisions applicable to Mr. Greenleaf's option, please see "Change in Control Benefits" below.

# Nancy Lynch

In September 2013, we entered into a letter agreement with Nancy Lynch, M.D. in connection with her appointment as our chief medical officer. Under this agreement, Dr. Lynch's initial base salary is \$260,000 per year, and she is initially eligible to receive an annual cash bonus equal to 40% of her base salary, subject to satisfaction of objective or subjective criteria established by our board of directors. For a period of 12 months after the termination of her employment, Dr. Lynch will be subject to certain restrictions on competition with us and on the solicitation of our employees and customers. Dr. Lynch has an at-will employment relationship with us.

In connection with the commencement of her employment, we paid Dr. Lynch a sign-on bonus of \$25,000, subject to repayment to us if she resigns before completing 12 months of employment.

Pursuant to her letter agreement, Dr. Lynch received an option to purchase up to 300,000 shares of our common stock, as described in more detail above under "Outstanding Equity Awards at 2013 Fiscal Year-End." In addition, for information regarding the vesting acceleration provisions applicable to Dr. Lynch's option, please see "Change in Control Benefits" below.

# Stephen Kennedy

In July 2013, we entered into a letter agreement with Stephen Kennedy in connection with his appointment as our senior vice president of operations. Under this agreement, Mr. Kennedy's initial base salary is \$285,000 per year, and he is initially eligible to receive an annual cash bonus equal to 35% of his base salary, subject to satisfaction of objective or subjective criteria established by our board of directors. For a period of 12 months after the termination of his employment, Mr. Kennedy will be subject to certain restrictions on competition with us and on the solicitation of our employees and customers. Mr. Kennedy has an at-will employment relationship with us.

Pursuant to his letter agreement, Mr. Kennedy received an option to purchase up to 300,000 shares of our common stock, as described in more detail above under "Outstanding Equity Awards at 2013 Fiscal Year-End." In addition, for information regarding the vesting acceleration provisions applicable to Mr. Kennedy's option, please see "Change in Control Benefits" below.

### 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 May 12, 2014. Under this agreement, Mr. Gridley's initial base salary will be \$350,000 per year, and he is initially eligible to receive an annual cash bonus, with a target equal to 40% of his base salary, subject to satisfaction of objective or subjective criteria established by our board of directors (and pro-rated for his first year of employment). For a period of 12 months after the termination of his employment, Mr. Gridley will be subject to certain restrictions on competition with us and on 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 2,133,098 shares of our common stock. In addition, if, prior to the consummation of this offering, we close an additional sale of our preferred stock, as described in Mr. Gridley's letter agreement, including the third closing available to be called under the amended and restated Series A Purchase Agreement (as described below), he will be granted an additional option to purchase up to a number of shares such that, together with the original option, Mr. Gridley's options represent 4% of our common stock, including shares issuable upon conversion of option and warrants, outstanding at that time. The options will vest 25% after the first 12 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.

## **Severance Benefits**

#### Peter Greenleaf

Pursuant to Mr. Greenleaf's employment agreement, if we had terminated Mr. Greenleaf's employment without cause or if he had resigned for good reason, we would have continued to pay Mr. Greenleaf his base salary and the employer portion of premiums under COBRA for himself and his eligible dependents for a period of 12 months following such termination or resignation of employment. Such benefits would have been subject to Mr. Greenleaf's execution of a general release of all claims he may have against us and certain related parties.

For purposes of his employment agreement, cause meant Mr. Greenleaf's unauthorized use or disclosure of our confidential information or trade secrets which causes material harm to us; material breach of any material 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; continuing 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 employment agreement, good reason meant, without Mr. Greenleaf's consent, a material reduction in his base salary, relocation of his principal workplace by more than 40 miles or a change in his title or position that materially reduces his level of authority or responsibility. Mr. Greenleaf's resignation of employment was not for good reason.

In February 2014, we entered into a separation agreement and general release of all claims with Mr. Greenleaf in connection with his resignation of employment. Pursuant to such agreement, all 2,099,704 shares subject to his 2013 option grant expired on his resignation date.

#### Nancy Lynch

If we terminate Dr. Lynch's employment without cause or if she resigns for good reason, we will continue to pay Dr. Lynch her base salary and the employer portion of premiums under COBRA for herself and her eligible dependents for a period of 12 months following the termination of her employment. Such benefits are subject to Dr. Lynch's execution of a general release of all claims she may have against us and certain related parties.

The definition of cause in Dr. Lynch's letter agreement is the same as that in Mr. Greenleaf's employment agreement, as described above. For purposes of her letter agreement, good reason means, without Dr. Lynch's consent, a material reduction in her base salary, material breach of our obligations under her letter agreement, or a change in her title or position that materially reduces her level of authority or responsibility.

#### Stephen Kennedy

If we terminate Mr. Kennedy's employment without cause, 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. In addition, his stock options will continue to vest during the nine-month period following his termination.

For purposes of his letter agreement, cause means Mr. Kennedy's indictment or conviction of any felony or any crime involving dishonesty or moral turpitude, breach of his letter agreement or his proprietary information, inventions and nonsolicitation agreement with us, refusal to abide by or comply with the legal directives of our board of directors, dishonesty, fraud or misconduct with respect to our affairs or business, gross negligence or failure to perform his duties or violation of our policies regarding business ethics, drug or alcohol use, equal employment opportunity or sexual or other unlawful harassment.

# Patrick O'Donnell

In March 2013, we entered into a separation agreement and general release of all claims with Patrick O'Donnell in connection with his resignation of employment. Pursuant to such agreement, Mr. O'Donnell is entitled to receive continued payment of his base salary and payment of his premiums for healthcare continuation coverage under COBRA for 12 months. In addition, 354,395 shares subject to a 2012 option grant vest in equal monthly installments during the 12-month period following the effective date of the separation agreement. The remaining shares subject to such option expired on his resignation date. All of the benefits to which Mr. O'Donnell is entitled pursuant to such separation agreement are contingent on his providing continuing transition assistance to us during such 12-month period. The aggregate value of his cash severance is \$275,000 and the estimated aggregate value of his COBRA premiums is \$16,000.

# **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. Under this agreement, if we terminate Mr. Gridley's employment without cause or Mr. Gridley resigns for good reason, we will 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. In addition, if the termination occurs during the first year of Mr. Gridley's employment and prior to our change in control, then Mr. Gridley's options will be deemed to be vested with respect to 1/48<sup>th</sup> of the shares for each month of employment completed by Mr. Gridley prior to his termination. 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.

For purposes of Mr. Gridley's letter agreement, cause means Mr. Gridley's unauthorized use or disclosure of our confidential information or trade secrets which causes 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 means, 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.

## **Change in Control Benefits**

In the event that we experience a change in control and, within 12 months after such change in control, an employee or other service provider (including one of our officers) is terminated by us without cause or such individual resigns for good reason, 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 our board of directors, 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 Mr. Greenleaf's employment agreement, described above.

### **Retirement Benefits**

We have established a 401(k) tax-deferred savings plan, which permits participants, including our named executive officers, to make contributions by salary deduction pursuant to Section 401(k) of the Internal Revenue 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. Greenleaf and a signing bonus to Dr. Lynch, each in connection with the commencement of their employment with us, as described in the Summary Compensation Table above.

In addition, as described above under "Change in Control Benefits," equity awards granted to our employees and other service providers, including our officers, generally become fully vested and (if applicable) exercisable if we are subject to a change in control and, within 12 months after such change in control, such individual is terminated by us without cause or such individual resigns for good reason.

## **Equity Plans**

# 2013 Equity Incentive Plan

Our board of directors adopted our 2013 Plan in November 2013, and we expect our stockholders to approve the 2013 Plan prior to the completion of this offering. The 2013 Plan became effective immediately on adoption although no awards will be made under it until the effective date of the registration statement of which this prospectus is a part. Our 2013 Plan will replace our 2012 Equity Incentive Plan described below (2012 Plan), and no further grants will be made under our 2012 Plan following completion of this offering. However, awards outstanding under the 2012 Plan will continue to be governed by their existing terms.

**Share Reserve.** The number of shares of our common stock available for issuance under our 2013 Plan will equal the sum of (a) 5,600,000 shares, (b) the number of shares of our common stock remaining available for

issuance under our 2012 Plan as of the effective date of the registration statement of which this prospectus is a part, and (c) the number of shares of our common stock subject to awards under our 2012 Plan that subsequently expire or lapse unexercised and shares issued pursuant to such awards that are forfeited or repurchased by us (such combined number not to exceed 5,460,682 shares). The number of shares reserved for issuance under the 2013 Plan will be increased automatically on the first business day of each of our fiscal years during the term of the plan, commencing in 2015, by a number equal to the smallest of:

- 1,960,000 shares;
- 3.5% of the number of shares of common stock outstanding on December 31 of the prior year; and
- the number of shares determined by our board of directors.

In general, to the extent that any awards under the 2013 Plan are forfeited, terminate, expire or lapse without the issuance of shares, or if we repurchase the shares subject to awards granted under the 2013 Plan, those shares will again become available for issuance under the 2013 Plan, as will shares applied to pay the exercise or purchase price of an award or to satisfy tax withholding obligations related to any award. All share numbers described in this summary of the 2013 Plan will automatically adjust in the event of a stock split, a stock dividend, a reverse stock split or similar occurrence.

**Administration**. The compensation committee of our board of directors administers the 2013 Plan. The compensation committee has complete discretion to make all decisions relating to the 2013 Plan and outstanding awards, including repricing outstanding options and modifying outstanding awards.

*Eliqibility.* Employees, non-employee directors and consultants are eligible to participate in our 2013 Plan.

Types of Award. Our 2013 Plan provides for the following types of awards:

- incentive and nonstatutory stock options;
- · stock appreciation rights;
- restricted share awards;
- · stock unit awards; and
- performance cash awards.

**Options and Stock Appreciation Rights.** The exercise price for options granted under the 2013 Plan may not be less than 100% of the fair market value of our common stock on the grant date. Optionees may pay the exercise price in cash or, with the consent of the compensation committee and as set forth in the applicable option grant agreement:

- with shares of common stock that the optionee already owns;
- by an immediate sale of shares through a broker approved by us, if shares of our common stock are publicly traded;
- through a net exercise procedure;
- · by delivery of a full-recourse promissory note; or
- by other methods permitted by applicable law.

An optionee who exercises a stock appreciation right receives the increase in value of our common stock over the exercise price. The exercise price for stock appreciation rights may not be less than 100% of the fair market value of our common stock on the grant date. The settlement value of a stock appreciation right may be paid in cash, shares of our common stock, or a combination.

Options and stock appreciation rights vest as determined by the compensation committee at the time of grant. In most cases, they will vest over a four-year period following the date of grant. Options and stock appreciation rights expire at the time determined by the compensation committee but in no event more than ten years after they are granted. These awards generally expire earlier if the participant's service terminates earlier. No participant may be granted stock options and stock appreciation rights under our 2013 Plan covering more than 500,000 shares in any calendar year except that we may grant a new employee up to an additional 500,000 shares in the calendar year such employee is hired.

**Restricted Shares and Stock Units**. Restricted shares and stock units may be awarded under the 2013 Plan in return for any lawful consideration, and participants who receive restricted shares or stock units generally are not required to pay cash for their awards. In general, these awards will be subject to vesting. Vesting may be based on length of service, the attainment of performance-based milestones or a combination of both, as determined by the compensation committee. No participant may be granted restricted share awards and stock units covering more than shares during any single calendar year. This annual limit is in addition to any stock options and stock appreciation rights the participant may receive during a calendar year. Settlement of vested stock units may be made in the form of cash, shares of common stock, or a combination.

**Performance Cash Awards.** Performance cash awards may be granted under the 2013 Plan that qualify as performance-based compensation that is not subject to the income tax deductibility limitations imposed by Section 162(m) of the Internal Revenue Code, if the award is approved by our compensation committee and the grant or vesting of the award is tied solely to the attainment of performance goals during a designated performance period. No participant may be paid more than \$1,000,000 in cash in any calendar year pursuant to a performance cash award granted under the 2013 Plan. Performance goals for the grant or vesting of awards under the 2013 Plan may be based on any one of, or combination of, the following:

Earnings (before or after taxes)

Earnings per share

Earnings before interest, taxes and depreciation

Earnings before interest, taxes, depreciation and amortization

Total stockholder return

Return on equity or average stockholders' equity Return on assets, investment or capital employed

Operating income Gross margin Operating margin Net operating income

Net operating income after tax Return on operating revenue

Objective corporate or individual strategic goals

Sales or revenue (using a measure thereof that complies with Section

162(m))

Expense or cost reduction

Working capital

Economic value added (or an equivalent metric)

Market share

Cash measures including cash flow and cash balance

Operating cash flow Cash flow per share Share price Debt reduction Customer satisfaction Stockholders' equity

Contract awards or backlog

Objective individual performance goals

To the extent a performance award is not intended to comply with Section 162(m) of the Internal Revenue Code, the compensation committee may select other measures of performance.

Corporate Transactions. In the event we are a party to a merger, consolidation or certain change in control transactions, outstanding awards granted under the 2013 Plan, and all shares acquired under the 2013 Plan, will be subject to the terms of the definitive transaction agreement (or, if there is no such agreement, as determined by our compensation committee). Unless an award agreement provides otherwise, such treatment shall include any of the following with respect to each outstanding award:

• the continuation, assumption or substitution of an award by us or the acquiror or surviving corporation;

- the cancellation of the unvested portion of options and stock appreciation rights without payment of any consideration;
- the full exercisability of outstanding options and stock appreciation rights and full vesting of the common shares subject to options and stock appreciation rights, followed by cancellation of such options and stock appreciation rights;
- the cancellation of the vested portion of options and stock appreciation rights in exchange for a payment equal to the excess, if any, of the value that a holder of a share of our common stock receives in the transaction over the exercise or purchase price of such award;
- the cancellation of outstanding stock units (whether vested or unvested) in exchange for a payment equal to the value that a holder of a share of our common stock receives in such transaction, which payment may be subject to vesting based on the participant's continuing service with the surviving or acquiring entity; or
- the assignment of any repurchase or reacquisition rights held by us to the surviving or acquiring entity.

The compensation committee is not required to treat all awards, or portions thereof, in the same manner.

The compensation committee has the discretion to provide that an award granted under the 2013 Plan will vest on an accelerated basis if we are subject to a change in control or if the participant is subject to an involuntary termination, either at the time such award is granted or afterward.

A change in control includes:

- any person acquiring beneficial ownership of more than 50% of our total voting power;
- · the sale or other disposition of all or substantially all of our assets; or
- our merger or consolidation after which our voting securities represent 50% or less of the total voting power of the surviving or acquiring entity.

*Changes in Capitalization.* In the event that there is a specified type of change in the capital structure of our common stock, such as a stock split, reverse stock split or dividend paid in common stock, proportionate adjustments will automatically be made to the kind and maximum number of shares:

- reserved for issuance under the 2013 Plan;
- by which the share reserve may increase automatically each year;
- that may be granted to a participant in a year (as established under the 2013 Plan pursuant to Section 162(m) of the Internal Revenue Code);
- · that may be issued upon the exercise of incentive stock options; and
- covered by each outstanding option, stock appreciation right and stock unit, the exercise price applicable to each outstanding option and stock
  appreciation right, and the repurchase price, if any, applicable to restricted shares.

In the event that there is a declaration of an extraordinary dividend payable in a form other than our common stock in an amount that has a material effect on the price of our common stock, a recapitalization, a spin-off or a similar occurrence, the compensation committee may make such adjustments as it deems appropriate, in its sole discretion.

**Amendments or Termination**. Our board of directors may amend or terminate the 2013 Plan at any time and for any reason. If our board of directors amends the 2013 Plan, it does not need stockholder approval of the

amendment unless required by applicable law, regulation or rules. The 2013 Plan will continue in effect for ten years, unless our board of directors decides to terminate the plan earlier or unless our board of directors and stockholders later approve an extension of this term.

## 2012 Equity Incentive Plan

Our board of directors adopted our 2012 Plan in July 2012, and it has been approved by our stockholders. The 2012 Plan became effective on adoption. No further awards will be made under our 2012 Plan following the completion of this offering; however, awards outstanding under our 2012 Plan will continue to be governed by their existing terms.

**Share Reserve.** As of July 10, 2014, up to 6,583,847 shares of our common stock have been reserved for issuance under the 2012 Plan. As of July 10, 2014, options to purchase 4,934,205 shares of common stock were outstanding under the 2012 Plan, and 1,123,165 shares of common stock remained available for future issuance under the 2012 Plan. Unissued shares subject to awards that expire, are terminated, surrendered or forfeited, and shares subject to awards that are repurchased by, or are surrendered or forfeited to, us at not more than the price paid for such shares, again become available for issuance under the 2012 Plan.

**Administration**. Our board of directors administers the 2012 Plan. The board of directors has complete discretion to make all decisions relating to the 2012 Plan and outstanding awards, including repricing outstanding options and modifying outstanding awards in other ways.

*Eligibility*. Employees, non-employee members of our board of directors, consultants and other persons determined by our board of directors to have made, or who are expected to make, contributions to us are eligible to participate in our 2012 Plan.

**Types of Awards.** Our 2012 Plan provides for the following types of awards:

- incentive and nonstatutory stock options;
- restricted share awards; and
- other stock-based awards.

**Options**. The exercise price for options granted under our 2012 Plan may not be less than 100% of the fair market value of our common stock on the grant date. Optionees may pay the exercise price in cash or in one, or by any combination of, the following forms of payment, as permitted by our board of directors in its sole discretion:

- by an immediate sale of the shares through a broker approved by us, if shares of our common stock are publicly traded;
- with shares of common stock that the optionee already owns;
- · by delivery of a full-recourse promissory note; or
- · by other methods permitted by applicable law.

Options vest as determined by our board of directors at the time of grant. In general, we have granted options that vest over a four-year period following the date of grant. Options expire at the time determined by our board of directors, but in no event more than ten years after they are granted. Options generally expire earlier if the optionee's service terminates earlier.

**Restricted Shares**. Restricted shares may be awarded under the 2013 Plan in return for any lawful consideration. In general, these awards will be subject to vesting. Vesting may be based on length of service, the attainment of performance-based milestones, or a combination, as determined by our board of directors.

*Corporate Transactions*. In the event that we are a party to a change in control, our board of directors shall, in its sole discretion, provide for one or any combination of the following with respect to outstanding awards:

- continuation, assumption or substitution of an award by us or the surviving or acquiring entity;
- acceleration of the date of exercise or vesting of an award;
- exchange of an award for the right to participate in an equity or other employee benefit plan of any successor corporation;
- cancellation of the award in exchange for a payment equal to the excess, if any, of the value that a holder of a share of our common stock receives in the transaction over the exercise price of such award; or
- termination of the award immediately prior to the consummation of such transaction.

Our board of directors is not required to treat all awards, or portions thereof, in the same manner. Our board of directors has the discretion to provide that an award granted under the 2012 Plan will vest on an accelerated basis if we are subject to a change in control or if the participant is subject to an involuntary termination, either at the time such award is granted or afterward.

A change in control includes:

- any person acquiring beneficial ownership of 50% or more of our total voting power;
- a proxy contest that results in the replacement of a majority of our directors;
- a reorganization, merger or consolidation after which our stockholders own 50% or less of the surviving corporation;
- our complete liquidation or dissolution; or
- a sale or other disposition of all or substantially all of our assets.

Changes in Capitalization. In the event that there is a specified type of change in the capital structure of our common stock, such as a stock split, reverse stock split, stock dividend, extraordinary cash dividend, recapitalization, spin-off, split-up, or other similar change in capitalization or similar event, the number and class of shares available under our 2012 Plan, the number and class of securities, vesting schedule and exercise price per share subject to each outstanding option granted under the 2012 Plan, the repurchase price per security subject to repurchase, and the terms of each other outstanding award shall be adjusted by (or substituted awards may be made, if applicable) to the extent our board of directors determines that such an adjustment (or substitution) is appropriate.

# 2013 Employee Stock Purchase Plan

Our 2013 Employee Stock Purchase Plan (2013 ESPP) was adopted by our board of directors in November 2013 and we expect our stockholders to approve it prior to completion of this offering. The 2013 ESPP will become effective as of the effective date of the registration statement of which this prospectus is a part. Our 2013 ESPP is intended to qualify under Section 423 of the Internal Revenue Code.

**Share Reserve.** We have reserved 1,120,000 shares of our common stock for issuance under the 2013 ESPP. The number of shares reserved for issuance under the 2013 ESPP will automatically be increased on the first business day of each of our fiscal years, commencing in 2015, by a number equal to the least of:

- 560.000 shares:
- 1% of the shares of common stock outstanding on the last business day of the prior fiscal year; or
- the number of shares determined by our board of directors.

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).

Administration. The compensation committee of our board of directors will administer the 2013 ESPP.

*Eligibility*. All of our employees are eligible to participate if we employ them for more than 20 hours per week and for more than five months per year. Eligible employees may begin participating in the 2013 ESPP at the start of any offering period.

*Offering Periods*. Each offering period will last a number of months determined by the compensation committee, not to exceed 27 months. A new offering period will begin periodically, as determined by the compensation committee. Offering periods may overlap or may be consecutive. Unless otherwise determined by the compensation committee, two offering periods of six months' duration will begin each fiscal year on May 1 and November 1. However, the first offering period will start on the effective date of the registration statement related to this offering and will end on April 30, 2014, with the first purchase date occurring on April 30, 2014.

**Amount of Contributions.** Our 2013 ESPP permits each eligible employee to purchase common stock through payroll deductions. Each employee's payroll deductions may not exceed 15% of the employee's cash compensation. Each participant may purchase up to the number of shares determined by our board of directors on any purchase date, not to exceed 3,500 shares. Each participant may not hold rights to purchase stock under our 2013 ESPP that would accrue at a rate that exceeds \$25,000 worth of our stock for each calendar year that the rights remain outstanding. Participants may withdraw their contributions at any time before stock is purchased.

Purchase Price. The price of each share of common stock purchased under our 2013 ESPP will be the lower of:

- 85% of the fair market value per share of our common stock on the first day of the applicable offering period or, in the case of the first offering period, 85% of the fair market value per share of our common stock as of the effective date of the registration statement of which this prospectus is a part (which is the price at which one share of common stock is offered to the public in this offering); and
- 85% of the fair market value per share of common stock on the purchase date.

Other Provisions. Employees may end their participation in the 2013 ESPP at any time. Participation ends automatically upon termination of employment with the company. If a change in control occurs and the acquirer does not continue or assume the 2013 ESPP, our 2013 ESPP will terminate and shares will be purchased with the payroll deductions accumulated to date by participating employees. Our board of directors or the compensation committee may amend or terminate the 2013 ESPP at any time. If we increase the number of shares of common stock reserved for issuance under the 2013 ESPP, except for the automatic increases described above, then we must seek the approval of our stockholders. The 2013 ESPP will terminate automatically 20 years after its adoption by our board of directors, unless it is extended by our board of directors and such extension is approved by our stockholders within 12 months thereafter.

## CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

The following is a description of transactions since January 1, 2012 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 our board of directors, including a majority of the independent and disinterested members of our board of directors. 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 our board of directors, including a majority of the independent and disinterested members of our board of directors, and are on terms no less favorable to us than those that we could obtain from unaffiliated third parties.

## Series A and Series A-1 Financings

On July 20, 2012, we entered into a stock purchase agreement with investors, including certain of our existing stockholders at the time who were represented by members of our board of directors, including ProChon Holdings, BV, Altima Restructure Fund Limited (or its predecessor entities), entities affiliated with Boston Millennia Partners and Foundation Medical Partners II, L.P. (Series A Purchase Agreement), to raise up to \$49.0 million through the sale of shares of our Series A convertible preferred stock, \$0.001 par value per share (Series A Preferred Stock), at a purchase price of \$1.00 per share (Series A Financing). In order to consummate the Series A Financing, we were required to effect a recapitalization pursuant to which Histogenics Finance Corporation, a Delaware corporation (Finance Corp), was formed and subsequently merged into our company (Recapitalization). Further, as described below, certain outstanding convertible promissory notes were converted into shares of Series A Preferred Stock or common stock. Pursuant to the Recapitalization and the Series A Purchase Agreement, the investors received the right to purchase shares of Finance Corp's Series A Preferred Stock. In addition, the investors agreed to purchase additional shares of our Series A Preferred Stock upon our achievement of certain milestones, as described below.

# The Recapitalization

Pursuant to the Recapitalization, which was effected on July 20, 2012, each outstanding share of Finance Corp's common stock and all shares of our common stock and Series A Preferred Stock, and any options and warrants with respect to such shares, outstanding immediately prior to the closing of the Recapitalization were cancelled without consideration. All of the accrued interest on our convertible notes issued in the aggregate principal amount of \$12.0 million pursuant to a note purchase agreement dated as of May 13, 2011 was cancelled, and the outstanding principal amount was converted into 6,250,001 shares of our common stock. All of the accrued interest on our convertible notes issued in the aggregate principal amount of \$5.95 million pursuant to a note purchase agreement dated as of January 16, 2012 was cancelled, and the outstanding principal amount was converted into 5,950,000 shares of our Series A Preferred Stock and warrants to purchase an aggregate of 107,613 shares of our common stock. Each right to purchase shares of Finance Corp's Series A Preferred Stock was converted into a right to purchase shares of our Series A Preferred Stock at a price of \$1.00 per share and a warrant to purchase 0.018085922 shares of our common stock at an exercise price of \$0.07.

# The Series A Purchase Agreement

Upon entry into the Series A Purchase Agreement, we issued an aggregate of 28,602,031 shares of Series A Preferred Stock for an aggregate consideration of \$28.6 million, which included the conversion of certain convertible promissory notes. Prior to being amended and restated, as described below, the Series A Purchase Agreement also provided for the purchase and sale of 20,547,968 additional shares of Series A Preferred Stock (Milestone Shares) to the investors in the Series A Financing upon the completion of certain milestones

(Milestone Closing). The achievement of the following milestones was necessary for the Milestone Closing to occur: (1) 85% of the 245 patients in the NeoCart Phase 3 clinical trial must be enrolled; (2) 125 of such patients must reach the one-year end point in the NeoCart Phase 3 clinical trial; and (3) analysis indicating that NeoCart is likely to be approved by the FDA must be obtained (collectively, Milestones). Further, we were required to provide notice of the achievement of the Milestones to the investors in the Series A Financing, and the holders of at least a majority of the issued and outstanding Series A Perferred Stock purchased in the initial closing under the Series A Purchase Agreement must agree that the Milestones were met or waive the Milestones. The Series A Purchase Agreement also provided that each individual investor under the Series A Purchase Agreement could, in its sole discretion, waive the Milestones and purchase such investor's share of the Milestone Shares at any time without obligating other investors to purchase their share of the Milestone Shares. The obligation to effect the Milestone Closing was to terminate upon the completion of an initial public offering, but the provisions relating to the Milestone Closing and the Milestone Shares were removed in connection with the Series A-1 Financing, as described below.

#### Rakin Stock Purchase Agreement

On October 31, 2012, our board of directors appointed Kevin Rakin to our board of directors. In connection with his appointment, we entered into a stock purchase agreement with Mr. Rakin pursuant to which Mr. Rakin purchased 150,000 shares of Series A Preferred Stock at a purchase price of \$1.00 per share and a warrant exercisable for \$0.07 per share to purchase up to 2,264 shares of our common stock (Rakin Stock Purchase Agreement), for an aggregate purchase price of \$150,000. Pursuant to the Rakin Stock Purchase Agreement, Mr. Rakin also became a party to the Investors' Rights Agreement and the Stockholders' Agreement described below.

# The Series A-1 Financing

On December 18, 2013, we amended and restated the Series A Purchase Agreement in order to, among other matters, waive the Milestones and raise an additional \$10.3 million (Series A-1 Financing) from the sale of 10,323,988 shares of our Series A-1 preferred stock, \$0.001 par value per share (Series A-1 Preferred Stock and, together with Series A Preferred Stock, Preferred Stock) to our existing investors from the Series A Financing investors, including certain of our existing stockholders who were represented by members of our board of directors, including ProChon Holdings, BV, Sofinnova Venture Partners VIII, L.P. and Split Rock Partners II, L.P. The amended and restated Series A Purchase Agreement also provided for the purchase and sale of 10,323,980 additional shares of Series A-1 Preferred Stock (Conditional Shares) to the investors in the Series A-1 Financing upon the completion of certain conditions (Conditional Closing). The achievement of the following conditions was necessary for the Conditional Closing to occur: (1) we receive the approval of a majority of the members of our board of directors; (2) there not be an initial public offering of our common stock; (3) we have less than two million dollars in cash or cash equivalents; (4) five new patients be enrolled in our NeoCart Phase 3 clinical trial prior to June 2014; and (5) that no material adverse effect have occurred since December 18, 2013. The Conditional Closing was completed May 27, 2014 and the Conditional Shares were sold and issued on that date, resulting in aggregate proceeds of \$10.3 million.

In connection with the Series A-1 Financing, we entered into a Royalty Agreement to pay to each of the purchasers of shares of our Preferred Stock and the common stock issuable upon the conversion thereof (Net Sales Payment Recipients) a payment equal to, in the aggregate, three percent of Net Sales (as defined below) during such calendar year (Net Sales Payment). The purchasers of Series A Preferred Stock were previously entitled to a payment equal to, in the aggregate, two percent of Net Sales during such calendar year. The Net Sales Payment is to be distributed among the Net Sales Payment Recipients pro rata based on percentages set forth in the Royalty Agreement. Pursuant to the Royalty Agreement, Net Sales means the gross amount received by us for or on account of sales of our products less: (1) amounts repaid or credited by reason of actual rejection or return of applicable products; (2) reasonable and customary trade, quantity or cash rebates or discounts to the extent allowed and taken; (3) amounts for outbound transportation, insurance, handling and shipping; and (4) taxes, customs duties and other governmental charges levied on or measured by sales of products, as adjusted for rebates and refunds. Excluded from Net Sales are amounts attributable to any sale of any product between or among us and any of our affiliates or subsidiaries.

At the election of the majority of the Net Sales Payment Recipients (Majority Recipients), all or a portion of the Net Sales Payments will be redeemed by us. The Majority Recipients can elect (Election) to have each Net Sales percentage point redeemed for \$10.0 million payable in cash or shares of our common stock. Cash payments will be subject to our ability to make such payments out of funds legally available under Delaware law. Subject to the foregoing, redemption would occur within 45 days following an Election. The Majority Recipients may make an Election any time after January 1, 2017 and prior to January 1, 2019, but each Election must be at least six months apart. Each redemption of a Net Sales percentage point will reduce by a percentage point the royalty rate used to calculate the Net Sales Payment Recipients' share of Net Sales based on the sales of our products. Once all three percentage points have been redeemed, the right of the Net Sales Payment Recipients to receive the Net Sales Payments will automatically terminate.

The right of the Net Sales Payment Recipients to receive the Net Sales Payments will continue after this offering and is personal to each Net Sales Payment Recipient such that the sale of the Net Sales Payment Recipient's Preferred Stock or underlying common stock will not transfer with such sale, but will remain with such Net Sales Payment Recipient.

Also in connection with the Series A-1 Financing, our amended and restated Series A Purchase Agreement, along with several other escrow agreements executed therewith, provide for the escrowing of certain shares of our capital stock to satisfy the obligations of certain of our stockholders under that certain agreement with Purpose Co., Ltd. (f/k/a Takagi Sangyo Co. Ltd. and f/k/a Takagi Industrial Co., Ltd.) (Purpose) dated June 22, 2012 (Purpose Agreement). Pursuant to these escrow agreements, we hold in escrow shares of our preferred stock and warrants exercisable for our common stock, representing an aggregate of 4,000,000 shares of our common stock which are to be issued to Purpose in order to satisfy the obligations to Purpose immediately upon the effectiveness of this offering. We believe this number of shares, based on the required calculations in the Purpose Agreement, would allow us to reallocate the number of shares necessary to satisfy our obligation to Purpose for an offering up to approximately \$\frac{1}{2}\$, which we do not expect to exceed the proposed maximum offering price under this prospectus.

The following table summarizes the purchases of our Preferred Stock and common stock by the beneficial holders of more than five percent of our capital stock or entities affiliated with them (excluding any issued and outstanding warrants to purchase our common stock):

Name of Stockholder	Histogenics Director	Number of Series A Preferred Stock Shares <sup>(1)</sup>	Number of Series A-1 Preferred Stock Shares	Number of Common Stock Shares <sup>(1)</sup>	Aggregate Purchase Price <sup>(2)</sup>
Altima Restructure Fund Limited		1,715,453	1,270,053	833,542	\$ 3,833,331
Entities affiliated with Boston Millennia Partners	_	1,253,670	895,480	1,129,792	\$ 3,298,302
ProChon Holdings BV	Michael Lewis	6,663,563	4,929,285	3,125,000	\$ 14,771,400
Sofinnova Venture Partners VIII, L.P.(3)	_	8,750,000	6,250,000	_	\$ 15,000,000
Split Rock Partners II, LP	Joshua Baltzell	5,833,333	4,166,667	_	\$ 10,000,000

<sup>(1)</sup> Includes shares issued upon the conversion of certain convertible promissory notes then outstanding, for which the converted principal and accrued interest are included in the aggregate purchase price. (2) Excludes the consideration paid for any warrants.

<sup>(3)</sup> Garheng Kong, M.D., Ph.D. was a managing member of the general partner of Sofinnova Venture Partners VIII, L.P. and is the current director designated by Sofinnova Venture Partners VIII, L.P. However, Dr. Kong is no longer a managing member of the general partner of Sofinnova Venture Partners VIII, L.P. and as such no longer has any voting or dispositive power over the shares owned by Sofinnova Venture Partners VIII, L.P.

## **ProChon Biotech Ltd. Acquisition Obligations**

In May 2011, ProChon Biotech Ltd. (ProChon), an Israeli corporation, became our wholly owned subsidiary (ProChon Acquisition). As part of the transactions surrounding the ProChon Acquisition, we (as the successor in interest to ProChon) and ProChon Holdings BV (ProChon BV), a current stockholder, entered into an agreement with Professor Avner Yayon (Yayon Agreement). Under the Yayon Agreement, ProChon BV is obligated to transfer to Professor Yayon a number of shares equal to 1.5% of our issued and outstanding capital stock from its own holdings immediately prior to the completion of this offering. Pursuant to the Yayon Agreement we are not obligated to issue any additional shares of our common stock in this offering. Upon completion of this offering, all obligations of ProChon BV under the Yayon Agreement will be satisfied in full.

# **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 outstanding Preferred Stock, including certain of our existing stockholders who were represented by members of our board of directors, including ProChon Holdings, BV, Sofinnova Venture Partners VIII, L.P. and Split Rock Partners II, L.P. Under this agreement, we granted information and inspection rights that will terminate upon the closing of this offering. In addition, the holders of 49,249,999 shares of our common stock as of July 10, 2014, including the shares of common stock issuable upon automatic conversion of our Preferred Stock, who are parties to the Investors' Rights Agreement are provided rights to demand registration of shares of common stock issuable upon conversion of their preferred stock and to participate in a registration of our common stock that we may decide to do, from time to time. These registration rights will survive this offering and will terminate no later than the fifth anniversary of this offering. These demand registration rights, however, may not be exercised until six months after the completion of this offering. Certain of the shares subject to this agreement are held by affiliates of certain of our directors and by holders of five percent of our capital stock. For more information regarding the Investors' Rights Agreement, see "Description of Capital Stock—Registration Rights."

# Stockholders' Agreement

On December 18, 2013, we entered into a second amended and restated stockholders' agreement (Stockholders' Agreement) with certain holders of our common stock and Preferred Stock, including certain of our existing stockholders who were represented by members of our board of directors, including ProChon Holdings, BV, Sofinnova Venture Partners VIII, L.P. and Split Rock Partners II, L.P. Under the terms of the Stockholders' Agreement, the parties have agreed, subject to certain conditions, to vote their shares so as to elect as directors the nominees designated by certain of our investors, including Sofinnova Venture Partners VIII, L.P., which has designated Garheng Kong, Ph.D., M.D., Split Rock Partners II, L.P., which has designated Joshua Baltzell, and certain other investors (including ProChon Holdings BV), which have designated Michael Lewis. In addition, the majority of the foregoing designated directors have the right to designate a director and have designated John H. Johnson. In addition, the parties to the Stockholders' Agreement have agreed to vote their shares so as to elect to our board of directors our Chief Executive Officer and additional at-large directors nominated by the holders of our common stock and the holders of our Preferred Stock, voting together as a single class, which is currently vacant. The Stockholders' Agreement also provides for rights of first refusal and co-sale relating to the shares of our common stock and common stock issuable upon conversion of the shares of Preferred Stock held by the parties thereto. The Stockholders' Agreement will terminate immediately prior to the completion of this offering.

In addition, the Stockholders' Agreement contains provisions relating to the obligation of certain of our stockholders pursuant to the Purpose Agreement. Under the Purpose Agreement, if we were to enter into a merger, reorganization or consolidation in which our stockholders, prior to such event, do not retain a majority of the voting power in the surviving corporation, or a sale or exclusive license of all or substantially all of our assets or intellectual property, then, upon the closing of such event of liquidation, we or our stockholders will pay Purpose 7.8125% of the net proceeds of the event (Purpose Obligation). If we undertake an initial public offering of our common stock instead of undertaking an event of liquidation, then we or our stockholders shall pay the

consideration in shares of our common stock. In order to determine the number of shares of our common stock to be issued to Purpose in the event of an initial public offering, pursuant to the Purpose Agreement, we will subtract the transaction costs of the initial public offering, the amount of indebtedness, if any, and the amount and preferences of our preferred stock from the pre-initial public offering value, as determined by our pricing committee. This amount will then be multiplied by 7.8125%, or such lesser amount as determined pursuant to the Purpose Agreement. Pursuant to the Stockholders' Agreement, certain of our stockholders have agreed to satisfy the Purpose Obligation by the transfer of shares of our common stock at the time of an event of liquidation or initial public offering.

#### **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.

# **Policies and Procedures for Related Party Transactions**

In November 2013, we adopted a related party transaction policy under which our directors and executive officers, 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 our board of directors 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.

## PRINCIPAL STOCKHOLDERS

The following table provides information concerning beneficial ownership of our capital stock as of July 10, 2014, and as adjusted to reflect the sale of the common stock being sold in this offering, 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 (on an as-converted basis):
- each of our named executive officers;
- · each of our directors; and
- all of our current directors and executive officers as a group.

Beneficial ownership is determined in accordance with the rules of the SEC, and thus it represents sole or shared voting or investment power with respect to our securities. Shares of common stock subject to options or warrants currently exercisable or exercisable within 60 days of July 10, 2014, are deemed outstanding and beneficially owned by the person holding such options or warrants for purposes of computing the number of shares and percentage beneficially owned by such person, but are not deemed outstanding for purposes of computing the percentage beneficially owned by any other person. Except as indicated in the footnotes to the below table, and subject to applicable community property laws, the persons or entities named have sole voting and investment power with respect to all shares of our common stock shown as beneficially owned by them.

The following table lists the percentage of shares beneficially owned before this offering based on 56,026,477 shares of common stock outstanding as of July 10, 2014, which includes 49,249,999 shares of common stock issuable upon the automatic conversion of all outstanding shares of convertible preferred stock upon the closing of this offering, as if the conversion had occurred as of July 10, 2014.

The table also lists the percentage of shares beneficially owned after this offering based on shares of common stock outstanding immediately after the completion of this offering, assuming no exercise of the underwriters' over-allotment option to purchase up to an additional shares of our common stock.

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.

		Number of Shares Beneficially Owned		Percentage of Shares Beneficially Owned	
Name and Address of Beneficial Owner	Before the Offering	After the Offering <sup>(12)</sup>	Before the Offering	After the Offering <sup>(12)</sup>	
5% Stockholders				<u></u>	
ProChon Holdings BV <sup>(1)</sup> Stonehage SA, Rue du Puit-Godet 12, PO Box 126 2005 Neuchatel Switzerland	14,839,506		26.4%		
Sofinnova Venture Partners VIII, L.P. <sup>(2)</sup> 2800 Sand Hill Road, Suite 150 Menlo Park, CA 94025	15,157,413		27.0%		
Split Rock Partners II, LP <sup>(3)</sup> 1600 El Camino Real, Suite 290 Menlo Park, CA 94025	10,104,942		18.0%		
Altima Restructure Fund Limited <sup>(4)</sup> 11 Slingsby Place, 2nd Floor St. Martin's Courtyard WC2E 9AB London United Kingdom	3,850,379		6.9%		
Entities Affiliated with Boston Millennia Partners <sup>(5)</sup> 30 Rowes Wharf, Suite 400 Boston, MA 02110	3,301,496		5.9%		
Directors and Named Executive Officers					
Joshua Baltzell <sup>(6)</sup>	10,104,942		18.0%		
John H. Johnson	<u> </u>	_	_	_	
Garheng Kong, M.D., Ph.D.	_	_	_	_	
Michael Lewis <sup>(7)</sup>	14,839,506		26.4%		
Kevin Rakin <sup>(8)</sup>	395,342		*		
Peter Greenleaf <sup>(9)</sup>	_	_	_	_	
Adam Gridley	_	_			
Stephen Kennedy	_	_	_	_	
Nancy Lynch, M.D.		_			
Patrick O'Donnell <sup>(10)</sup>	354,395		*		
All current executive officers and directors as a group (9 persons)(11)	25,547,233		45.6%		

(footnotes continued on following page)

<sup>\*</sup> Less than one percent of the outstanding shares of common stock.

(1) Shareholdings consist of 11,592,848 shares of common stock issuable upon conversion of preferred stock, 3,125,000 shares of common stock and a warrant to purchase 121,658 shares of common stock held by ProChon Holdings BV (ProChon Holdings). ProChon Holdings' economic interest is owned in part by a family trust associated with Michael Lewis, who is referenced in footnote 7 below. ProChon Holdings has sole voting and investment power over the shares of capital stock owned.

Holdings has sole voting and investment power over the shares of capital stock owned.

(2) Shareholdings consist of 15,000,000 shares of common stock issuable upon conversion of preferred stock and a warrant to purchase 157,413 shares of common stock held by Sofinnova Venture Partners VIII, L.P. (SVP VIII). Sofinnova Management VIII, L.L.C. (SM VIII) is the general partner of SVP VIII and Anand Mehra, Michael Powell, Srinivas Akkarju and James I. Healy, are the managing members of SM VIII (Managing Members). SVP VIII, SM VIII and the Managing Members may be deemed to have shared voting and dispositive power over the shares owned by SVP VIII. Such persons and entities disclaim beneficial ownership over the shares owned by SVP VIII except to the extent of any pecuniary interest therein.

(3) Shareholdings consist of 10,000,000 shares of common stock issuable upon conversion of preferred stock and a warrant to purchase 104,942 shares of common stock. Voting and investment power over the shares is delegated to Split Rock Partners II Management, LLC, the general partner of Split Rock Partners II, LP. Split Rock Partners II Management, LLC has delegated voting and investment decisions to three individuals who require a two-thirds vote to act. Split Rock Partners II Management, LLC disclaims beneficial ownership of the shares except to the extent of any pecuniary interest.

- (4) Shareholdings consist of 2,985,506 shares of common stock issuable upon conversion of preferred stock, 833,542 shares of common stock and a warrant to purchase 31,331 shares of common stock held by Altima Restructure Fund Limited (ARF). Altima Partners LLP (Altima Partners), a limited a limited liability partnership organized under the laws of England and Wales, which acts as investment advisor to ARF, with respect to the shares of common stock directly beneficially owned by ARF. Redenko Milakovic, a citizen of Germany serves as chief investment officer of Altima Partners.
- Shareholdings consist of 1,784,485 shares of common stock issuable upon conversion of preferred stock, 938,090 shares of common stock and a warrant to purchase 18,727 shares of common stock held by Boston Millennia Partners II Limited Partnership; 85,481 shares of common stock issuable upon conversion of preferred stock, 44,937 shares of common stock and a warrant to purchase 897 shares of common stock held by Boston Millennia Partners II-A Limited Partnership; 254,112 shares of common stock issuable upon conversion of preferred stock, 133,585 shares of common stock and a warrant to purchase 2,667 shares of common stock held by Boston Millennia Partners GmbH & Co. KG; 16,046 shares of common stock issuable upon conversion of preferred stock, 8,435 shares of common stock and a warrant to purchase 95 shares of common stock held by Strategic Advisors Fund Limited Partnership; and 9,026 shares of common stock issuable upon conversion of preferred stock, 4,745 shares of common stock and a warrant to purchase 168 shares of common stock held by Boston Millennia Associates II Partnership. The securities owned by entities affiliated with Boston Millennia Partners are subject to the voting and investment control of Glen Partners II Limited Partnership, the sponsor of these entities, or its affiliates.

  Mr. Baltzell is affiliated with Split Rock Partners II, LP. Mr. Baltzell disclaims beneficial ownership of the shares held by the entities affiliated with Split Rock Partners II, LP. referenced in footnote 3 above,
- except to the extent of his pecuniary interest therein.
- Mr. Lewis has a beneficial interest in certain trusts that own an economic interest in ProChon Holdings BV referenced in footnote 1 above. Mr. Lewis disclaims beneficial ownership of such economic
- Shareholdings include (a) 142,718 shares of restricted common stock that are subject to a right of repurchase by us in the event Mr. Rakin's service terminates prior to vesting of these shares, of which 35,678 shares are or will be vested within 60 days of July 10, 2014, (b) 150,000 shares of common stock issuable upon conversion of preferred stock owned directly by Mr. Rakin, (c) 100,000 shares of common stock issuable upon conversion of preferred stock owned by the Kevin L. Rakin Irrevocable Trust, of which Mr. Rakin disclaims beneficial ownership and (d) a warrant to purchase 2,624 shares of common
- Mr. Greenleaf resigned his employment on February 28, 2014. As of February 28, 2014, Mr. Greenleaf was not vested in any of the options previously granted and such options lapsed per his separation agreement.
- (10) Mr. O'Donnell resigned his employment on March 5, 2013. Shareholdings include 354,395 shares of common stock issuable upon the exercise of options exercisable with 60 days of July 10, 2014.
- (11) Shareholdings include 207,443 shares of common stock issuable upon the exercise of options exercisable within 60 days of July 10, 2014 and 229,224 shares of common stock issuable upon the exercise of warrants exercisable within 60 days of July 10, 2014.
- (12) The following stockholders will deliver the indicated numbers of shares of common stock to Purpose immediately after the effectiveness of this offering, pursuant to obligations under the Purpose Agreement to deliver to Purpose shares of common stock with a value, based upon the initial public offering price of this offering, equal to 7.8125% of the net proceeds of this offering (Consideration). The stockholders named below beneficially own greater than five percent of our outstanding common stock (on an as-converted basis) or are otherwise our affiliates. Ten other stockholders or warrant holders who are not specifically named below each beneficially own less than five percent of our outstanding common stock (on an as-converted basis) and are not otherwise our affiliates.

	Percentage of Consideration Allocated under Purpose	Number of Shares of Common Stock
Name of Beneficial Owner	Agreement	Transferred
ProChon Holdings BV	30.94%	·
Sofinnova Venture Partners VIII, L.P.	15.86%	
Split Rock Partners II, LP	10.58%	
Altima Restructure Fund Limited	8.14%	
Entities Affiliated with Boston Millennia Partners	9.05%	
Kevin Rakin and Affiliates	0.27%	
Ten Non-Affiliate Stockholders Each Holding Less Than Five Percent of Our Outstanding Common Stock Not Listed Above (in the aggregate)	25.16%	

## DESCRIPTION OF CAPITAL STOCK

#### General

Following the closing of this offering, our authorized capital stock will consist of 100,000,000 shares of common stock, par value \$0.001 per share, and 10,000,000 shares of preferred stock, par value \$0.001 per share. The following description summarizes some of the terms of our certificate of incorporation and bylaws. This description does not purport to be complete and is qualified in its entirety by the provisions of our certificate of incorporation and bylaws, copies of which have been filed as exhibits to the registration statement of which this prospectus is a part.

#### Common Stock

As of July 10, 2014, there were 56,026,477 shares of our common stock outstanding, held of record by 20 stockholders, assuming conversion of all outstanding shares of our Preferred Stock into, and exercise of all outstanding warrants for, shares of common stock immediately prior to the closing of this offering.

**Voting Rights.** Each holder of common stock is entitled to one vote for each share of common stock held on all matters submitted to a vote of the stockholders, including the election of directors. Our certificate of incorporation and bylaws do not provide for cumulative voting rights. Because of this, the holders of a majority of the shares of common stock entitled to vote in any election of directors can elect all of the directors standing for election, if they should so choose.

*Dividends.* Subject to preferences that may be applicable to any then outstanding preferred stock, the holders of our outstanding shares of common stock are entitled to receive dividends, if any, as may be declared from time to time by our board of directors out of legally available funds. At present, we have no plans to issue dividends. See the section titled "Dividend Policy" above.

*Liquidation.* In the event of our liquidation, dissolution or winding up, holders of common stock will be entitled to share ratably in the net assets legally available for distribution to stockholders after the payment of all of our debts and other liabilities, subject to the satisfaction of any liquidation preference granted to the holders of any outstanding shares of preferred stock.

**Other Rights and Preferences.** Holders of our common stock have no preemptive, conversion or subscription rights, and there are no redemption or sinking fund provisions applicable to our common stock. The rights, preferences and privileges of the holders of common stock are subject to, and may be adversely affected by, the rights of the holders of shares of any series of our preferred stock that we may designate and issue in the future.

*Fully Paid and Nonassessable.* All of our outstanding shares of common stock are, and the shares of common stock to be issued in this offering will be, fully paid and nonassessable.

## **Preferred Stock**

Upon the closing of this offering, we will have no shares of our preferred stock outstanding. Outstanding shares of Series A Preferred Stock will be converted into 28,602,031 shares of common stock and outstanding shares of Series A-1 Preferred Stock will be converted into 20,647,968 shares of common stock immediately prior to the closing of this offering.

Under the terms of our certificate of incorporation, our board of directors is authorized to issue preferred stock in one or more series, to establish the number of shares to be included in each such series and to fix the designation, powers, preferences and rights of such shares and any qualifications, limitations or restrictions thereof. The issuance of preferred stock may have the effect of delaying, deferring or preventing a change in control of our company without further action by the stockholders and may adversely affect the voting and other rights of the

holders of common stock. The issuance of preferred stock with voting and conversion rights may adversely affect the voting power of the holders of common stock, including the loss of voting control to others. At present, we have no plans to issue any preferred stock.

#### Options

As of July 10, 2014, options to purchase 4,934,205 shares of our common stock were outstanding under our 2012 Plan at a weighted-average exercise price of \$0.52 per share, of which 718,472 were vested and exercisable as of that date.

#### Warrante

As of July 10, 2014, warrants to purchase 2,337,787 shares of our common stock were outstanding at a weighted average exercise price of \$0.0387 per share.

The warrants issued in connection with the Series A Financing and pursuant to the Rakin Stock Purchase Agreement are exercisable following the occurrence of certain events for an aggregate of up to 516,841 shares of our common stock, at an exercise price of \$0.07 per share (Warrants). The Warrants are exercisable in whole or in part dependent upon the amount of consideration paid to Purpose by the holder of such Warrant. Immediately prior to the closing of this offering, the Warrants will become exercisable for shares of common stock at an exercise price of \$0.07 per share. We expect to enter into an agreement with holders of the Warrants whereby they agree to net exercise the warrants effective and contingent upon the consummation of this offering.

We issued warrants in connection with an amendment to our advisor agreement with Boston Equity Advisors, LLC (BEA) and the Series A Financing to certain BEA affiliates, namely, Arnold Freedman, Mark Butts and Oded Ben-Joseph (BEA Warrants). The BEA Warrants are immediately exercisable for 583,334 shares, 583,333 shares and 583,333 shares, respectively, of our common stock, at an exercise price of \$0.001 per share. Immediately prior to the closing of this offering, these warrants will become exercisable for an aggregate of 1,750,000 shares of common stock at an exercise price of \$0.001 per share. The holders of these warrants entered into an escrow agreement. Pursuant to the escrow agreement, a portion of the warrants will be exercised for shares of our common stock, which assumes an initial offering price of \$1.000 per share. The holders of these shares of common stock will then be transferred to Purpose in partial satisfaction of the obligations of BEA and its affiliates to Purpose under the Stockholders' Agreement.

We issued a warrant to Silicon Valley Bank in connection with entering into a loan and security agreement with Silicon Valley Bank in June 2014. This warrant is exercisable for an aggregate of 70,946 shares of our common stock, subject to certain adjustments, at an exercise price of \$0.74 per share. The warrant is immediately exercisable and terminates ten years after the date issued.

## **Registration Rights**

## **Demand Registration Rights**

Pursuant to the Investors' Rights Agreement, the holders of at least 50% of the registrable shares of our common stock issued or issuable upon conversion of our Preferred Stock can request that we file up to two registration statements registering all or a portion of their registrable shares. As of July 10, 2014, the holders of 49,249,999 shares of our common stock, including shares issuable upon the automatic conversion of our Preferred Stock, have demand registration rights. Under specified circumstances, we also have the right to defer filing of a requested registration statement for a period of not more than 90 days, which right may not be exercised more than once during any period of 12 consecutive months. These registration rights are subject to additional conditions and limitations, including the right of the underwriters to limit the number of shares included in any such registration under certain circumstances.

## Form S-3 Registration Rights

Pursuant to the Investors' Rights Agreement, if we are eligible to file a registration statement on Form S-3, the holders of at least ten percent of the registrable shares of common stock issued or issuable upon the conversion of preferred stock have the right to demand that we file additional registration statements, including a shelf registration statement, for such holders on Form S-3.

## Piggyback Registration Rights

Pursuant to the Investors' Rights Agreement, whenever we propose to file a registration statement under the Securities Act, other than with respect to a registration related to employee benefit or similar plans, a registration on any form which does not include substantially the same information as would be required to be included in this registration statement, or a registration in which the only common stock being registered is common stock issuable upon conversion of debt securities which are also being registered, the holders of registrable shares of common stock issued or issuable upon conversion of our convertible preferred stock are entitled to notice of the registration and have the right to include their registrable shares in such registration. As of July 10, 2014, the holders of 49,249,999 shares of our common stock, including shares issuable upon the automatic conversion of our Preferred Stock, will be entitled to notice of this registration and will be entitled to include their shares of common stock in the registration statement but we anticipate that such right will be waived prior to this offering. The underwriters of any underwritten offering will have the right to limit the number of shares having registration rights to be included in the registration statement.

## **Expenses of Registration**

We are required to pay all expenses relating to any demand, Form S-3 or piggyback registration, other than underwriting discounts and commissions, subject to certain limited exceptions. We will not pay for any expenses of any demand registration if the request is subsequently withdrawn by the holders of a majority of the shares requested to be included in such a registration statement, subject to limited exceptions.

## **Expiration of Registration Rights**

The registration rights described above will expire for each holder upon the earlier of (1) five years after this offering is completed and (2) the closing of a deemed liquidation event as defined in our certificate of incorporation.

Holders of all of our shares with these registration rights have signed or are expected to sign agreements with the underwriters prohibiting the exercise of their registration rights for 180 days following the date of this prospectus. These agreements are described below under "Underwriting."

## Other Stockholder Rights

The Stockholders' Agreement provides certain rights of first refusal and co-sale rights to certain of our stockholders. In addition, (1) the Stockholders' Agreement obligates certain of our stockholders regarding the voting of their shares in elections of our directors and provides certain rights of indemnification and (2) certain of our investors are entitled to observer rights pursuant to certain management rights letters that we entered into with such investors. The Stockholders' Agreement and the management rights letters will terminate upon the completion of this offering.

## Anti-Takeover Effects of Delaware Law and Our Certificate of Incorporation and Bylaws

Delaware law, our certificate of incorporation and our bylaws contain provisions that could make the following transactions more difficult: an acquisition of us by means of a tender offer; an acquisition of us by means of a proxy contest or otherwise; or the removal of our incumbent officers and directors. It is possible that these provisions could make it more difficult to accomplish or could deter transactions that stockholders may otherwise consider to be in their best interest or in our best interests, including transactions which provide for payment of a premium over the market price for our shares.

These provisions, summarized below, are intended to discourage coercive takeover practices and inadequate takeover bids. These provisions are also designed to encourage persons seeking to acquire control of us to first negotiate with our board of directors. We believe that the benefits of the increased protection of our potential ability to negotiate with the proponent of an unfriendly or unsolicited proposal to acquire or restructure us outweigh the disadvantages of discouraging these proposals because negotiation of these proposals could result in an improvement of their terms.

## **Undesignated Preferred Stock**

The ability of our board of directors, without action by the stockholders, to issue up to 10,000,000 shares of undesignated preferred stock with voting or other rights or preferences as designated by our board of directors could impede the success of any attempt to change control of us. The existence of authorized but unissued shares of preferred stock may have the effect of deferring hostile takeovers or delaying changes in control or management of our company.

## Stockholder Action by Written Consent; Stockholder Meetings

Our certificate of incorporation and bylaws eliminate the right of stockholders to act by written consent without a meeting. As a result, a holder controlling a majority of our capital stock would not be able to amend our bylaws or remove directors without holding a meeting of our stockholders called in accordance with our bylaws. Our bylaws provide that a special meeting of stockholders may be called only by our chairman of the board, chief executive officer or president, or by a resolution adopted by a majority of our board of directors. These provisions might delay the ability of our stockholders to force consideration of a proposal or for stockholders controlling a majority of our capital stock to take any action, including the removal of directors.

## Requirements for Advance Notification of Stockholder Nominations and Proposals

Our bylaws establish advance notice procedures with respect to stockholder proposals to be brought before a stockholder meeting and the nomination of candidates for election as directors, other than nominations made by or at the direction of the board of directors or a committee of the board of directors. These provisions could have the effect of delaying until the next stockholder meeting stockholder actions that are favored by the holders of a majority of our outstanding voting securities.

## Staggered Board

Our board of directors is divided into three classes. The directors in each class will serve for a three-year term, one class being elected each year by our stockholders. For more information on the classified board, see "Management—Board of Directors—Classified Board." This system of electing and removing directors may discourage a third-party from making a tender offer or otherwise attempting to obtain control of us, because it generally makes it more difficult for stockholders to replace a majority of the directors.

## Removal of Directors

Our certificate of incorporation provides that no member of our board of directors may be removed from office by our stockholders except for cause and, in addition to any other vote required by law, upon the approval of holders of at least two-thirds of the total voting power of all of our outstanding voting stock then entitled to vote in the election of directors.

## **Board of Directors Vacancies**

Our restated certificate of incorporation and amended and restated bylaws authorize our board of directors to fill vacant directorships. In addition, the number of directors constituting our board of directors is set only by resolution adopted by a majority vote of our entire board of directors. These provisions will prevent a stockholder from increasing the size of our board of directors and gaining control of our board of directors by filling the resulting vacancies with its own nominees.

## Stockholders Not Entitled to Cumulative Voting

Our certificate of incorporation does not permit stockholders to cumulate their votes in the election of directors. Accordingly, the holders of a majority of the outstanding shares of our common stock entitled to vote in any election of directors can elect all of the directors standing for election, if they choose, other than any directors that holders of our preferred stock may be entitled to elect.

#### **Amendment of Charter Provisions**

The amendment of any of the above provisions, except for the provision making it possible for our board of directors to issue preferred stock, would require approval by holders of at least two-thirds of the total voting power of all of our outstanding voting stock.

The provisions of Delaware law, our certificate of incorporation and our bylaws could have the effect of discouraging others from attempting hostile takeovers and, as a consequence, they may also inhibit temporary fluctuations in the market price of our common stock that often result from actual or rumored hostile takeover attempts. These provisions may also have the effect of preventing changes in the composition of our board and management. It is possible that these provisions could make it more difficult to accomplish transactions that stockholders may otherwise deem to be in their best interests.

#### **Choice of Forum**

Upon the completion of this offering, our restated certificate of incorporation will provide that the Court of Chancery of the State of Delaware will be the exclusive forum for any derivative action or proceeding brought on our behalf; any action asserting a breach of fiduciary duty; any action asserting a claim against us arising pursuant to the Delaware General Corporation Law, our restated certificate of incorporation or our amended and restated bylaws; or any action asserting a claim against us that is governed by the internal affairs doctrine. The enforceability of similar choice of forum provisions in other companies' certificates of incorporation has been challenged in legal proceedings, and it is possible that a court could find these types of provisions to be inapplicable or unenforceable.

## **Transfer Agent and Registrar**

The transfer agent and registrar for our common stock will be Broadridge Financial Solutions, Inc.

## **NASDAQ Global Market**

We have applied to list our common stock on the NASDAQ Global Market under the symbol "HSGX."

#### SHARES ELIGIBLE FOR FUTURE SALE

Prior to this offering, there has been no market for our common stock. Future sales of shares of our common stock in the public market could adversely affect market prices prevailing from time to time. Furthermore, because only a limited number of shares will be available for sale shortly after this offering due to existing contractual and legal restrictions on resale described below, there may be sales of substantial amounts of our common stock in the public market after the restrictions lapse. This may adversely affect the prevailing market price of our common stock and our ability to raise equity capital in the future.

Upon completion of this offering, we will have shares of common stock outstanding, assuming no exercise of the underwriters' over-allotment option, the conversion of all outstanding shares of preferred stock and no exercise of outstanding options or warrants after March 31, 2014. All of the shares sold in this offering, including any of the shares sold upon the underwriters' exercise of their over-allotment option, will be freely transferable without restriction or registration under the Securities Act, except for any shares purchased by one of our existing "affiliates," as that term is defined in Rule 144 under the Securities Act. The remaining shares of common stock existing are "restricted securities" as defined in Rule 144. Restricted securities may be sold in the public market only if registered or if their resale qualifies for an exemption from registration under Rules 144 or 701 of the Securities Act.

As a result of the contractual 180-day lock-up period described below and the provisions of Rules 144 and 701, these shares will be available for sale in the public market as follows:

- · no restricted shares will be eligible for sale in the public market immediately upon completion of this offering; and
- shares will be eligible for sale in the public market beginning 180 days from the date of this prospectus (subject, in some cases, to volume limitations), upon the expiration of the 180-day lock-up and market standoff agreements entered into prior to our initial public offering and the lapse of our right of repurchase with respect to any unvested shares, if applicable.

## **Lock-up Agreements**

We, all of our directors and officers and all of our other stockholders have agreed not to sell or otherwise transfer or dispose of any of our securities for a period of 180 days from the date of this prospectus, subject to certain exceptions. Cowen and Company LLC, as representative of the several underwriters, may permit early releases of shares subject to the lock-up agreements. See "Underwriting" for a description of the lock-up provisions.

## **Rule 144**

In general, a person who has beneficially owned our restricted common shares for at least six months would be entitled to sell their securities subject only to the availability of current public information about us and subject to the lock-up agreements described above, provided that (1) such person is not deemed to have been one of our affiliates at the time of, or at any time during the 90 days preceding, a sale, and (2) we are subject to the Securities Exchange Act periodic reporting requirements for at least 90 days before the sale. In addition, under Rule 144, any person who is not an affiliate of ours and has beneficially owned their shares for at least one year, including the holding period of any prior owner other than one of our affiliates, would be entitled to sell such shares immediately upon the closing of this offering without regard to whether current public information about us is available. Persons who have beneficially owned restricted common shares for at least six months but who are our affiliates at the time of, or any time during the 90 days preceding, a sale, would be subject to additional restrictions, by which such person would be entitled to sell, upon expiration of the lock-up agreements described above, within any three-month period only a number of shares that does not exceed the greater of either of the following:

• one percent of the number of common shares then outstanding, which will equal approximately shares immediately after this offering assuming no exercise of the underwriters' option to purchase additional shares, based on the number of common shares outstanding as of March 31, 2014; or

 the average weekly trading volume of our common shares during the four calendar weeks preceding the filing of a notice on Form 144 with respect to the sale;

provided, in each case, that we are subject to the Securities Exchange Act periodic reporting requirements for at least 90 days before the sale. Such sales both by affiliates and by a person selling shares on behalf of our affiliates must also comply with the manner of sale, current public information and notice provisions of Rule 144.

#### **Rule 701**

In general, Rule 701 permits resales of shares in reliance upon Rule 144 but without compliance with certain restrictions, including the holding period requirement, of Rule 144. Any employee, officer or director of or consultant to us who purchased shares under a written compensatory plan or contract before the date of this prospectus may be entitled to rely on the resale provisions of Rule 701. Rule 701 permits affiliates to sell their shares acquired pursuant to Rule 701 under Rule 144 without complying with the holding period requirements of Rule 144. Rule 701 further provides that non-affiliates may sell such shares in reliance on Rule 144 without having to comply with the holding period, public information, volume limitation or notice provisions of Rule 144. All holders of shares issued under Rule 701 are required to wait until 90 days after the date of this prospectus before selling such shares. All Rule 701 shares are, however, subject to lock-up agreements and will only become eligible for sale upon the expiration of these lock-up agreements.

## **Registration Rights**

Upon completion of this offering, the holders of 49,249,999 shares of our common stock and the holders of warrants to purchase up to 2,337,787 shares of our common stock have the right to have their shares registered under the Securities Act. See the "Description of Capital Stock – Registration Rights." All such shares are covered by lock-up agreements. Following the expiration of the lock-up period, registration of these shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act immediately upon the effectiveness of the registration, except for shares purchased by our affiliates.

## **Equity Plan**

We intend to file with the SEC one or more registration statements on Form S-8 under the Securities Act to register all shares of common stock subject to outstanding stock options and common stock issued or issuable under our stock plans. We expect to file the registration statement covering shares offered pursuant to our stock plans shortly after the date of this prospectus, permitting the resale of such shares by non-affiliates in the public market without restriction under the Securities Act and the sale by affiliates in the public market subject to compliance with the resale provisions of Rule 144 but subject in each case to compliance with the lock-up agreements described above.

## MATERIAL U.S. FEDERAL INCOME TAX CONSIDERATIONS

The following is a general discussion of the material U.S. federal income tax consequences of the purchase, ownership and disposition of our common stock as of the date hereof.

This discussion is based on the provisions of the Internal Revenue Code of 1986, as amended (Code), and regulations, rulings and judicial decisions as of the date hereof. Those authorities may be changed, possibly with retroactive effect, or subject to different interpretations. This discussion is limited to persons who hold shares of our common stock as capital assets within the meaning of Section 1221 of the Code (generally, property held for investment). Moreover, this discussion does not address all the U.S. federal income tax consequences and does not address foreign, state, local, estate (except to the extent specifically provided herein) or other tax considerations that may be relevant to you in light of your personal circumstances. This discussion does not address special situations, including those of: brokers or dealers in securities; regulated investment companies; real estate investment trusts; persons holding common stock as a part of a hedging, integrated, conversion or constructive sale transaction or a straddle; traders in securities that elect to use a mark-to-market method of accounting for their securities holdings; persons liable for alternative minimum tax; persons whose "functional currency" is not the U.S. dollar; investors in pass-through entities (such as a partnership); persons who acquired our common stock through the exercise of employee stock options or otherwise as compensation; U.S. expatriates, "controlled foreign corporations," "passive foreign investment companies," financial institutions, insurance companies, tax-exempt organizations, or entities or arrangements treated as partnerships or other pass-through entities for U.S. federal income tax purposes.

If you are a partnership holding our common stock, the tax treatment of a partner will generally depend upon the status of the partner and the activities of the partnership. If you are a partner in a partnership holding our common stock, you should consult your tax advisor.

EACH PROSPECTIVE PURCHASER IS ADVISED TO CONSULT A TAX ADVISOR REGARDING THE U.S. FEDERAL, STATE, LOCAL AND FOREIGN INCOME, ESTATE AND OTHER TAX CONSEQUENCES OF PURCHASING, OWNING AND DISPOSING OF OUR COMMON STOCK.

## **Consequences to United States Holders**

The following is a summary of the U.S. federal income tax consequences that will apply to you if you are a United States Holder of shares of our common stock. A "United States Holder" of common stock means a beneficial owner of common stock that is for U.S. federal income tax purposes:

- an individual citizen or resident of the United States;
- a corporation (or other entity taxable as a corporation) created or organized in or under the laws of the United States or any state thereof or the District of Columbia;
- an estate the income of which is subject to U.S. federal income taxation regardless of its source; or
- a trust if it is subject to the primary supervision of a court within the United States and one or more United States persons have the authority to control all substantial decisions of the trust or has a valid election in effect under applicable U.S. Treasury regulations to be treated as a United States person.

## **Distributions on Common Stock**

In general, if you receive a distribution with respect to our common stock, such distributions will be treated as a dividend to the extent of our current and accumulated earnings and profits as determined for U.S. federal income tax purposes. Any portion of a distribution that exceeds our current and accumulated earnings and profits will first be applied to reduce your tax basis in our common stock and, to the extent such portion exceeds your tax basis, the excess will be treated as gain from the disposition of the common stock, the tax treatment of which is discussed below under "Sale, Exchange or Other Disposition of Common Stock."

Under current legislation, dividend income may be taxed to an individual at rates applicable to long term capital gains, provided that a minimum holding period and other limitations and requirements are satisfied. Any dividends that we pay to a United States Holder that is a U.S. corporation will qualify for a deduction allowed to U.S. corporations in respect of dividends received from other U.S. corporations equal to a portion of any dividends received, subject to generally applicable limitations on that deduction. In general, a dividend distribution to a corporate United States Holder may qualify for the 70% dividends received deduction if the United States Holder owns less than 20% of the voting power and value of our stock. You should consult your tax advisor regarding the holding period and other requirements that must be satisfied in order to qualify for the dividends-received deduction and the reduced maximum tax rate on dividends.

## Sale, Exchange or Other Disposition of Common Stock

You will generally recognize capital gain or loss on a sale, exchange or certain other dispositions of our common stock. Your gain or loss will equal the difference between your amount realized and your tax basis in the stock. Your amount realized will include the amount of any cash and the fair market value of any other property received for the stock. The gain or loss recognized on a sale or exchange of stock will be long-term capital gain or loss if you have held the stock for more than one year. Long-term capital gains of non-corporate taxpayers are generally taxed at lower rates than those applicable to ordinary income. The deductibility of capital losses is subject to certain limitations.

#### **Medicare Contribution Tax**

Recently enacted legislation requires certain United States Holders who are individuals, estates or certain trusts to pay a 3.8% tax on the lesser of (1) the United States person's "net investment income" for the relevant taxable year and (2) the excess of the United States person's modified gross income for the taxable year over a certain threshold (which in the case of individuals will be between \$125,000 and \$250,000 depending on the individual's circumstances). Net investment income generally includes, among other things, dividends and capital gains from the sale or other dispositions of stock, unless such dividend income or gains are derived in the ordinary course of the conduct of a trade or business (other than a trade or business that consists of certain passive or trading activities). A United States Holder that is an individual, estate or trust should consult its tax advisor regarding the applicability of the Medicare tax to its income and gains in respect of its investment in our common stock.

## Information Reporting and Backup Withholding

Under certain circumstances, U.S. Treasury regulations require information reporting and backup withholding on certain payments on common stock or on the sale thereof. When required, we will report to the Internal Revenue Service and to each United States Holder the amounts paid on or with respect to our common stock and the U.S. federal withholding tax, if any, withheld from such payments. A United States Holder will be subject to backup withholding on the dividends paid on the common stock and proceeds from the sale of the common stock at the applicable rate if the United States Holder (a) fails to provide us or our paying agent with a correct taxpayer identification number or certification of exempt status (such as a certification of corporate status), (b) has been notified by the Internal Revenue Service that it is subject to backup withholding as a result of the failure to properly report payments of interest or dividends, or (c) in certain circumstances, has failed to certify under penalty of perjury that it is not subject to backup withholding. A United States Holder may be eligible for an exemption from backup withholding by providing a properly completed Internal Revenue Service Form W-9 to us or our paying agent.

Backup withholding does not represent an additional U.S. federal income tax. Any amounts withheld from a payment to a United States Holder under the backup withholding rules will be allowed as a credit against such holder's U.S. federal income tax liability and may entitle the holder to a refund, provided that the required information or returns are timely furnished by the holder to the Internal Revenue Service.

## **Consequences to Non-United States Holders**

The following is a summary of the U.S. federal income tax consequences that will apply to you if you are a Non-United States Holder of shares of our common stock. A "Non-United States Holder" is a beneficial owner of common stock (other than an entity or arrangement treated as a partnership for U.S. federal income tax purposes) that is not a United States Holder.

#### **Distributions on Common Stock**

If you receive a distribution in respect of shares of our common stock and such distribution is treated as a dividend (see "Consequences to United States Holders – Distributions on Common Stock"), as a Non-United States Holder, you will generally be subject to withholding of U.S. federal income tax at a 30% rate or such lower rate as may be specified by an applicable income tax treaty. To claim the benefit of a lower rate under an income tax treaty, you must properly file with the payor an Internal Revenue Service Form W-8BEN, or successor form, certifying under penalty of perjury that you are not a United States person (as defined under the Code) and claiming an exemption from or reduction in withholding under the applicable tax treaty. Special certification and other requirements apply to you if you are a pass-through entity rather than a corporation or individual or if our common stock is held through certain foreign intermediaries.

If dividends are considered effectively connected with the conduct of a trade or business by you within the United States and, where a tax treaty applies, are attributable to a U.S. permanent establishment (or, if you are an individual, fixed base) of yours, those dividends will not be subject to withholding tax, but instead will be subject to U.S. federal income tax on a net basis at applicable graduated individual or corporate rates as if you were a United States person (as defined under the Code), unless an applicable income tax treaty provides otherwise, provided an Internal Revenue Service Form W-8ECI, or successor form, is filed with the payor. In addition, if you are required to provide an Internal Revenue Service Form W-8ECI or successor form, as discussed above, you must also provide your tax identification number. If you are a foreign corporation, any effectively connected dividends may, under certain circumstances, be subject to an additional "branch profits tax" at a rate of 30% or such lower rate as may be specified by an applicable income tax treaty.

If you do not timely provide the relevant paying agent with the required certification but are eligible for a reduced rate of U.S. withholding tax pursuant to an income tax treaty, you may obtain a refund of any excess amounts withheld by filing an appropriate claim for refund with the Internal Revenue Service.

## Gain on Disposition of Common Stock

Subject to the discussion below under "Foreign Account Legislation," as a Non-United States Holder, you generally will not be subject to U.S. federal income tax on any gain recognized on the sale or other disposition of our common stock (including a distribution with respect to our common stock that is treated as a sale or exchange) unless:

- the gain is considered effectively connected with the conduct of a trade or business by you within the United States and, where a tax treaty applies, is attributable to a U.S. permanent establishment (or, if you are an individual, fixed base) of yours, in which case, you will generally be subject to tax on the net gain derived from the sale under regular graduated U.S. federal income tax rates as if you were a United States person (as defined in the Code) and, if you are a corporation, you may be subject to an additional branch profits tax equal to 30% or such lower rate as may be specified by an applicable income tax treaty;
- you are an individual who is present in the United States for 183 or more days in the taxable year of the sale or other disposition and certain other conditions are met, in which case, you will be subject to a 30% (or such lower rate as may be specified by an applicable income tax treaty) tax on the gain derived from the sale, which may be offset by U.S. source capital losses; or
- we are or have been a "United States real property holding corporation" for U.S. federal income tax purposes at any time within the shorter of the five-year period ending on the date of disposition or

the period you held our common stock. As long as our common stock is regularly traded on an established securities market, within the meaning of section 897(c)(3) of the Code, these rules will apply only if you actually or constructively hold more than 5% of our common stock at any time during the applicable period that is specified in the Code. We believe that we are not currently, and are not likely to become, a United States real property holding corporation.

## Information Reporting and Backup Withholding Tax

We must report annually to the Internal Revenue Service and to each of you the amount of dividends paid to you and the tax withheld with respect to those dividends, regardless of whether withholding was required. Copies of the information returns reporting those dividends and withholding may also be made available by the Internal Revenue Service to the tax authorities in the country in which you reside under the provisions of an applicable income tax treaty or other applicable agreements.

Backup withholding tax may also apply to dividend payments made to you on or with respect to our common stock unless you certify under penalty of perjury that you are a Non-United States Holder (and we do not have actual knowledge or reason to know that you are a United States person (as defined under the Code)) or you otherwise establish an exemption.

Information reporting and, depending on the circumstances, backup withholding will apply to the proceeds of a sale of our common stock within the United States or conducted through United States-related financial intermediaries unless the beneficial owner certifies under penalty of perjury that it is a Non-United States Holder (and the payor does not have actual knowledge or reason to know that the beneficial owner is a United States person (as defined under the Code)) or the holder otherwise establishes an exemption.

Any amounts withheld under the backup withholding rules generally will be allowed as a refund or a credit against your U.S. federal income tax liability provided that the required procedures are followed.

You should consult your tax advisor regarding the application of the information reporting and backup withholding rules to you.

## U.S. Federal Estate Taxes

Common stock owned or treated as owned by an individual who is a Non-United States Holder (as specifically defined for U.S. federal estate tax purposes) at the time of death will be included in the individual's gross estate for U.S. federal estate tax purposes and may be subject to U.S. federal estate tax, unless an applicable estate tax treaty provides otherwise.

## Foreign Account Legislation

Recently enacted legislation generally will impose a withholding tax of 30% on any dividends on our common stock paid to a "foreign financial institution" as defined in Section 1471(d)(4) of the Code, unless such institution enters into an agreement with the U.S. government to, among other things, collect and provide to the U.S. tax authorities substantial information regarding U.S. account holders of such institution (which includes certain equity and debt holders of such institution, as well as certain account holders that are foreign entities with U.S. owners). The legislation will also generally impose a withholding tax of 30% on any dividends on our common stock paid to a "non-financial foreign entity" as defined in Section 1472(d) of the Code unless such entity provides the withholding agent with either certification that such entity does not have any substantial U.S. owners or identification of the direct and indirect substantial U.S. owners of the entity. Finally, withholding of 30% also generally will apply to the gross proceeds of a disposition of our common stock paid to a foreign financial institution or to a non-financial foreign entity unless the reporting and certification requirements described above have been met. An intergovernmental agreement between the United States and an applicable non-U.S. country may modify the requirements discussed above. Under certain circumstances, a Non-United

States Holder of our common stock may be eligible for refunds or credits of such taxes. You are encouraged to consult with your own tax advisor regarding the possible implications of this legislation on your investment in our common stock. Under current Treasury Regulations (as modified by recent guidance released by the Internal Revenue Service on July 12, 2103), withholding provisions described above will generally apply to payments of dividends on our common stock made on or after July 1, 2014 and to payments of gross proceeds from a sale or other disposition of such stock on or after January 1, 2017.

#### UNDERWRITING

Cowen and Company, LLC is acting as representative of each of the underwriters named below. Subject to the terms and conditions set forth in an underwriting agreement among us and the underwriters, we have agreed to sell to the underwriters, and each of the underwriters has agreed, severally and not jointly, to purchase from us, the number of shares of our common stock set forth opposite its name below.

<u>Name</u>	Number of Shares
Cowen and Company, LLC	
Needham & Company, LLC	
Roth Capital Partners, LLC	
Total	

Subject to the terms and conditions set forth in the underwriting agreement, the underwriters have agreed, severally and not jointly, to purchase all of the shares sold under the underwriting agreement if any of these shares are purchased. If an underwriter defaults, the underwriting agreement provides that the purchase commitments of the nondefaulting underwriters may be increased or the underwriting agreement may be terminated.

We have agreed to indemnify the several underwriters against certain liabilities, including liabilities under the Securities Act relating to losses or claims resulting from material misstatements in or omissions from this prospectus, the registration statement of which this prospectus is a part, certain free writing prospectuses that may be used in the offering and in any marketing materials used in connection with this offering and to contribute to payments the underwriters may be required to make in respect of those liabilities.

The underwriters are offering the shares, subject to prior sale, when, as and if issued to and accepted by them, subject to approval of legal matters by their counsel, including the validity of the shares, and other conditions contained in the underwriting agreement, such as the receipt by the underwriters of officers' certificates and legal opinions. The underwriters reserve the right to withdraw, cancel or modify offers to the public and to reject orders in whole or in part.

### **Commissions and Discounts**

The representative has advised us that the underwriters propose initially to offer the shares to the public at the public offering price set forth on the cover page of this prospectus and to dealers at that price less a concession not in excess of \$ per share. After the initial offering, the public offering price, concession or any other term of this offering may be changed.

The following table shows the public offering price, underwriting discount and proceeds before expenses to us. The information assumes either no exercise or full exercise by the underwriters of their over-allotment option.

		Without	With
	Per Share	Option	Option
Public offering price	\$	\$	\$
Underwriting discount	\$	\$	\$
Proceeds, before expenses, to Histogenics	\$	\$	\$

The underwriting agreement provides that the obligations of the several underwriters to pay for and accept delivery of the shares of common stock offered by this prospectus are subject to the approval of certain legal matters by their counsel and to certain other conditions. The underwriters are obligated to take and pay for all of

the shares of common stock offered by this prospectus if any such shares are taken. However, the underwriters are not required to take or pay for the shares covered by the underwriters' over-allotment option described below. If an underwriter defaults, the underwriting agreement provides that the purchase commitments of the non-defaulting underwriters may be increased.

The underwriters initially propose to offer part of the shares of common stock directly to the public at the offering price listed on the cover page of this prospectus and part to certain dealers. After the initial offering of the shares of common stock, the offering price and other selling terms may from time to time be varied by the representative.

We have granted to the underwriters an option, exercisable for 30 days from the date of this prospectus, to purchase up to additional shares of common stock at the public offering price listed on the cover page of this prospectus, less underwriting discounts and commissions. The underwriters may exercise this option solely for the purpose of covering over-allotments, if any, made in connection with the offering of the shares of common stock offered by this prospectus. To the extent the option is exercised, each underwriter will become obligated, subject to certain conditions, to purchase about the same percentage of the additional shares of common stock as the number listed next to the underwriter's name in the preceding table bears to the total number of shares of common stock listed next to the names of all underwriters in the preceding table.

The estimated offering expenses payable by us, exclusive of the underwriting discounts and commissions, are approximately \$\) million, which includes legal, accounting and printing costs and various other fees associated with the registration and listing of our common stock. We have also agreed to reimburse the underwriters for certain of their expenses in an amount up to \$\) as set forth in the underwriting agreement.

The underwriters have informed us that they do not intend sales to discretionary accounts to exceed five percent of the total number of shares of common stock offered by them.

## **No Sales of Similar Securities**

We, our executive officers and directors and our other existing security holders have agreed not to sell or transfer any shares of our common stock or securities convertible into, exchangeable for, exercisable for, or repayable with shares of our common stock, for 180 days after the date of this prospectus without first obtaining the written consent of the representative. Specifically, we and these other persons have agreed, with certain limited exceptions, not to directly or indirectly:

- offer, pledge, announce the intention to sell, sell or contract to sell any shares of our common stock;
- sell any option or contract to purchase any shares of our common stock;
- purchase any option or contract to sell any shares of our common stock;
- grant any option, right or warrant to purchase any shares of our common stock;
- · dispose of or otherwise transfer any shares of our common stock;
- · demand that we file a registration statement related to our common stock; or
- enter into any swap or other agreement that transfers, in whole or in part, the economic consequence of ownership of any shares of our common stock, whether any such swap or transaction is to be settled by delivery of shares or other securities, in cash or otherwise.

This lock-up provision also applies to securities convertible into or exchangeable or exercisable for or repayable with shares of our common stock. It also applies to shares of our common stock owned now or acquired later by the person executing the agreement or for which the person executing the agreement later acquires the power of disposition.

### Listing

We have applied to list our common stock on the NASDAQ Global Market under the symbol "HSGX." In order to meet the requirements for listing on that exchange, the underwriters have undertaken to sell a minimum number of shares to a minimum number of beneficial owners as required by that exchange.

Before this offering, there has been no public market for our common stock. The initial public offering price will be determined through negotiations between us and the representative. In addition to prevailing market conditions, the factors to be considered in determining the initial public offering price are:

- the valuation multiples of publicly traded companies that the representative believes to be comparable to us;
- our financial information;
- the history of, and the prospects for, our company and the industry in which we compete;
- an assessment of our management, its past and present operations and the prospects for, and timing of, our future revenues;
- the present state of our development; and
- the above factors in relation to market values and various valuation measures of other companies engaged in activities similar to ours.

An active trading market for the shares may not develop. It is also possible that after this offering the shares will not trade in the public market at or above the initial public offering price.

## **Price Stabilization, Short Positions and Penalty Bids**

Until the distribution of the shares is completed, SEC rules may limit underwriters and selling group members from bidding for and purchasing shares of our common stock. However, the representative may engage in transactions that stabilize the price of our common stock, such as bids or purchases to peg, fix or maintain that price.

In connection with this offering, the underwriters may purchase and sell shares of our common stock in the open market. These transactions may include short sales, purchases on the open market to cover positions created by short sales and stabilizing transactions. Short sales involve the sale by the underwriters of a greater number of shares than they are required to purchase in this offering. "Covered" short sales are sales made in an amount not greater than the underwriters' over-allotment option described above. The underwriters may close out any covered short position by either exercising their over-allotment option or purchasing shares in the open market. In determining the source of shares to close out the covered short position, the underwriters will consider, among other things, the price of shares available for purchase in the open market as compared to the price at which they may purchase shares through the over-allotment option. "Naked" short sales are sales in excess of the over-allotment option. The underwriters must close out any naked short position by purchasing shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of our common stock in the open market after pricing that could adversely affect investors who purchase in this offering. Stabilizing transactions consist of various bids for or purchases of shares of our common stock made by the underwriters in the open market prior to the closing of this offering.

The underwriters may also impose a penalty bid. This occurs when a particular underwriter repays to the underwriters a portion of the underwriting discount received by it because the representative has repurchased shares sold by or for the account of such underwriter in stabilizing or short covering transactions.

Similar to other purchase transactions, the underwriters' purchases to cover the syndicate short sales may have the effect of raising or maintaining the market price of our common stock or preventing or retarding a decline in the market price of our common stock. As a result, the price of our common stock may be higher than the price

that might otherwise exist in the open market. The underwriters may conduct these transactions on NASDAQ, in the over-the-counter market or otherwise.

Neither we nor any of the underwriters make any representation or prediction as to the direction or magnitude of any effect that the transactions described above may have on the price of our common stock. In addition, neither we nor any of the underwriters make any representation that the representative will engage in these transactions or that these transactions, once commenced, will not be discontinued without notice.

## **Electronic Offer, Sale and Distribution of Shares**

In connection with this offering, certain of the underwriters or securities dealers may distribute prospectuses by electronic means, such as e-mail. In addition, one or more of the underwriters may facilitate Internet distribution for this offering to certain of their Internet subscription customers. Any such underwriter may allocate a limited number of shares for sale to its online brokerage customers. An electronic prospectus is available on the Internet websites maintained by any such underwriter. Other than the prospectus in electronic format, the information on the websites of any such underwriter is not part of this prospectus.

## Other Relationships

The underwriters and their respective affiliates are full service financial institutions engaged in various activities, which may include securities trading, commercial and investment banking, financial advisory, investment management, investment research, principal investment, hedging, financing and brokerage activities. Certain of the underwriters and their affiliates have engaged in, and may in the future engage in, investment banking and other commercial dealings in the ordinary course of business with us or our affiliates. They have received, or may in the future receive, customary fees and commissions for these transactions.

In the ordinary course of their various business activities, the underwriters and their respective affiliates may make or hold a broad array of investments and actively trade debt and equity securities (or related derivative securities) and financial instruments (including bank loans) for their own account and for the accounts of their customers, and such investment and securities activities may involve securities or instruments of the issuer. The underwriters and their respective affiliates may also make investment recommendations or publish or express independent research views in respect of such securities or instruments and may at any time hold, or recommend to clients that they acquire, long or short positions in such securities and instruments.

### **Selling Restrictions**

## European Economic Area

In relation to each country of the EEA that has implemented the Prospectus Directive (each, a Relevant Country) an offer to the public of any shares of our common stock may not be made in that Relevant Country, except that an offer to the public in that Relevant Country of any shares of our common stock may be made at any time under the following exemptions under the Prospectus Directive, if they have been implemented in that Relevant Country:

- (a) to any legal entity that is a qualified investor as defined in the Prospectus Directive;
- (b) to fewer than 100 or, if the Relevant Country has implemented the relevant provision of the 2010 PD Amending Directive, 150 natural or legal persons (other than qualified investors as defined in the Prospectus Directive), as permitted under the Prospectus Directive, subject to obtaining the prior consent of the representative for any such offer; or
- (c) in any other circumstances falling within Article 3(2) of the Prospectus Directive, provided that no such offer of shares of our common stock shall result in a requirement for the publication by us or any underwriter of a prospectus pursuant to Article 3 of the Prospectus Directive.

For the purposes of this provision, the expression an "offer to the public" in relation to any shares of our common stock in any Relevant Country means the communication in any form and by any means of sufficient information

on the terms of the offer and any shares of our common stock to be offered so as to enable an investor to decide to purchase any shares of our common stock, as the same may be varied in that Relevant Country by any measure implementing the Prospectus Directive in that Relevant Country, the expression "Prospectus Directive" means Directive 2003/71/EC (and amendments thereto, including the 2010 PD Amending Directive, to the extent implemented in the Relevant Country), and includes any relevant implementing measure in the Relevant Country, and the expression "2010 PD Amending Directive" means Directive 2010/73/EU.

## **United Kingdom**

Each underwriter has represented and agreed that:

- (a) it has only communicated or caused to be communicated and will only communicate or cause to be communicated an invitation or inducement to engage in investment activity (within the meaning of Section 21 of the Financial Services and Markets Act 2000 (FSMA)) received by it in connection with the issue or sale of the shares of our common stock in circumstances in which Section 21(1) of the FSMA does not apply to us; and
- (b) it has complied and will comply with all applicable provisions of the FSMA with respect to anything done by it in relation to the shares of our common stock in, from or otherwise involving the United Kingdom.

#### Canada

The common stock may be sold only to purchasers purchasing as principal that are both "accredited investors" as defined in National Instrument 45-106
Prospectus and Registration Exemptions and "permitted clients" as defined in National Instrument 31-103 Registration Requirements, Exemptions and Ongoing Registrant Obligations. Any resale of the common stock must be made in accordance with an exemption from the prospectus requirements and in compliance with the registration requirements of applicable securities laws.

#### Hona Kona

The common stock may not be offered or sold in Hong Kong by means of any document other than (1) in circumstances that do not constitute an offer to the public within the meaning of the Companies Ordinance (Cap. 32, Laws of Hong Kong), (2) to "professional investors" within the meaning of the Securities and Futures Ordinance (Cap. 571, Laws of Hong Kong) and any rules made thereunder or (3) in other circumstances that do not result in the document being a "prospectus" within the meaning of the Companies Ordinance (Cap. 32, Laws of Hong Kong) and no advertisement, invitation or document relating to the shares of common stock may be issued or may be in the possession of any person for the purpose of issue (in each case whether in Hong Kong or elsewhere), which is directed at, or the contents of which are likely to be accessed or read by, the public in Hong Kong (except if permitted to do so under the laws of Hong Kong) other than with respect to shares of common stock that are or are intended to be disposed of only to persons outside Hong Kong or only to "professional investors" within the meaning of the Securities and Futures Ordinance (Cap. 571, Laws of Hong Kong) and any rules made thereunder.

#### Singapore

This prospectus has not been registered as a prospectus with the Monetary Authority of Singapore. Accordingly, this prospectus and any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of shares of common stock may not be circulated or distributed, nor may the shares be offered or sold, or be made the subject of an invitation for subscription or purchase, whether directly or indirectly, to persons in Singapore other than (1) to an institutional investor under Section 274 of the Securities and Futures Act, Chapter 289 of Singapore (SFA), (2) to a relevant person pursuant to Section 275(1), or any person pursuant to Section 275(1A), and in accordance with the conditions specified in Section 275 of the SFA or (3) otherwise pursuant to, and in accordance with the conditions set forth in the SFA.

Where the shares of common stock are subscribed or purchased under Section 275 of the SFA by a relevant person that is:

- (a) a corporation (which is not an accredited investor, as defined in Section 4A of the SFA) the sole business of which is to hold investments and the entire share capital of which is owned by one or more individuals, each of whom is an accredited investor, or
- (b) a trust (where the trustee is not an accredited investor) whose sole purpose is to hold investments and each beneficiary of the trust is an individual who is an accredited investor,

shares, debentures and units of shares and debentures of that corporation or the beneficiaries' rights and interest (howsoever described) in that trust shall not be transferred within six months after that corporation or that trust has acquired the shares of common stock pursuant to an offer made under Section 275 of the SFA except:

- (a) to an institutional investor (for corporations, under Section 274 of the SFA) or to a relevant person defined in Section 275(2) of the SFA, or to any person pursuant to an offer that is made on terms that such shares, debentures and units of shares and debentures of that corporation or such rights and interest in that trust are acquired at a consideration of not less than US\$200,000 (or its equivalent in a foreign currency) for each transaction, whether such amount is to be paid for in cash or by exchange of securities or other assets, and further for corporations, in accordance with the conditions specified in Section 275 of the SFA;
- (b) where no consideration is or will be given for the transfer; or
- (c) where the transfer is by operation of law.

## **Switzerland**

The common stock may not be publicly offered in Switzerland and will not be listed on the SIX Swiss Exchange or on any other stock exchange or regulated trading facility in Switzerland. This document has been prepared without regard to the disclosure standards for issuance prospectuses under art. 652a or art. 1156 of the Swiss Code of Obligations or the disclosure standards for listing prospectuses under art. 27 ff. of the SIX Swiss Exchange Listing Rules or the listing rules of any other stock exchange or regulated trading facility in Switzerland. Neither this document nor any other offering or marketing material relating to the shares of common stock or the offering may be publicly distributed or otherwise made publicly available in Switzerland.

Neither this document nor any other offering or marketing material relating to the offering, or the shares of common stock have been or will be filed with or approved by any Swiss regulatory authority. In particular, this document will not be filed with, and the offer of common stock will not be supervised by, the Swiss Financial Market Supervisory Authority FINMA, and the offer of common stock has not been and will not be authorized under the Swiss Federal Act on Collective Investment Schemes (CISA). Accordingly, no public distribution, offering or advertising, as defined in CISA, its implementing ordinances and notices, and no distribution to any non-qualified investor, as defined in CISA, its implementing ordinances and notices, shall be undertaken in or from Switzerland, and the investor protection afforded to acquirers of interests in collective investment schemes under CISA does not extend to acquirers of common stock.

### **United Arab Emirates**

This offering has not been approved or licensed by the Central Bank of the United Arab Emirates (UAE), Securities and Commodities Authority of the UAE or any other relevant licensing authority in the UAE including any licensing authority incorporated under the laws and regulations of any of the free zones established and operating in the territory of the UAE, in particular the Dubai Financial Services Authority (DFSA), a regulatory authority of the Dubai International Financial Centre (DIFC). The offering does not constitute a public offer of securities in the UAE, DIFC or any other free zone in accordance with the Commercial Companies Law, Federal Law No 8 of 1984 (as amended), DFSA Offered Securities Rules and NASDAQ Dubai Listing Rules, accordingly, or otherwise. The common stock may not be offered to the public in the UAE or any of the free zones.

The common stock may be offered and issued only to a limited number of investors in the UAE or any of its free zones who qualify as sophisticated investors under the relevant laws and regulations of the UAE or the free zone concerned.

#### France

This prospectus (including any amendment, supplement or replacement thereto) is not being distributed in the context of a public offering in France within the meaning of Article L. 411-1 of the French Monetary and Financial Code (Code monétaire et financier).

This prospectus has not been and will not be submitted to the French Autorité des marchés financiers (AMF) for approval in France and accordingly may not and will not be distributed to the public in France.

Pursuant to Article 211-3 of the AMF General Regulation, French residents are hereby informed that:

- (1) the transaction does not require a prospectus to be submitted for approval to the AMF;
- (2) persons or entities referred to in Point 2°, Section II of Article L.411-2 of the Monetary and Financial Code may take part in the transaction solely for their own account, as provided in Articles D. 411-1, D. 734-1, D. 744-1, D. 754-1 and D. 764-1 of the Monetary and Financial Code; and
- (3) the financial instruments thus acquired cannot be distributed directly or indirectly to the public otherwise than in accordance with Articles L. 411-1, L. 411-2, L. 412-1 and L. 621-8 to L. 621-8-3 of the Monetary and Financial Code.

This prospectus is not to be further distributed or reproduced (in whole or in part) in France by the recipients of this prospectus. This prospectus has been distributed on the understanding that such recipients will only participate in the issue or sale of our common stock for their own account and undertake not to transfer, directly or indirectly, our common stock to the public in France, other than in compliance with all applicable laws and regulations and in particular with Articles L. 411-1 and L. 411-2 of the French Monetary and Financial Code.

#### **LEGAL MATTERS**

The validity of the common stock being offered will be passed upon for us by Gunderson Dettmer Stough Villeneuve Franklin & Hachigian, LLP, Boston, Massachusetts. Certain legal matters in connection with this offering will be passed upon for the underwriters by K&L Gates LLP, Boston, Massachusetts.

#### **EXPERTS**

The audited financial statements of Histogenics Corporation included in this prospectus and elsewhere in the registration statement have been so included in reliance upon the report of Grant Thornton LLP, independent registered public accountants, upon the authority of said firm as experts in accounting and auditing.

### WHERE YOU CAN FIND ADDITIONAL INFORMATION

We have filed with the SEC a registration statement on Form S-1 under the Securities Act with respect to the common stock we are offering. This prospectus, which constitutes a part of the registration statement, does not contain all of the information set forth in the registration statement, some items of which are contained in exhibits to the registration statement as permitted by the rules and regulations of the SEC. For further information with respect to us and our common stock, we refer you to the registration statement, including the exhibits and the consolidated financial statements and notes filed as a part of the registration statement. Statements contained in this prospectus concerning the contents of any contract or any other document are not necessarily complete. If a contract or document has been filed as an exhibit to the registration statement, please see the copy of the contract or document that has been filed. Each statement in this prospectus relating to a contract or document filed as an exhibit is qualified in all respects by the filed exhibit. The exhibits to the registration statement should be reviewed for the complete contents of these contracts and documents.

A copy of the registration statement, including the exhibits and the financial statements and notes filed as a part of the registration statement, may be inspected without charge at the SEC's Public Reference Room at 100 F Street, N.E., Washington, D.C. 20549, and copies of all or any part of the registration statement may be obtained from the SEC upon the payment of fees prescribed by it. You may call the SEC at 1-800-SEC-0330 for more information on the operation of the public reference facilities. The SEC maintains a website at www.sec.gov that contains reports, proxy and information statements and other information regarding companies, such as Histogenics, that file electronically with it.

Upon the completion of this offering, we will be subject to the information reporting requirements of the Securities Act and we will file reports, proxy statements and other information with the SEC. These reports, proxy statements and other information will be available for inspection and copying at the public reference room and website of the SEC referred to above. We also maintain a website at www.histogenics.com, at which you may access these materials free of charge as soon as reasonably practicable after they are electronically filed with, or furnished to, the SEC. Information contained on our website is not incorporated by reference into this prospectus, and you should not consider information contained on our website to be part of this prospectus or in deciding whether to purchase shares of our common stock.

# Histogenics Corporation (A Development Stage Company)

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## **Report of Independent Registered Public Accounting Firm**

Board of Directors and Stockholders Histogenics Corporation

We have audited the accompanying consolidated balance sheets of Histogenics Corporation (a Delaware corporation operating in the development stage) and subsidiary (the "Company") as of December 31, 2013 and 2012, and the related consolidated statements of operations, changes in convertible redeemable preferred stock and stockholders' deficit, and cash flows for each of the two years in the period ended December 31, 2013 and for the period from June 28, 2000 (date of inception) to December 31, 2013. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. We were not engaged to perform an audit of the Company's internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, 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. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Histogenics Corporation and subsidiary as of December 31, 2013 and 2012, and the results of their operations and their cash flows for the years then ended and for the period from June 28, 2000 (date of inception) to December 31, 2013, in conformity with accounting principles generally accepted in the United States of America.

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company has recurring significant cash flow deficits from operations and an accumulated deficit as of December 31, 2013, which raises substantial doubt about its ability to continue as a going concern. Management's plans related to these matters are also described in Note 1. The accompanying financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ Grant Thornton LLP

Boston, Massachusetts April 11, 2014

# Histogenics Corporation (A Development Stage Company)

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

	Decen	nber 31,		Pro Forma
	2012	2013	March 31, 2014	March 31, 2014
			(unaudited)	(unaudited)
ASSETS				
Current assets:	\$ 14,716	\$ 8,734	\$ 3,360	
Cash and cash equivalents	363	1,612	\$ 3,360 2,204	
Prepaid expenses and other current assets				
Total current assets	15,079	10,346	5,564	
Property and equipment, net	2,315 630	2,283 570	2,250 570	
Intangible asset Noncurrent deferred tax assets, net	2,480	1,058	1,058	
Restricted cash	2,460 522	522	522	
Other assets	18	17	17	
Total assets	<u>\$ 21,044</u>	\$ 14,796	\$ 9,981	
LIABILITIES, CONVERTIBLE REDEEMABLE PREFERRED STOCK AND STOCKHOLDERS' DEFICIT				
Current liabilities:				
Accounts payable	\$ 1,042	\$ 2,530	\$ 3,164	
Accrued expenses	418	1,035	797	
Current portion of deferred rent	168	168	213	
Current portion of deferred lease incentive	296	296	296	
Deferred tax liabilities, net	2,480	1,058	1,058	
Total current liabilities	4,404	5,087	5,528	
Deferred rent, long-term	551	392	309	
Deferred lease incentive, long-term	1,184	888	814	
Net sales distribution payment liability	_	13,100	13,760	
Warrant liability	129	636	512	
Other liability	4,868	13,176	10,902	
Total liabilities	11,136	33,279	31,825	
Commitments and contingencies (Note 7)				
Convertible redeemable preferred stock (Note 10):				
Series A convertible redeemable preferred stock, \$0.001 par value; authorized shares—28,602,031 at December 31, 2012 and 2013 and at March 31, 2014 (unaudited); issued and outstanding shares—28,602,031 at December 31, 2012 and 2013 and at March 31, 2014 (unaudited); liquidation preference of \$29,619 at December 31, 2012, \$31,989 at December 31, 2013 and \$32,649 at March 31, 2014				
(unaudited); no shares issued and outstanding, pro forma (unaudited)	29,619	42,617	42,617	
Series A-1 convertible redeemable preferred stock, \$0.001 par value; authorized shares—none at December 31, 2012 and 20,647,969 at December 31, 2013 and March 31, 2014 (unaudited); issued and outstanding shares—none at December 31, 2012 and 10,323,988 at December 31, 2013 and March 31, 2014 (unaudited); liquidation preference of \$0 at December 31, 2012, \$10,354 at December 31, 2013				
and \$10,561 at March 31, 2014 (unaudited); no shares issued and outstanding, pro forma (unaudited)	_	14.454	14,454	
		14,454	14,434	
Stockholders' deficit:				
Common stock, \$0.001 par value; authorized shares—65,000,000 at December 31, 2012 and 70,000,000 at December 31, 2013 and March 31, 2014 (unaudited); 6,311,096 shares issued and outstanding at December 31, 2012 and 6,418,033 shares issued and outstanding at December 31, 2013 and March 31, 2014 (unaudited); and issued and outstanding, pro forma (unaudited)	6	6	6	
Additional paid-in capital	65,319	35,188	35,264	
Deficit accumulated during the development stage	(85,036)	(110,748)	(114,185)	
Total stockholders' deficit	(19,711)	(75,554)	(78,915)	
Total liabilities, convertible redeemable preferred stock and stockholders' deficit	\$ 21,044	\$ 14,796	\$ 9,981	
total natifices, convertible redeemable preferred stock and stockholders deficit	\$ 21,044	J 14,/90	φ 9,901	

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

# Histogenics Corporation (A Development Stage Company)

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

	Years Ended December 31,				T	hree Months E	nded M	arch 31,	Jui	riod From ne 28, 2000 of Inception)	Period From June 28, 2000 (Date of Inception)		
	2	012	2	013		2013		2014		ember 31, 2013	to Ma	rch 31, 2014	
Revenue	\$	26	\$	8	(ur \$	audited) 5	\$ (u	naudited)	\$	401	(u \$	naudited) 401	
Total revenue	-	26	<del>-</del>	8	<u>*</u>	5	<u>*</u>		<del>-</del>	401	<del>-</del>	401	
Operating expenses:													
Research and development		11,941		11,946		1,908		3,347		56,680		60,027	
Selling, general and administrative		3,053		4,847		905		1,826		37,408		39,234	
Impairment of goodwill and intangible assets		_		60		_		_		2,230		2,230	
Total operating expenses		14,994		16,853		2,813		5,173		96,318		101,491	
Loss from operations		(14,968)	(	16,845)		(2,808)		(5,173)		(95,917)		(101,090)	
Other (expense) income:													
Interest expense, net		(798)		_		_		_		(5,419)		(5,419)	
Other expense, net		(13)		(52)		(15)		(2)		(133)		(135)	
Gain on extinguishment of debt		687		_		_		_		687		687	
Change in fair value of note payable to shareholder		(17)		_		_		_		(37)		(37)	
Change in fair value of warrant liability and other liability		(1,826)		(8,815)		107		1,738		(9,929)		(8,191)	
Total other expense, net		(1,967)		(8,867)		92		1,736		(14,831)		(13,095)	
Net loss	\$	(16,935)	\$ (	25,712)	\$	(2,716)	\$	(3,437)	\$	(110,748)	\$	(114,185)	
Earnings (loss) attributable to common stockholders—basic (Note 3)	\$	2,805	\$ (	56,003)	\$	(3,308)	\$	(3,437)					
Earnings (loss) attributable to common stockholders—diluted (Note 3)	\$	3,402	\$ (	56,003)	\$	(3,308)	\$	(3,437)					
Earnings (loss) per common share (Note 3):													
Basic	\$	1.00	\$	(8.94)	\$	(0.53)	\$	(0.55)					
Diluted	\$	0.26	\$	(8.94)	\$	(0.53)	\$	(0.55)					
Weighted-average shares used to compute earnings per common share (Note 3):													
Basic	2,8	318,293	6,2	64,690		5,250,001		6,290,589					
Diluted	12,	398,629	6,2	64,690		5,250,001		6,290,589					
Pro forma earnings (loss) per common share, basic and diluted (unaudited)	\$		\$		\$		\$						
Weighted-average shares used to compute pro forma net earnings (loss) per common share, basic and diluted (unaudited)													

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

# Histogenics Corporation (A Development Stage Company)

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

	Conv Rede Preferi	Series A vertible emable ved Stock Par Value	Conv Rede Preferr \$0.00	eries A-1 vertible emable red Stock 01 Par alue	Conv Rede Preferi \$0.0	Series B vertible emable red Stock 01 Par alue	2011 Se Conve Redee Preferre \$0.001 Val	rtible nable d Stock l Par	Conv Rede Prei Stock	ries A vertible emable ferred i \$0.001 Value	Com Rede Pre S \$0.0	ies A-1 vertible emable ferred tock 01 Par alue	Con Ste \$0.00	ss A nmon ock 11 Par llue	St \$0.0	ricted ock 01 Par alue	Additional Paid-In	Deficit Accumulated During the Development	Total Stockholders'
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Capital	Stage	Deficit
Balance at Inception, June 28, 2000	\$ —	s —	_	s —	_	s —	_	\$ —	_	\$ —	_	\$ —	_	\$ —	_	s —	\$ —	s —	s –
Issuance of common													4404		598		40.505		10.505
stock Purchase/statutory retirement of treasury	_	_	_	_	_	_	_	_	_	_	_	_	14,341	_	598	_	10,527	_	10,527
stock	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_
Issuance of common stock for services Conversion of common stock to convertible redeemable preferred	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_	8	_	8
stock Issuance of preferred stock on various dates, net of amounts allocated to issuance	500	7,500	_	_	_	_	_	_	_	_	_	_	(500)	_	_	_	(7,500)	_	(7,500)
costs of \$2,453 Re-Issuance of 2006 Series A-1	167	5,800	2,345	13,376	6,480	8,129	5,362,172	1,573	_	_	_	_	_	_	_	_	(3,299)	_	(3,299)
convertible redeemable preferred stock in July 2008	_	_	2,345	8,441	_	_	_	_	_	_	_	_	_	_	_	_	(8,441)	_	(8,441)
Issuance of preferred stock upon conversion on notes payable, net of amounts allocated to issuance costs of																			
\$441 in May 2011 Issuance of warrant in	_	_	_	_	_	_	10,724,321	15,530	_	_	_	_	_	_	_	_	_	_	_
exchange for license Extinguishment of preferred stock	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_	1,088	_	1,088
liquidation value on various dates Extinguishment of	_	(13,300)	(2,345)	(14,950)		_	_	_	_		_	_	_		_	_	28,250	_	28,250
accrued dividends	_	(1,483)	_	_	_	_	_	_	_	_	_	_	_	_	_	_	1,483	_	1,483
Vesting of restricted common stock	_	_	_	_	_	_	_	_	_	_	_	_	440	_	(440)	_	_	_	_
Repurchase of restricted common stock	_	_	_	_	_	_	_	_	_	_	_	_	_	_	(98)	_	(1)	_	(1)
Conversion of convertible redeemable preferred stock to common	(667)	(14,000)	(2.245)	(20.546)	(C. 400)	(15,000)							17.000					2.252	
stock Repricing of stock warrant issued for	(667)	(14,988)	(2,345)	(28,546)	(6,480)	(15,608)	_		_	_	_	_	17,899	_	_	_	55,790 163	3,352	59,142 163
licensing rights Recapitalization of	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_	163	_	163
equity Accruals of dividends	_		_		_		_	(12,826)	_	_	_	_	_	_	(60)	_	13,697	_	13,697
and accretion to redemption value	_	16,471	_	21,679	_	7,479	_	23,892	_	_	_	_	_	_	_	_	(66,169)	(3,352)	(69,521)
Beneficial conversion feature	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_	1,040		1,040
Stock-based compensation expense																	421		421
Net loss during the period from inception to December 31,											_		_				421	(60 101)	
2011	<u> </u>		=	=	=				_	=	=	_	I <u> —</u>	_	=	=		(68,101)	(68,101)

## Histogenics Corporation (A Development Stage Company)

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

	Conv Rede Preferr	Series A vertible emable red Stock Par Value	Conv Rede Prefer \$0.0	eries A-1 vertible emable red Stock 01 Par alue	Conv Rede Preferr \$0.00	Series B ertible emable ed Stock 01 Par alue	2011 Serio Converti Redeema Preferred S \$0.001 P Value	ble ble Stock	Series Converti Redeema Preferr Stock \$0. Par Val	ible able ed .001	Series A Convert Redeem Prefers Stock \$0.001 I Value	ible able red k Par	Class . Comm Stock \$0.001 I Value	on c Par	Restri Sto \$0.001 Val	ck l Par	Additional Paid-In	Deficit Accumulated During the Development	Total Stockholders'
D-l	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Capital	Stage	Deficit
Balance at December 31, 2011 Issuance of new Series A convertible redeemable preferred stock, net of amounts allocated to issuance costs and warrants of	_	_	_	_	_	_	16,086,493	28,169	_	_	_	_	32,180	_	_	_	27,057	(68,101)	(41,044)
\$2,146 in July 2012	_	_	_	_	_	_	_	_	22,652,031	20,506	_	_	_	_	_	_	117	_	117
Recapitalization of equity	_	_	_	_			(16,086,493)	(28,894)	5,950,000	5,950	_	_	6,217,821	6	_		42,019	_	42,025
Accruals of dividends and accretion to redemption value	_	_	_	_	_	_	(10,000,493)	725	3, <del>3</del> 30,000	3,163	_	_	U,217,021	_	_	_	(3,888)	_	(3,888)
Issuance of restricted common stock in October 2012															61,095				
Stock-based compensation	_	_	_	_	_	_	_	_	_	_	_	_	_	_	01,093	_	_	_	_
expense	_	_	_	_	_	_	_		_				_	_			14		14
Net loss Balance at																		(16,935)	(16,935)
December 31, 2012 Accruals of dividends and accretion to redemption	_	_	_	_	_	_	_	_	28,602,031	29,619	_	_	6,250,001	6	61,095	_	65,319	(85,036)	(19,711)
value Extinguishment of Series A convertible redeemable	_	_	_	_	_	_	_	_	_	2,291	_	_	_	_	_	_	(2,291)	_	(2,291)
preferred stock Reissuance of Series A convertible redeemable preferred stock	_		_				_	_	(28,602,031) 28,602,031	(31,910) 42,617	_	_	_				(28,000)	_	(28,000)
Issuance of Series A-1 convertible redeemable preferred stock, net of issuance costs of \$63	_	_	_	_	_	_	_	_	_	_	10,323,988	14,454	_	_	_	_	_	_	_
Issuance of restricted															04.622				
common stock Vesting of restricted stock							_	_		_			15,274	_	81,623 (15,274)			_	_
Stock-based compensation expense		_		_	_	_	_	_	_	_	_	_	-	_	(13,274)	_	158	_	158
Exercise of common stock													25.21						
options Net loss	_	_	_	_	_	_		_	_	_		_	25,314 —	_	_	_		(25,712)	2 (25,712)
Balance at December 31, 2013 Stock-based		_	_			_	_	_	28,602,031	42,617	10,323,988	14,454	6,290,589	6	127,444	_	35,188	(110,748)	(75,554)
compensation expense Net loss	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_	76	(2.427)	76
Balance at March 31,	_		_		_													(3,437)	(3,437)
2014 (unaudited)	<u> </u>	\$ —	_	\$ —	_	\$ —		<u>\$</u>	28,602,031	\$ 42,617	10,323,988	\$14,454	6,290,589	\$ 6	127,444	<u> </u>	\$ 35,264	\$ (114,185)	\$ (78,915)

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

# Histogenics Corporation (A Development Stage Company)

# Consolidated Statements of Cash Flows (In thousands)

	Years Decemb		Three M Ended M 2013		Period From June 28, 2000 (Date of Inception) to December 31, 2013	Period From June 28, 2000 (Date of Inception) to March 31, 2014
			(unaudited)	(unaudited)		(unaudited)
CASH FLOWS FROM OPERATING ACTIVITIES:						
Net loss Adjustments to reconcile net loss to net cash used in operating activities:	\$(16,935)	\$(25,712)	\$ (2,716)	\$ (3,437)	\$ (110,748)	\$ (114,185)
Depreciation	638	566	124	153	5,759	5,912
Deferred rent and lease incentive Impairment of goodwill and intangible asset	(464)	(455)	(74)	(74)	(1,486)	(1,560)
Loss on sale of property and equipment	_	60	_		2,230	2,230
* * * *		20	20	_	8	8
Stock-based compensation Non-cash interest expense	14	158	10	76	593	669
Write-off of shareholder note receivable	_	_	_	_	206	206
			_	_	100	100
Change in fair value of note payable to stockholder  Gain on extinguishment of debt	17 (687)	_		_	37 (687)	37 (687)
Non-cash consideration for licensed technology	3,115				4.367	4,367
Change in fair value of liabilities	1,826	8,815	(107)	(1,738)	9,929	8,191
Amortization of deferred financing costs	196	_	(34)	(38)	919	881
Amortization of debt discount					1,936	1,936
Issuance of stock for services	_	_	_	_	8	8
Other non-cash items					9	9
Changes in operating assets and liabilities:						
Prepaid expenses and other current assets Other non-current assets	230 41	(156) 1	98	243	(340)	(97) (538)
Accounts payable	(228)	804	(67) 126	34	(538) 5	39
Accrued expenses	5	617	(139)	(238)	2,797	2,559
Net cash used in operating activities	(12,232)	(15,282)	(2,759)	(5,019)	(84,896)	(89,915)
CASH FLOWS FROM INVESTING ACTIVITIES:						
Purchases of property and equipment	(79)	(604)	(51)	(120)	(4,611)	(4,731)
Proceeds from sale of property and equipment	_	50	50	_	68	68
Advances on shareholder notes receivable	_	_	_	_	(100)	(100)
Cash acquired during ProChon acquisition	_	_	_	_	1,318	1,318
Net cash used in investing activities	(79)	(554)	(1)	(120)	(3,325)	(3,445)
CASH FLOWS FROM FINANCING ACTIVITIES:						
Proceeds from the issuance of term note			_	_	1,500	1,500
Borrowings under equipment term loan Repayments of term note and equipment term loan			_	_	1,400 (2,900)	1,400 (2,900)
Issuance of Series A convertible promissory notes	_	_	_	_	14,387	14,387
Issuance of Series B convertible promissory notes	59	_	_	_	12,000	12,000
Issuance of Series A-1 convertible promissory notes	5,950	_	_	_	5,950	5,950
Issuance of common stock to investors		_	_	_	10,525	10,525
Issuance of 2005 Series A preferred stock	_	_	_	_	2,500	2,500
Issuance of 2006 Series A-1 preferred stock, net of issuance costs of \$1,574	_	_		_	13,628	13,628
Issuance of 2008 Series B preferred stock, net of issuance costs of \$879	_	_	_	_	8,351	8,351
Issuance of Series A preferred stock, net of issuance costs of \$1,973	20,679	—	_	_	20,679	20,679
Issuance of Series A-1 preferred stock, net of issuance costs of \$63	_	10,261	_	_	10,261	10,261

	Years Decem		Three M Ended M		Period From June 28, 2000 (Date of Inception) to December 31.	Period From June 28, 2000 (Date of Inception) to March 31,
	2012	2013	2013	2014	2013	2014
Costs associated with Initial Dublic Offering		(400)	(unaudited)	(unaudited)	(400)	(unaudited)
Costs associated with Initial Public Offering Deferred financing costs		(409)	<u> </u>	(235)	(409) (919)	(644) (919)
Proceeds from the exercise of common stock options	_	2	_	_	2	2
Net cash provided by (used in) financing activities	26,688	9,854		(235)	96,955	96,720
Net increase (decrease) in cash and cash equivalents	14,377	(5,982)	(2,760)	(5,374)	8,734	3,360
Cash and cash equivalents—Beginning of period	339	14,716	14,716	8,734		
Cash and cash equivalents—End of period	\$14,716	\$ 8,734	\$ 11,956	\$ 3,360	\$ 8,734	\$ 3,360
Supplemental disclosure of noncash investing and financing activities						
Conversion of common stock to 2005 Series A preferred stock	<u>\$</u>	<u>\$</u>	<u> </u>	<u> </u>	\$ 7,500	\$ 7,500
Conversions of preferred stock into common stock	<u>\$</u>	<u>\$</u>	<u>\$</u>	\$	\$ 59,142	\$ 59,142
Recapitalization	\$42,025	\$ —	\$ —	\$ —	\$ 55,722	\$ 55,722
Warrant issued to an advisor in connection with the issuance of Series A Preferred Stock	\$ 117	\$ —	\$ —	\$ —	\$ 117	\$ 117
Warrants issued to investors in connection with the issuance of Series A Preferred Stock	\$ 56	\$ —	\$ —	\$ —	\$ 56	\$ 56
Accretion of dividends and redemption value on convertible preferred stock	\$ 3,888	\$ 2,291	\$ 592	\$ —	\$ 75,700	\$ 75,700
Conversion of convertible notes payable and accrued interest into preferred stock	\$19,081	\$ —	\$ —	\$ —	\$ 35,052	\$ 35,052
Issuance of 2011 Series A Preferred Stock and common stock to acquire ProChon	\$ —	\$ —	\$ —	\$ —	\$ 1,574	\$ 1,574
Issuance of a note payable as part of the consideration to acquire ProChon	\$ —	\$ —	\$ —	\$ —	\$ 650	\$ 650
Extinguishment of Series A Preferred Stock (Note 10)	\$ —	\$28,000	\$ —	\$ —	\$ 28,000	\$ 28,000
Leasehold improvements acquired through lease incentive	\$ —	\$ —	<u> </u>	<u> </u>	\$ 3,184	\$ 3,184

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

## Histogenics Corporation (A Development Stage Company)

Notes to Consolidated Financial Statements (In thousands, except share and per share data)

## 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 is a regenerative medicine company engaged in developing and commercializing products in the musculoskeletal segment of the marketplace. The Company combines cell therapy and tissue engineering technologies to develop products for tissue repair and regeneration focusing on patients suffering from particular cartilage-derived pain and immobility. The Company is developing technology and products to reverse or prevent cartilage damage, including NeoCart for the repair of cartilage lesions. NeoCart is currently in a Phase 3 clinical trial in the United States under a special protocol assessment with the U.S. Food and Drug Administration ("FDA") for the treatment of knee cartilage damage.

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 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 to normal. The acquisition of ProChon provides the Company with access to a significant portfolio of intellectual property, including proprietary cell growth factors, in addition to furthering opportunities for the use of biomaterials to create more effective solutions for regenerating human tissue. In the aggregate, the fair value of the consideration paid to acquire ProChon was \$2,224. The acquisition led to goodwill and intangible assets including IPR&D and a licensing agreement which have been impaired as discussed in Note 2.

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 generated revenues from its planned principal operations. In addition, expenses have primarily been for research and development and administrative costs. As a result, the Company is considered a development stage company.

The Company is subject to a number of risks similar to other entities in the development stage. The developmental nature of its activities is such that significant inherent risks exist in the Company's operations. Principal among these risks are the successful development of therapeutics, protection of proprietary therapeutics, compliance with government regulations, ability to obtain adequate financing, fluctuations in operating results, dependence on key personnel and collaborative partners, adoption of the Company's products by the physician community, rapid technological changes inherent in the markets targeted, and substitute products and competition from larger companies.

## **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 subsidiary, ProChon. All significant intercompany accounts and transactions are eliminated in consolidation.

## **Going Concern Uncertainty**

The revenue and income potential of the Company's business and market are unproven. The Company has experienced net losses and negative cash flows from operating activities since its inception, and as of

## Histogenics Corporation (A Development Stage Company)

Notes to Consolidated Financial Statements (In thousands, except share and per share data)

December 31, 2012 and 2013 and March 31, 2014, had a deficit accumulated during the development stage of \$85,036, \$110,748 and \$114,185, respectively. The Company expects to continue to incur net losses in the foreseeable future. A successful transition to attaining profitable operations is dependent upon achieving a level of revenues adequate to support the Company's cost structure.

On various dates in July and November 2012, the Company received \$20,679 in net proceeds from the first tranche of the Series A Convertible Redeemable Preferred Stock ("Series A Preferred") financing. Upon the achievement of certain milestones (as described in Note 10) or the vote of at least a majority of the holders of the outstanding shares, the Company may be able to obtain funding in the form of future tranches of Series A Preferred of \$20,648. As described in further detail in Note 10, on December 18, 2013, the Company entered into an Amended and Restated Series A and A-1 Preferred Stock Purchase Agreement and received \$10,324, half of the \$20,648 noted above, from the sale of Series A-1 Preferred Stock ("Series A-1 Preferred"). Subject to the Company's achievement of certain milestones or the approval of at least a majority of the holders of the outstanding Series A Preferred and Series A-1 Preferred shares to waive such milestone conditions, investors committed to invest the remaining \$10,324 from the sale of Series A-1 Preferred Stock, to close no later than December 31, 2014. As of March 31, 2014, the Company will continue to rely on external sources of funding for its operations for the foreseeable future. These sources of funding would primarily include public and private equity and debt offerings. If the Company is not able to secure adequate additional funding, the Company may be forced to make reductions in spending, extend payment terms with suppliers, liquidate assets where possible, or suspend or curtail planned programs, including clinical trials. Any of these actions could materially harm the Company's business, results of operations, and future prospects. Even if the Company is able to raise additional capital, such financings may only be available on unfavorable terms, or could result in significant dilution of stockholders' interests.

The Company's recurring losses from operations and negative cash flows raise substantial doubt about its ability to continue as a going concern. The accompanying 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. The Company may never become profitable, or if it does, it may not be able to sustain profitability on a recurring basis.

### 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

## **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, fair value estimates of warrant liabilities and derivatives, net sales distribution payment liability, purchase price allocations, estimated useful lives of fixed assets and intangible assets and accruals relating to clinical trials. 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's actual results may differ from these estimates under different assumptions or conditions.

## Histogenics Corporation (A Development Stage Company)

Notes to Consolidated Financial Statements (In thousands, except share and per share data)

## **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 expense, net" in the consolidated statements of operations.

## **Reverse Stock Split**

Effective May 13, 2011, the Company's board of directors voted to approve a 1-for-15,000 reverse stock split. Accordingly, all historical share and per share amounts in the consolidated financial statements have been retroactively adjusted for all periods presented to give effect to a 1-for-15,000 reverse stock split of all of the Company's capital stock, including reclassifying an amount equal to the reduction in par value as a result of the decreased shares to additional paid-in capital.

### **Unaudited Interim Financial Information**

The accompanying interim consolidated balance sheet as of March 31, 2014, the consolidated statements of operations and consolidated statements of cash flows for the three months ended March 31, 2013 and 2014 and the period from June 28, 2000 (inception) to March 31, 2014, the consolidated statements of convertible redeemable preferred stock and stockholders' deficit for the three months ended March 31, 2014 and the related footnote disclosures are unaudited. These unaudited interim consolidated financial statements have been prepared in accordance with U.S. GAAP. In management's opinion, the unaudited interim consolidated financial statements have been prepared on the same basis as the audited financial statements and include all adjustments (including normal recurring adjustments) necessary for the fair presentation of the Company's financial position as of March 31, 2014 and its results of operations and its cash flows for the three months ended March 31, 2013 and 2014 and the period from June 28, 2000 (inception) to March 31, 2014. The results for the three months ended March 31, 2014 are not necessarily indicative of the results expected for the full fiscal year or any other interim period.

## Unaudited Pro Forma Balance Sheet and Earnings (Loss) per Share Information

The unaudited pro forma consolidated balance sheet information as of March 31, 2014 assumes the conversion of all outstanding shares of convertible redeemable preferred stock into shares of the Company's common stock, assuming an initial public offering, or IPO, price of \$ per share (the mid-point of the price range set forth on the cover of this prospectus). The pro forma consolidated balance sheet was prepared as though the completion of the IPO contemplated by this prospectus had occurred on March 31, 2014. Shares of common stock issued in such IPO and any related net proceeds are excluded from the pro forma information.

Unaudited pro forma earnings (loss) per share applicable to common stockholders is computed using the weighted-average number of common shares outstanding after giving effect to the conversion of all the outstanding convertible redeemable preferred stock into shares of common stock as if such conversion had occurred at the beginning of the period presented, or the date of original issuance, if later, and excludes the gain on extinguishment of preferred stock and the accretion of dividends.

## Histogenics Corporation (A Development Stage Company)

## Notes to Consolidated Financial Statements (In thousands, except share and per share data)

## **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 (Waltham, 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.

Information about the Company's operations in different geographic regions is presented in the tables below:

	 Years Ended December 31, 2012 2013					h 31,		June (Ince	od from 28, 2000 ption) to er 31, 2013	Period from June 28, 2000 (Inception) to March 31, 2014		
	 .012		113		013		2014	Decemb	er 31, 2013			
				(unau	ıdited)	(una	udited)			(una	udited)	
Revenues:												
United States	\$ _	\$	_	\$	_	\$	_	\$	244	\$	244	
Israel	 26		8		5				157		157	
Total Revenues	\$ 26	\$	8	\$	5	\$	_	\$	401	\$	401	

	As of	December 31,	As of	s of March 31,	
	2012	2013	(ui	2014 naudited)	
Long-lived assets:			•	,	
United States	\$2,179	\$2,266	\$	2,234	
Israel	136	17		16	
Total long-lived assets	\$2,315	\$2,283	\$	2,250	

## **Fair Value Measurements**

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

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

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. The fair value hierarchy gives the highest priority to quoted prices in active markets (observable inputs) and the lowest priority to the Company's assumptions (unobservable inputs). Fair value measurements should be

## Histogenics Corporation (A Development Stage Company)

## Notes to Consolidated Financial Statements (In thousands, except share and per share data)

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 and minimize the use of unobservable inputs 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, 2012 and 2013 and March 31, 2014 other than the money market fund described in the "Cash and Cash Equivalents" section below and 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.

Transfers are calculated on values as of the transfer date. There were no transfers between Levels 1, 2 and 3 during the years ended December 31, 2012 and 2013 and the three months ended March 31, 2014.

## Histogenics Corporation (A Development Stage Company)

Notes to Consolidated Financial Statements (In thousands, except share and per share data)

The Company has liabilities classified as Level 3 that are measured by management at fair value on a quarterly basis as described in Note 9.

#### **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.

## **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.

The Company's cash equivalents, which consist of money market funds, are measured at fair value on a recurring basis. As of December 31, 2012 and 2013 and March 31, 2014, the carrying amount of cash and cash equivalents was \$14,716, \$8,734 and \$3,360, respectively, which approximates fair value and was determined based upon Level 1 inputs. Money market funds are valued using quoted market prices with no valuation adjustments applied. Accordingly, these securities are categorized as Level 1.

#### **Business Combinations**

The Company assigns the value of the consideration transferred to acquire or merge with a business to the tangible assets and identifiable intangible assets acquired and liabilities assumed on the basis of their fair values at the date of acquisition. The Company assesses the fair value of assets, including intangible assets, using a variety of methods, including present-value models. Each asset is measured at fair value from the perspective of a market participant. Transaction costs and restructuring costs associated with the transaction are expensed as incurred. Consideration transferred is measured on the date of the transaction. The consideration transferred in excess of the fair value of the assets acquired less the fair value of the liabilities assumed, if any, is recorded as goodwill on the Company's balance sheet. In the event the fair value of the assets acquired less the fair value of the liabilities assumed exceeds the value of the consideration transferred, a bargain purchase would be deemed to have occurred and a gain would be recorded on the Company's statement of operations.

## **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 will be depreciated in accordance with the below guidelines once placed into service. Maintenance and repair costs are expensed as incurred. Costs which materially improve or

## Histogenics Corporation (A Development Stage Company)

## Notes to Consolidated Financial Statements (In thousands, except share and per share data)

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
Office equipment
Caboratory equipment
Casehold improvements
Office equipment
Casehold improvements
Stimated Useful Lives
3 to 5 years
Shorter of the remaining lease term or useful life

Upon retirement or sale, the cost of assets disposed and the related accumulated depreciation is 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. While the Company's current and historical operating losses and negative cash flows are indicators of impairment, management believes that future cash flows to be received support the carrying value of its long-lived assets and, accordingly, has not recognized any impairment losses since inception, other than the write-off of an intangible asset as discussed in the "Intangible Asset" section below.

Impairments, if any, are recognized in earnings. An impairment loss would be recognized in an amount equal to the excess of the carrying amount over the undiscounted expected future cash flows.

## Goodwill

Goodwill is recorded when the consideration paid for a business acquisition exceeds the fair value of net tangible and identifiable intangible assets acquired. Goodwill and other intangible assets with indefinite useful lives are not amortized, but rather tested annually on December 31, for impairment or more frequently if indicators are present or changes in circumstances suggest that impairment may exist.

Goodwill could be impaired due to market conditions, reduced expected future cash flows, or other factors or events. Should the fair value of goodwill at the measurement date fall below its carrying value, a charge for impairment of goodwill could occur in that period. Impairment is assessed at the reporting unit level using a two-step approach. The first step of the impairment test involves comparing the fair value of the reporting unit with its aggregate carrying values, including goodwill. Management determines the fair value of a reporting unit using the income approach methodology of valuation that includes the multiple period discounting method as well as other generally accepted valuation methodologies. If the carrying amount of the reporting unit exceeds the reporting unit's fair value, management performs the second step of the goodwill impairment test to determine the amount of impairment loss. The second step of the goodwill impairment test involves comparing the implied fair value of the reporting unit's goodwill with the carrying value of that goodwill.

For the year ended December 31, 2011 the Company had recorded a goodwill impairment charge of \$1,840 in the ProChon operating segment.

## Histogenics Corporation (A Development Stage Company)

Notes to Consolidated Financial Statements (In thousands, except share and per share data)

## **Intangible Assets**

As part of the ProChon acquisition, the Company acquired a license agreement that ProChon entered into with AT Grade S.R.L. ("AT Grade") in 2010. In December 2011, the Company and AT Grade determined that the licensing agreement relationship was no longer part of their strategic programs and the Company evaluated the licensing agreement for impairment. As a result of the impairment test, the Company recorded an impairment charge of \$330 in the consolidated statement of operations for the year ended December 31, 2011, leaving the license agreement with a net book value of \$0. The Company and AT Grade agreed to formally terminate the license agreement in March 2012.

As of December 31, 2012 and 2013 and March 31, 2014, the Company's intangible asset consists of acquired in-process research and development ("IPR&D") obtained through the acquisition of ProChon. IPR&D represents the fair value assigned to research and development assets that have not been completed at the date of acquisition. The value assigned to acquired IPR&D is determined by estimating the costs to develop the acquired technology into commercially viable products, estimating the resulting revenue from the projects, and discounting the net cash flows to present value. The revenue and costs projections used to value acquired IPR&D were, as applicable, reduced based on the probability of success of developing a new product. Additionally, the projections considered the relevant market sizes and growth factors, expected trends in technology and the nature and expected timing of new product introductions by the Company and its competitors. The rates utilized to discount the net cash flows to their present value were commensurate with the stage of development of the projects and uncertainties in the economic estimates used in the projections described above.

IPR&D is considered an indefinite-lived intangible asset and is assessed for impairment annually or more frequently if impairment indicators exist. When performing the impairment assessment, the Company first assesses qualitative factors to determine whether it is necessary to recalculate the fair value of its acquired IPR&D. If the Company believes, as a result of the qualitative assessment, that it is more likely than not that the fair value of acquired IPR&D is less than its carrying amount, it calculates the fair value using the same methodology as described above. If the carrying value of the Company's acquired IPR&D exceeds its fair value, then the intangible asset is written-down to its fair value. For the year ended December 31, 2013, the Company determined that there was no impairment of its IPR&D.

The Company performed its annual impairment test of its IPR&D as of December 31, 2013 using an income approach, including a discount rate of 14%, applied to probability-adjusted after-tax cash flows. The Company believes that the assumptions are representative of those a market participant would use in estimating the fair value of the IPR&D. The Company also notes that the pursuit of the underlying IPR&D has been delayed because the Company's core focus has been on the development of NeoCart. The results of the impairment test indicated a decline in the fair market value of the IPR&D and an impairment charge of \$60 was required for the year ended December 31, 2013. As the Company's core focus has been on the development of NeoCart, there is a risk of further impairment in the near future.

## Histogenics Corporation (A Development Stage Company)

## Notes to Consolidated Financial Statements (In thousands, except share and per share data)

Intangible assets, net of accumulated amortization and impairment charges, are summarized as follows:

		As of De	cember 31, 20	12			As of D	ecember 31, 20	13		As of March 31, 2014					
	Cost	Accumulated Amortization and Impairments		Net Book Value		Cost	Accumulated Amortization and Impairments		Net Book Value		Cost	Accumulated Amortization and Impairments		Net Book Value		
												(1	unaudited)			
IPR&D	\$630	\$	_	\$	630	\$630	\$	(60)	\$	570	\$570	\$	_	\$	570	
	\$630	\$		\$	630	\$630	\$	(60)	\$	570	\$570	\$		\$	570	

## **Initial Public Offering Costs**

The Company defers direct incremental costs attributable with the initial public offering ("IPO") of its common stock. These costs represent legal, accounting and other direct costs related to the Company's efforts to raise capital through a public sale of its common stock. Future costs will be deferred until the completion of the IPO, at which time they will be reclassified to additional paid-in capital as a reduction of the IPO proceeds. If the Company terminates its plan for an IPO or delays such plan for more than 90 days, any costs deferred will be expensed immediately. As of December 31, 2013, IPO costs were \$1,093 and are included in prepaid expenses and other assets in the consolidated balance sheet. Of the \$1,093 in IPO costs, the Company has paid \$409 with the remaining \$684 included in accounts payable in the consolidated balance sheet. As of March 31, 2014, IPO costs were \$1,928 and are included in prepaid expenses and other assets in the consolidated balance sheet. Of the \$1,928 in IPO costs, the Company has paid \$644 with the remaining \$1,284 included in accounts payable in the consolidated balance sheet.

## **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 Waltham, 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 lease for its Waltham, Massachusetts facility provides for fixed increases in minimum annual rental payments. The total amount of rental payments due over the lease term is being charged to rent expense ratably over the life of the lease.

## **Convertible Redeemable Preferred Stock**

The Company classifies convertible redeemable preferred stock that is redeemable outside of the Company's control outside of permanent equity. The Company recorded such redeemable preferred stock at fair value upon issuance, net of any issuance costs or discounts, and the carrying value is being increased by periodic accretion to its redemption value up to the date the preferred stock is determined to be redeemable. In the absence of retained earnings these accretion charges are recorded against additional paid in capital, if any, and then to accumulated deficit.

# Histogenics Corporation (A Development Stage Company)

Notes to Consolidated Financial Statements (In thousands, except share and per share data)

# 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. 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**

The Company's revenue has principally consisted of BioCart product revenue in Israel, collaboration revenue from a license agreement with AT Grade and government grant funding received from the Internal Revenue Service ("IRS") as a qualifying therapeutic discovery project ("QTDP") credit pursuant to the Patient Protection and Affordable Care Act. The Company's license and collaboration agreement contains multiple elements, all of which are accounted for as collaboration revenue. The Company recognizes revenue when all four of the following criteria are met: (1) persuasive evidence that an agreement exists; (2) delivery of the products and/or services has occurred; (3) the selling price is fixed or determinable; and (4) collectability is reasonably assured. Revenues consisted of the following:

		Ended iber 31,			nths Ended ch 31,		June	od from 28, 2000	June	od from 28, 2000
	2012	2013	20	13	201	4		ption) to per 31, 2013		ption) to h 31, 2014
			(unau	dited)	(unaud	lited)	(una	audited)		
Revenues:										
Collaboration Revenue	\$ 26	\$ 8	\$	5	\$	_	\$	104	\$	104
Product Revenue	_	_		_		_		53		53
Grant Revenue	_	_		_		_		244		244
Total Revenues	\$ 26	\$ 8	\$	5	\$	_	\$	401	\$	401

## Product Revenue

The Company generated product revenue through the commercial sale of BioCart in Israel. Revenue from sales of BioCart is recognized when the product has been delivered and all obligations have been satisfied.

# Collaboration Revenue

The Company entered into a collaborative arrangement for the exclusive right to produce, use, and market BioCart in Italy. The terms of this agreement included multiple deliverables by the Company (including license rights, and research and development services) in exchange for consideration to the Company for a combination of diligence milestone payments, minimum royalty payments and royalties for commercial activity in Italy.

# Histogenics Corporation (A Development Stage Company)

# Notes to Consolidated Financial Statements (In thousands, except share and per share data)

Multiple-deliverable arrangements, such as license and development agreements, are analyzed to determine whether the deliverables can be separated or whether they must be accounted for as a single unit of accounting. When deliverables are separable, consideration received is allocated to the separate units of accounting based on the relative selling price method and the appropriate revenue recognition principles are applied to each unit. When the Company determines that an arrangement should be accounted for as a single unit of accounting, it must determine the period over which the performance obligations will be performed and revenue will be recognized.

The assessment of multiple-deliverable arrangements requires judgment in order to determine the appropriate unit of accounting, the estimated selling price of each unit of accounting and the point in time that, or period over which, revenue should be recognized.

The Company recognizes revenue from milestone payments when earned, provided that (1) the milestone event is substantive in that it can only be achieved based in whole or in part on either the Company's performance or on the occurrence of a specific outcome resulting from the Company's performance and its achievability was not reasonably assured at the inception of the agreement; (2) the Company does not have ongoing performance obligations related to the achievement of the milestone; and (3) it would result in the receipt of additional payments. A milestone payment is considered substantive if all of the following conditions are met: (a) the milestone payment is non-refundable; (b) achievement of the milestone was not reasonably assured at the inception of the arrangement; (c) substantive effort is involved to achieve the milestone; and (d) the amount of the milestone payment appears reasonable in relation to the effort expended, the other milestones in the arrangement and the related risk associated with the achievement of the milestone.

Collaboration arrangements providing for payments to the Company upon the achievement of research and development milestones generally involve substantial uncertainty as to whether any such milestone would be achieved. In the event a milestone is considered to be substantive, the Company expects to recognize future payments as revenue in connection with the milestone as it is achieved. Collaboration arrangements providing for payments to the Company upon the achievement of milestones that are solely contingent upon the performance of a collaborator also involve substantial uncertainty as to whether any such milestone would be achieved. For such contingent milestones, even if they do not meet the definition of a substantive milestone, since they are based solely upon a collaborator's effort, the Company expects to recognize future payments as revenue when earned under the applicable arrangement, provided that collection is reasonably assured.

## Government Grant Revenue

Under the Patient Protection and Affordable Care Act, the Company received government grant revenue in 2010 as a QTDP. Under section 48(D)(c)(1) of the Code, a QTDP is a tax benefit in the form of a credit or a grant targeted to therapeutic discovery projects that show a reasonable potential to treat areas of unmet medical need, reduce the cost of health care or advance the goal of curing cancer within 30 years. Revenue from government grants is recorded on a gross basis when awarded by the IRS in accordance with the terms of the grant award.

# **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 inlicensed 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

# Histogenics Corporation (A Development Stage Company)

# Notes to Consolidated Financial Statements (In thousands, except share and per share data)

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, as the case may be.

#### **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 selling, 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 any performance-based or awards with market conditions from its inception through March 31, 2014.

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.

# Histogenics Corporation (A Development Stage Company)

Notes to Consolidated Financial Statements (In thousands, except share and per share data)

# **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.

## **Earnings (Loss) per Common Share**

Earnings (loss) per common share is calculated using the two-class method, which is an earnings allocation formula that determines earnings (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 is allocated to each share on an as-converted basis as if all of the earnings for the period had been distributed. The participating securities do not include a contractual obligation to share in losses of the Company and are not 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 earnings (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 earnings (loss) per share if their effect is antidilutive.

# Histogenics Corporation (A Development Stage Company)

# Notes to Consolidated Financial Statements (In thousands, except share and per share data)

# **Recently Adopted Accounting Pronouncements**

In July 2013, the Financial Accounting Standards Board issued guidance that eliminates diversity in practice surrounding the presentation of unrecognized tax benefits when a net operating loss carryforward, a similar tax loss, or a tax credit carryforward exists. An entity is required to net an unrecognized tax benefit with a deferred tax asset for a net operating loss carryforward, a similar tax loss, or a tax credit carryforward if the carryforward would be used to settle additional tax due upon disallowance of a tax position. The Company's adoption of this guidance on January 1, 2014 is not expected to have a material impact on the consolidated financial statements.

# 3. EARNINGS (LOSS) PER COMMON SHARE

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

	Years Ended D	,	Three Months Ended March 31		
	2012	2013	2013 (unaudited)	2014 (unaudited)	
Numerator:			(unauarca)	(unadated)	
Net loss	\$ (16,935)	\$ (25,712)	\$ (2,716)	\$ (3,437)	
Recapitalization (Note 10)	41,588	`-		`— ´	
Extinguishment of Series A Preferred Stock (Note 10)	_	(28,000)	_	_	
Accruals of dividends and accretion to redemption value of					
preferred stock	(3,888)	(2,291)	(592)	_	
Loss (earnings) attributable to participating restricted stock and					
preferred stock shareholders	(17,960)	_	_	_	
Earnings (loss) attributable to common stockholders—basic	2,805	(56,003)	(3,308)	(3,437)	
Effect of convertible notes	597	<del>_</del>	_	_	
Earnings (loss) attributable to common stockholders—diluted	\$ 3,402	\$ (56,003)	\$ (3,308)	\$ (3,437)	
Denominator:	<del></del>				
Weighted-average number of common shares used in earnings (loss) per					
share—basic	2,818,293	6,264,690	6,250,001	6,290,589	
Effect of dilutive convertible redeemable preferred stock	612,388	_	_	_	
Effect of convertible notes	8,691,636	_	_	_	
Effect of warrants to purchase common stock	776,312	_	_	_	
Weighted-average number of common shares used in earnings (loss) per					
share—diluted	12,898,629	6,264,690	6,250,001	6,290,589	
Earnings (loss) per share—basic	\$ 1.00	\$ (8.94)	\$ (0.53)	\$ (0.55)	
Effect of convertible preferred stock dividends	(0.12)	<u>'</u> — '	<u> </u>	·— ·	
Effect of convertible notes	(0.40)	_	_	_	
Effect of warrants to purchase common stock	(0.22)	_	_	_	
Earnings (loss) per share—diluted	\$ 0.26	\$ (8.94)	\$ (0.53)	\$ (0.55)	

# Histogenics Corporation (A Development Stage Company)

# Notes to Consolidated Financial Statements (In thousands, except share and per share data)

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):

	Years Ended December 31,		Three Months Er	nded March 31,
	2012 2013		2013	2014
			(unaudited)	(unaudited)
Convertible redeemable preferred stock and dividends	_	38,926,019	28,602,031	38,926,019
Restricted stock and options to purchase common stock	1,054,702	5,414,588	3,461,923	3,108,634
Warrants	_	1,750,000	1,750,000	1,750,000

The Company also had certain warrants and other liabilities outstanding as of December 31, 2012 and 2013 and March 31, 2013 and 2014 which could obligate the Company and/or its stockholders to issue shares of common stock upon the occurrence of various future events at prices and in amounts that are not determinable until the occurrence of those future events. For the year ended December 31, 2013 and as of March 31, 2013 and 2014, these included the net sales distribution payment liability. See Note 9, "Warrants, Other Liability and Net Sales Distribution Payment Liability" for additional details. Because the necessary conditions for the conversion or exercise of these instruments had not been satisfied as of December 31, 2012 and 2013 and March 31, 2013 and 2014, the Company has excluded these instruments from the table above and the calculation of diluted net income per share for those periods.

The equity-classified warrants, which were issued on July 20, 2012 and are immediately exercisable into 1,750,000 shares of common stock, are included in the calculation of diluted earnings per share for the year ended December 31, 2012. They were included in the table above for the year ended December 31, 2013 and three months ended March 31, 2013 and 2014 because they would be anti-dilutive for this period. See Note 9, "Warrants, Other Liability and Net Sales Distribution Payment Liability," for additional details.

# 4. PREPAID EXPENSES AND OTHER CURRENT ASSETS

Prepaid expenses and other current assets consisted of the following:

	As of Dece 2012	mber 31, 2013	As of March 31, 2014 (unaudited)
Employee benefits	\$ 200	\$ —	\$
Deposits	10	290	234
Undelivered laboratory and office equipment	_	57	9
Insurance	23	11	10
IPO costs	_	1,093	1,928
Prepaid rent	_	128	4
Other current assets	130	33	19
Prepaid expenses and other current assets	\$ 363	\$ 1,612	\$ 2,204

# Histogenics Corporation (A Development Stage Company)

# Notes to Consolidated Financial Statements (In thousands, except share and per share data)

# 5. PROPERTY AND EQUIPMENT

Property and equipment consisted of the following:

	As of Dece	As of March 31,	
	2012	2013	2014 (unaudited)
Office equipment	\$ 454	\$ 460	\$ 464
Laboratory equipment	1,644	1,838	1,926
Leasehold improvements	5,364	5,489	5,489
Construction in progress	_	145	145
Software	_	_	29
Total property and equipment	7,462	7,932	8,053
Less: accumulated deprecation	(5,147)	(5,649)	(5,803)
Property and equipment, net	\$ 2,315	\$ 2,283	\$ 2,250

Depreciation expense related to property and equipment amounted to \$638, \$566, \$124, \$153, \$5,759 and \$5,912 for the years ended December 31, 2012 and 2013, three months ended March 31, 2013 and 2014, and the period from June 28, 2000 (inception) to December 31, 2013 and March 31, 2014, respectively.

# 6. ACCRUED EXPENSES

Accrued expenses consisted of the following:

	As of Dec	As of March 31,	
	2012	2013	2014 (unaudited)
Accrued compensation	\$ 320	\$ 128	<b>\$</b> 175
Accrued professional fees	2	667	488
Other	96	240	134
Total accrued expenses	\$ 418	\$ 1,035	\$ 797

# 7. COMMITMENTS AND CONTINGENCIES

# **Operating Leases**

The Company leases its office and research facilities in Waltham, Massachusetts under a non-cancellable operating lease, which expires in 2017. Terms of the agreement 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. In January 2014, the Company entered into an agreement with a third party to sublease an additional facility in Waltham, Massachusetts. The term of the sublease extends from February 1, 2014 through July 30, 2015. The Company expects to make fixed rent payments of \$163 over the term of the sublease. The Company's wholly-owned subsidiary, ProChon, leases facilities in Woburn, Massachusetts and Israel.

# Histogenics Corporation (A Development Stage Company)

# Notes to Consolidated Financial Statements (In thousands, except share and per share data)

Aggregate minimum annual lease commitments of the Company under its non-cancellable operating leases as of December 31, 2013, including payments made through March 31, 2014, are as follows:

Year Ending December 31,	
2014	\$1,234
2015	1,076
2016	985
2017	968
Thereafter	_
Total minimum lease payments	\$4,263

The preceding data reflects existing leases and does not include replacements upon their expiration. Rent expense under operating lease agreements amounted to approximately \$649, \$648, \$156, \$151, \$4,164 and \$4,315 for the years ended December 31, 2012 and 2013, the three months ended March 31, 2013 and 2014, and the period from June 28, 2000 (inception) to December 31, 2013 and March 31, 2014, respectively. In addition, the Company maintained a stand-by letter of credit in connection with the Waltham facility lease of \$522 at December 31, 2012 and December 31, 2013 and March 31, 2014. This amount is classified as restricted cash in the consolidated balance sheets.

As an inducement to enter into its Waltham facility lease, the lessor agreed to provide the Company with a construction allowance of up to \$3,184 for special tenant improvements. Amounts paid by the lessor related to tenant improvements are considered inducements to enter into the lease. The Company has recorded these costs in the consolidated balance sheet as leasehold improvements, with the corresponding liability as deferred lease incentive. This liability is amortized on a straight-line basis over the term of the lease as a reduction of rent expense.

In April 2012, the Company entered into an agreement with a third party ("Subtenant") to sublease a portion of its leased facility in Waltham ("Sublease"). The Sublease term extends from April 15, 2012 until March 31, 2015. The Subtenant has the option to request an extension of the sublease term after March 31, 2014. All improvements made to the space are subject to the terms of the primary lease between the Company and the landlord. The Subtenant is responsible for any improvements made to the space at its own cost. Under the terms of the Sublease, the Company receives \$16 from the Subtenant in fixed rent payments per month, as well as an additional variable amount for reimbursement of utilities, operating expenses, and property taxes. As of March 31, 2014, the Company has received \$387 in rent payments from the Subtenant throughout the sublease term. These payments are recorded as a reduction of rent expense in the consolidated statements of operations. The Company expects to receive future rent payments from the Subtenant over the remaining sublease term of approximately \$197.

In addition, the Company entered into a sublease agreement for its Woburn, Massachusetts facility, with the term extending from October 28, 2009 until May 30, 2016. The Company receives \$3 from the subtenant in fixed rent payments per month.

# **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.

# Histogenics Corporation (A Development Stage Company)

# Notes to Consolidated Financial Statements (In thousands, except share and per share data)

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 application, and knowledge related to the manufacture and use of a hydrogel material in conjunction with NeoCart and certain other products ("Hydrogel License Agreement"). As of March 31, 2014, the Company has paid an aggregate \$3,150 in commercialization milestones under the terms of the Hydrogel License Agreement, which has been expensed to research and development, consisting of the following:

- An exclusivity payment of \$1,000;
- A \$2,000 revenue share reduction fee consisting of a reinstatement fee of \$1,000 and an additional \$1,000 paid in six equal quarterly payments of \$167; and
- Annual patent maintenance fee of \$50 totaling \$150 as of March 31, 2014.

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

- Annual patent maintenance fee of \$50 for 2014;
- · A one-time \$3,000 payment upon approval of an eligible product by the United States Food and Drug Administration ("FDA"); and
- Royalties in the single digits of the net sales of NeoCart and of 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 length of the license agreement extends to the expiration date of Stanford University's last to expire domestic or foreign patents as set forth in the Tissue Regeneration License Agreement. As of March 31, 2014, the Company has paid an aggregate \$610 in patent reimbursement costs, royalty fees, and commercialization milestone payments under the terms of the Tissue Regeneration License Agreement, which has been recorded to research and development expense in the consolidated statements of operations, consisting of the following:

- Milestone payments of \$85;
- Reimbursement of patent costs of \$375; and
- An annual royalty fee of \$10 from 2002 through 2013 (totaling \$120) and a \$30 royalty fee upon signing of the Tissue Regeneration License Agreement.

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

- A one-time \$300 payment upon approval of an eligible product by the FDA;
- An annual minimum non-refundable royalty fee of \$10 for the life of the license that may be used to offset up to 50% of each earned royalty
  described below; and
- Royalties in the low single digits of net sales.

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# Honeycomb License

In March 2013, the Company entered into a license agreement with Koken Co., Ltd. ("Koken") for a non-exclusive, non-transferable and non-sublicensable right to use its know-how related to the process for manufacturing atelocollagen honeycomb sponge materials, which is used in scaffolds (the "Honeycomb License Agreement"). Pursuant to the Honeycomb License Agreement, the Company paid Koken a fee in March 2013 for such right. Under the terms of the Honeycomb License Agreement, future commitments will be based on the amount of materials supplied to the Company and may vary from period to period over the term of the agreement.

## Plasmid License

In January 2008, the Company entered into an exclusive license agreement with Yeda Research and Development Co., Ltd. ("Yeda") for rights relating to high level expression of heterologous proteins and plasmid p80 BS (the "Plasmid License Agreement"), which rights are jointly owned by Yeda and the Company. Under the terms of the Plasmid License Agreement, the Company was granted an exclusive worldwide license to manufacture, use and sell heterologous proteins and plasmid p80 BS.

The Company is required to pay Yeda a yearly, non-refundable license fee of \$2 which is creditable against royalties payable by the Company to Yeda during the one-year period in which such fee was paid. Yeda is entitled a royalty fee of a low single digit percentage rate of net sales of the licensed products, a low single digit percentage rate of net sales for combination products (meaning the combination of the licensed product with at least one other active ingredient, material or medical device that would have a clinical effect if administered independently) and a low double digit percentage rate of all of the Company's sublicensing receipts.

## Tissue Processor Sub-License

In December 2005, the Company entered into an exclusive agreement to sub-license certain technology from Purpose, Co., which is owned by a stockholder of the Company ("Sub-License Agreement"). The original license agreement ("Original Agreement") was entered into in August 2001 with Brigham and Women's Hospital, Inc. ("Brigham and Women's"). 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 March 31, 2014, the Company has paid an aggregate \$772 over the term of the Sub-License Agreement in royalty and sub-license payments under the terms of the Sub-License Agreement, which was recorded to research and development expense in the consolidated statements of operations.

The Sub-License Agreement was amended and restated in June 2012. Under the amended and restated agreement, the Company made Purpose, Co., the sole supplier of equipment, which the Company uses in its manufacturing processes, and granted Purpose, Co. distribution rights of the Company's products for certain territories. In exchange, Purpose, Co. allowed for the use of its technology (owned or licensed) and manufactured and serviced exogenous tissue processors by the Company. Under the terms of the agreement, as amended, Purpose, Co. granted the Company (a) exclusive rights to all of Purpose, Co.'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, Co. an exclusive license

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in Japan for the use of all of the Company's technology and a payment of \$250 to reimburse Purpose, Co. for development costs on a next generation tissue processer.

Additionally, in conjunction with the amendment of the Sub-License Agreement, the Company granted Purpose, Co. the right to receive a portion of any consideration received by the Company and/or its stockholders as part of a liquidity event. The consideration payable to Purpose, Co. in the event of a liquidity event will equal 7.8125% of the net proceeds received by the Company and/or its stockholders. In the event that the Company requires financing in excess of \$48,000, the percentage of the consideration required to be paid to Purpose, Co. is subject to dilution pursuant to the additional amount of equity investment beyond the \$48,000. In the event the Company undertakes an IPO of its common stock, the Company and/or its stockholders will be obligated to pay Purpose, Co. the required compensation in shares of its common stock. In determining the aggregate number of shares to be issued to Purpose, Co. in such event, the shares to be issued will be calculated as the pre-IPO value determined by the Company less the transaction costs of the IPO, the amount of post-effective date indebtedness, and the amount of all rights and preferences of the investors multiplied by 7.1825%. This consideration payable to Purpose, Co. was determined to be a liability, which will be accounted for at fair value and remeasured at each reporting date. The initial value of the consideration payable to Purpose, Co. was \$3,115, which was recorded to research and development expense during the year ended December 31, 2012. The value of the consideration payable to Purpose, Co., or the "Other Liability," was \$4,868, \$13,176, and \$10,902 at December 31, 2012, December 31, 2013 and March 31, 2014, respectively. The changes in the fair value of the consideration payable to Purpose, Co. were recorded to "change in fair value of warrant liability and other liability" in the consolidated statements of operations.

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, for the life of the license;
- An annual payment of \$25 through May 4, 2014;
- \$200 of milestone payments; and
- · Royalties in the low single digits of net sales of a licensed product.

## The OCS Agreement

In connection with its research and development, the Company accrued and received grants from the Office of Chief Scientist of the Ministry of Industry and Trade in Israel ("OCS") in the aggregate of \$1,100 for funding the fibroblast growth factor ("FGF") program. In consideration for this grant, the Company is committed to pay royalties at a rate of 3-5% of the sales of sponsored products developed using the grant money, up to the amount of the participation payments received. The Company committed to pay up to 100% of grants received plus interest according to the LIBOR interest rate if the sponsored product is produced in Israel. If the manufacturing of the sponsored product takes place outside of Israel, the royalties can increase up to but no more than 300% of grants received, depending on the percentage of the manufacturing of sponsored product that takes place outside of Israel.

# **Severance Agreements**

In March 2013, the Company entered into a severance agreement with its former chief executive officer for a total of \$275, payable in bi-weekly installments of approximately \$11 through March 2014. The expense

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associated with this severance agreement has been included as a component of selling, general and administrative expense in the accompanying consolidated statements of operations. At March 31, 2014 the remaining accrual was \$0.

In February 2014, the Company entered into a severance agreement with its former vice president of clinical affairs for a total of \$118, payable in bi-weekly installments of approximately \$10 through August 2014. The expense associated with this severance agreement has been included as a component of selling, general and administrative expense in the accompanying consolidated statements of operations. At March 31, 2014 the remaining accrual was \$98.

## **Engineering Agreement**

The Company entered into an agreement with ST3 Development Corporation to purchase a multi-unit bioreactor system, which is expected to allow the Company to add additional manufacturing capacity for its current NeoCart production process. Pursuant to the agreement, the Company will be required to make payments totaling \$567, which are comprised of a deposit of \$150 paid in May 2013 with the remaining \$417 to be paid upon the Company's acceptance of the delivery of the system, which is expected in June 2014.

#### **Legal Proceedings**

The Company is not currently a party to any legal proceedings.

## 8. RELATED PARTY CONVERTIBLE PROMISSORY NOTES

On various dates in 2006, the Company obtained bridge financing in the form of issuing promissory notes to existing investors totaling \$1,100, convertible upon the closing of the next round of financing occurring prior to July 13, 2006. The notes bore interest at 3.0% per annum and converted upon the consummation of the next round of financing for which proceeds were greater than \$1,000. On July 19, 2006, the Company issued 2,345 shares of Series A-1 Convertible Redeemable Preferred Stock ("2006 Series A-1 Preferred") at a purchase price of \$6,375.27 per share, which effected the conversion of the \$1,100 in promissory notes.

On various dates in 2008, the Company obtained bridge financing in the form of issuing promissory notes to existing investors totaling \$3,010, which bore interest at 8.0% per annum, convertible upon the closing of the next round of financing. On July 19, 2008, the Company issued 6,480 shares of Series B Convertible Redeemable Preferred Stock ("2008 Series B Preferred") at a purchase price of \$1,390.12 per share, which effected the conversion of the \$3,010 in promissory notes into 6,480 shares of 2008 Series B Preferred.

On various dates in 2009, 2010 and February 2011, the Company issued promissory notes to existing investors totaling \$14,387, which bore interest at 8.0% per annum, convertible upon the closing of the next round of financing. On May 13, 2011, in connection with the recapitalization, the Company converted the promissory notes and accrued interest of \$1,584 into 10,724,321 shares of 2011 Series A Preferred.

As part of the issuance of the promissory notes in 2008, 2009, 2010 and 2011, the Company issued warrants to the existing investors to purchase 2,273 shares of 2008 Series B Preferred. The fair value of these warrants were originally recorded as a discount to the face value of the notes, and the Company accreted \$1,936 of interest expense associated with this discount. The discount on the face value also created a beneficial conversion feature for the note holder and the Company allocated \$1,040 to additional paid-in-capital. The warrants were recorded

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# Notes to Consolidated Financial Statements (In thousands, except share and per share data)

on the Company's consolidated balance sheet as a long-term liability at the fair value of the instrument at the date of issuance and were remeasured at each balance sheet date to their fair value.

On various dates beginning in May 13, 2011, the Company issued promissory notes to existing investors totaling \$12,000. The promissory notes bore interest at 8.0% per annum and converted upon the earliest of the consummation of the next round of financing for which proceeds were greater than \$27,000, the consummation of a deemed liquidation event, or May 1, 2012. As part of the recapitalization in July 2012 (Note 10), the notes and all accrued and unpaid interest were converted into 6,250,001 shares of common stock.

On various dates in 2012, the Company issued promissory notes to existing investors totaling \$5,950. The promissory notes bore interest at 8.0% per annum and converted upon the earliest of the consummation of the next round of financing, the consummation of a deemed liquidation event, or May 1, 2012. On July 20, 2012, in conjunction with the Company's recapitalization of its equity and issuance of the Series A Preferred, the notes and all accrued and unpaid interest automatically converted into 5,950,000 shares of the Series A Preferred.

# 9. WARRANTS, OTHER LIABILITY AND NET SALES DISTRIBUTION PAYMENT LIABILITY

## Historical Warrants

As part of the issuance of convertible notes in 2008, 2009, 2010 and 2011, the Company issued warrants to purchase an aggregate of 4,582 shares of 2008 Series B Preferred with an exercise price of \$1,350.00 per share. The shares of 2008 Series B Preferred had certain non-standard anti-dilution provisions which resulted in the warrants being recorded as a liability and remeasured at each period at fair value. The fair value of the warrant liability as of December 31, 2010 was \$850. The warrants were cancelled as part of the 2011 recapitalization as discussed in Note 10. At the time of the cancellation the fair value of the warrant liability was \$871. The warrant liability was valued using the PWERM. The valuation as of the 2011 recapitalization utilized several scenarios including: (a) 60% probability of various financings with enterprise valuations ranging from \$50,000 to \$250,000 for various levels of dilution and (b) a 40% probability of liquidation.

## Warrant Liability and Other Liability

In connection with the issuance of the Series A Preferred on July 20, 2012, the Company issued Common Stock Warrants (the "Common Stock Warrants") to each participating investor. The Common Stock Warrants are exercisable into an aggregate of 516,841 shares of the Company's common stock upon a defined liquidity event of either a sale of the Company or an IPO. The number of common shares may be decreased in the event that the percentage of the total equity required to be paid as part of the contingent payment of the Other Liability (described in Note 7) is decreased. The Common Stock Warrants are exercisable at \$0.07 per share and are only exercisable in the event that the contingent payment is required to be settled for the Other Liability. The fair value of the Common Stock Warrants is classified as a long-term liability in the accompanying consolidated balance sheets.

# 3% Net Sales Distribution Payment

In connection with the sale of Series A-1 Preferred, purchasers of Series A Preferred forfeited their right to receive a 2% net sales distribution payment described in Note 10. The 2% net sales distribution payment was replaced with a new royalty agreement under which the purchasers of Series A-1 Preferred ("Royalty Recipients") are entitled to receive a net sales distribution payment equal to 3% of net sales during the calendar

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year. At the election of the Royalty Recipients, all or a portion of the net sales distribution payments are required to be redeemed by the Company. The Royalty Recipients can elect to have each net sales percentage point redeemed for \$10,000 payable in cash or the Company's common stock. The fair value of the net sales distribution payment is classified as a long-term liability in the Company's consolidated balance sheet as the "Net Sales Distribution Payment Liability" in the amount of \$13,100 and \$13,760 as of December 31, 2013 and March 31, 2014, respectively.

# Fair Value Methodology

The warrant liability was initially recorded on July 20, 2012 at fair value using the Option Pricing Model ("OM"). The fair value of the liability was determined from the calculated equity value. At each reporting date, the fair value of the warrant liability is remeasured using the PWERM model. The PWERM considers the changes in timing, probability, and values of preferred and common stock and other equity-linked securities based upon developments in the Company and the market utilizing management's assumptions and various future outcomes.

The change in valuation methodologies from the OM at July 20, 2012 to the PWERM at December 31, 2012 was made because the Company believed that there was a higher probability of a liquidity event in the following 15 months. As stated above, the PWERM is able to capture the changes in timing, probability, and values of the liquidity based upon developments in the Company and the markets which will better address the Company's need to obtain quarterly updates in valuation.

The Other Liability was initially recorded based on a combination of the PWERM and OM, utilizing management's assumptions. The fair value of the Other Liability is remeasured using PWERM at each reporting date. Changes in the fair value of the warrant liability and the Other Liability have been recorded as "change in the fair value of warrant liability and other liability" in the accompanying consolidated statements of operations.

The OM that was used to estimate the fair value of the warrant liability used the valuation of the Company's common stock as of the issuance date, July 20, 2012, to establish a basis of the equity value of the Company. A series of breakpoints was then determined based upon the contractual rights of the Company's outstanding instruments with an equity claim that can be settled upon a liquidity event. The Black-Scholes option pricing model was then used to determine the fair value of each equity value breakpoint. The model utilized the following inputs: (a) risk-free interest rate of 0.22%; (b) implied volatility of the Company's common stock of 99%; and (c) the expected term to a liquidity event of 1.7 years.

The Net Sales Distribution Payment Liability resulting from the December 18, 2013 financing was recorded at fair value using the PWERM from the December 31, 2013 valuation which was used for the December 18, 2013 financing. At each reporting date, the fair value of the liability is remeasured using the PWERM model. As stated above, the PWERM considers the changes in timing, probability, and values of preferred and common stock and other equity-linked securities based upon developments in the Company and the market utilizing management's assumptions and various future outcomes.

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The table below summarizes the fair value of the Common Stock Warrants, Other Liability and Net Sales Distribution Payment Liability as of December 31, 2012 and 2013 and March 31, 2014.

	Fair Value as of			
	December 31,	December 31,		Average Exercise
	2012	2013	March 31, 2014 (unaudited)	Price Per Share
Warrant liability	\$ 129	\$ 636	<b>\$</b> 512	\$ 0.07
Other Liability	4,868	13,176	10,902	n/a
Net Sales Distribution Payment Liability	_	13,100	13,760	n/a
Total fair value	\$ 4,997	\$ 26,912	\$ 25,174	

The following table provides quantitative information about the fair value measurement, including the range of assumptions for the significant unobservable inputs used in the PWERM valuations of the Common Stock Warrants, Other Liability and Net Sales Distribution Payment Liability:

		Valuation Assumptions as of	
	December 31, 2012	December 31, 2013	March 31, 2014
			(unaudited)
Acquisition scenarios			
Liquidity value	\$50 to \$250 million	\$50 to \$250 million	\$50 to \$250 million
Probability of occurrence	10.00% to 50.00%	5.00% to 10.00%	5.00% to 10.00%
Time to event	2.25 years	3.5 years	3.2 years
IPO scenarios			
Pre-money valuation	\$75 to \$150 million	\$81 to \$150 million	\$81 to \$150 million
Probability of occurrence	0.67% to 3.33%	5.00% to 38.00%	5.00% to 38.00%
Time to event	1.25 to 2.25 years	0.5 to 3.5 years	0.5 to 3.2 years
Probability of liquidation scenarios	20%	5%	5%
Discount for lack of marketability	28%	15%	5% to 20%

The above assumptions remained relatively consistent for the periods presented as a result of only minor changes in the remaining contractual term of the Common Stock Warrants due to the passage of time, with the largest change being the probability of occurrence as the IPO became a more realistic scenario. The increase in the time to event for the acquisition scenarios is due to the change in the timing of expected patient enrollment in the clinical trial from December 2014 to April 2015 as the pause in the clinical trial ended in December 2013. The decrease in the probability of liquidation scenarios is due to the re-start of the clinical trial in December 2013 as well as the increased probability of an IPO. The fair values per share of our underlying preferred stock were estimated using the same methodologies described above for the valuation of our common stock except the exceptions noted in the description above specific to each Common Stock Warrant, Other Liability and Net Sales Distribution Payment Liability.

Significant increases (decreases) in the significant unobservable inputs used in the fair value measurement of the Common Stock Warrants, Other Liability and Net Sales Distribution Payment Liability in isolation would result in a significantly higher (lower) fair value measurement.

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Liabilities measured at fair value on a recurring basis are as follows:

Description December 31, 2012	<u>Total</u>	Quoted prices in active markets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
Warrant liability	\$ 129	\$ —	\$ —	\$ 129
Other Liability	4,868	_	_	4,868
•	\$ 4,997	\$ —	\$ —	\$ 4,997
December 31, 2013				
Warrant liability	\$ 636	\$ —	\$ —	\$ 636
Other Liability	13,176	_	_	13,176
Net Sales Distribution Payment Liability	13,100	_	_	13,100
	\$26,912	<del>\$</del>	<del>\$</del> —	\$ 26,912
March 31, 2014 (unaudited)	<del></del>			
Warrant liability	\$ 512	\$ —	\$ —	\$ 512
Other Liability	10,902	_	_	10,902
Net Sales Distribution Payment Liability	13,760			13,760
	\$25,174	\$ <u> </u>	\$ —	\$ 25,174

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

	Years ended December 31,		Three months en	ended March 31,	
	2012	2013	2013	2014	
Beginning balance	\$ 670	\$ 4.997	(unaudited) \$ 4.997	(unaudited) \$ 26,912	
Issuance of warrants, Other Liability and Net Sales Distribution Payment	Ψ 0/0	Ψ 4,557	Ψ 4,557	Ψ 20,312	
Liability	3,171	13,100	_	_	
Change in fair value of warrant liability, Other Liability and Net Sales					
Distribution Payment Liability	1,843	8,815	(107)	(1,738)	
Extinguishment of note payable	(687)	_	_	_	
Ending balance	\$ 4,997	\$ 26,912	\$ 4,890	\$ 25,174	

# **Non-recurring Fair Value Measurement**

In connection with the issuance of the Series A Preferred on July 20, 2012, the Company issued a warrant to purchase its common stock to affiliates of an advisor. The warrant provides the holders with the right to purchase an aggregate of 1,750,000 shares of the Company's common stock at a per share exercise price of \$0.001. The warrants are exercisable, in whole or in part, immediately upon issuance and may be exercised on a cashless basis. The warrants expire on the tenth anniversary of issuance. The fair value of the warrants as of July 20, 2012 was estimated using the OM with the following inputs: (a) risk-free interest rate of 0.22%; (b) implied volatility of the Company's common stock of 99%; and (c) the expected term to a liquidity event of 1.7 years. The fair

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value of the warrants as of July 20, 2012 was \$117, which was recorded as a reduction to Series A Preferred and a credit to additional paid-in capital.

## **Note Payable**

On July 20, 2012, as part of the Company's sale of Series A Preferred (Note 10), the note payable related to the ProChon acquisition was extinguished as an obligation of the Company for no consideration. The note payable had a fair value at the date of extinguishment of \$687 and has been recorded as a gain on the extinguishment of debt in the accompanying consolidated statement of operations.

## 10. CAPITAL AND CONVERTIBLE REDEEMABLE PREFERRED STOCK

As of December 31, 2013, the authorized capital stock of the Company included 70,000,000 shares of common stock, par value \$0.001 per share, 6,418,033 of which were issued and outstanding. As of December 31, 2013, 49,250,000 shares of preferred stock were authorized, designated as Series A Preferred and Series A-1 Preferred of which 28,602,031 and 10,323,988 were issued and outstanding, respectively.

On May 13, 2011, prior to the acquisition of ProChon, the Company consummated a recapitalization of its outstanding equity in which it, among other actions, (a) redeemed all of the issued and outstanding shares of (1) 2006 Series A-1 Preferred (1,874 shares) into 8,595 shares of common stock and (2) 2008 Series B Preferred (6,030 shares) into 6,030 shares of common stock, (b) converted \$14,387 of convertible notes and \$1,584 of accrued interest into 10,724,321 shares of newly created 2011 Series A Preferred Stock, and (c) cancelled all warrants held by the investors. All prior dividends that had accrued on the 2006 Series A-1 Preferred and 2008 Series B Preferred through May 13, 2011 were forfeited by the holders as part of the recapitalization. All of the conversions of preferred stock were made in accordance with the contractual arrangements and were accounted for as conversions. The redemption of the convertible notes and accrued interest was considered an extinguishment and was accounted for as a capital contribution of \$12,826.

Immediately after the conversions of the 2006 Series A-1 Preferred and 2008 Series B Preferred, the Company effected a reverse stock split in which each of the Company's stockholders received one share of common stock in exchange for 15,000 shares of common stock. Following the reverse stock split, the Company had 32,180 shares of common stock outstanding.

On July 20, 2012, in connection with the issuance of the Series A Preferred, the Company effected a recapitalization. The recapitalization resulted in (a) 32,180 shares of common stock and 16,086,493 shares of 2011 Series A Preferred being cancelled, (b) \$12,000 in principal of the convertible notes issued in 2011 converted into 6,250,001 shares of common stock, and (c) \$5,950 in principal of convertible notes issued in 2012 were converted into 5,950,000 shares of Series A Preferred. The accrued interest related to the convertible notes of \$1,131 was cancelled as part of this transaction. As the holders of the convertible notes were also stockholders of the Company at the time of the recapitalization, the cancellation of the common and preferred stock and the conversion of the notes were accounted for as one capital transaction. The Company accounted for the cancellation of the common and preferred stock and conversion of the convertible notes as a capital transaction resulting in an increase to equity of \$42,025, of which \$41,588 is treated as earnings attributable to common stockholders in the calculation of net income (loss) per share. The difference of \$437 is attributable to the issuance of common stock at its fair value.

Also on July 20, 2012, the Company entered into a stock purchase agreement with outside investors to issue an aggregate of up to 49,000,000 shares of Series A Preferred at \$1.00 per share. The terms of the agreement require

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the investors to participate in multiple rounds of financing. The initial round closed on July 20, 2012 and in conjunction with this round on various dates in July and November 2012, the Company issued 22,562,031 shares of Series A Preferred and Common Stock Warrants to purchase up to 516,841 shares of common stock to the investors, and a warrant to purchase 1,750,000 shares of common stock to an advisor. Subject to the Company's achievement of certain milestones or the approval of at least a majority of the holders of the outstanding Series A Preferred shares to waive such milestone conditions, investors committed to invest an additional \$20,648 from the sale of Series A Preferred Stock, to close no later than March 2015. If an investor fails to participate in the second round of the financing, the previously issued shares of Series A Preferred will automatically convert to shares of common stock on a 10-to-1 basis.

In December 2013, the holders of the outstanding Series A Preferred shares agreed to waive the milestone conditions that were previously required to close the second round of the financing. On December 18, 2013, the Company entered into an Amended and Restated Series A and A-1 Preferred Stock Purchase Agreement, whereby the Company sold 10,323,988 shares of Series A-1 Preferred Stock, par value \$0.001, at a price of \$1.00 per share and the 3% net sales distribution payment royalty agreement discussed below, resulting in aggregate proceeds of \$10,324, half of the \$20,648 noted above. The Company incurred \$63 of issuance costs with this financing. Subject to the Company's achievement of certain milestones or the approval of at least a majority of the holders of the outstanding Series A Preferred and Series A-1 Preferred shares to waive such milestone conditions, investors committed to invest the remaining \$10,324 from the sale of Series A-1 Preferred Stock, to close no later than December 31, 2014.

In connection with the closing of the second round on December 18, 2013, holders of Series A Preferred forfeited their right to receive a 2% net sales distribution payment. The 2% net sales distribution payment was replaced with a new, freestanding royalty agreement under which the original purchasers of the Series A-1 Preferred are entitled to receive a net sales distribution payment equal to 3% of net sales during the calendar year, discussed in Note 9. The 2% net sales distribution payment was an embedded right in the Series A Preferred. The forfeiture of this right resulted in an extinguishment of all 28,602,031 outstanding shares of Series A Preferred.

Immediately following the extinguishment, 28,602,031 shares of the Series A Preferred were reissued (without the right to the 2% net sales distribution payment) and recorded at their fair value of \$42,617 or \$1.49 per share. The 10,323,988 shares of Series A-1 Preferred were recorded at their fair value of \$14,454 or \$1.40 per share. The new 3% net sales distribution payment, accounted for as a freestanding financial instrument, has been recorded at its fair value of \$13,100 as a long-term liability in the accompanying consolidated balance sheet. As part of the extinguishment, the Company recorded a reduction of additional paid-in capital of \$28,000, representing the difference between the extinguished carrying value of Series A Preferred of \$31,910 and the fair value of the net consideration transferred to stockholders of \$59,910. The \$28,000 is also treated as a reduction of earnings attributable to common stockholders in the calculation of net income (loss) per share.

# Common Stock

# General

The voting, dividend and liquidation rights of the holders of shares of common stock are subject to and qualified by the rights, powers and preferences of the holders of shares of preferred stock. Common stock has the characteristics described herein.

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# Notes to Consolidated Financial Statements (In thousands, except share and per share data)

## Voting

The holders of shares of common stock are entitled to one vote for each share of common stock held at all meetings of stockholders and written actions in lieu of meetings provided however that except as otherwise required by law, holders of common stock shall not be entitled to vote on any amendment to the corporation's certificate of incorporation that relates solely to the terms of one or more outstanding series of preferred stock.

#### Dividends

The holders of shares of common stock are not entitled to receive dividends.

## Liquidation

After payment to the holders of shares of preferred stock of their liquidation preferences, the holders of shares of common stock are entitled to share ratably in the Company's assets available for distribution to stockholders in the event of any voluntary or involuntary liquidation, dissolution or winding up of the Company or upon the occurrence of a deemed liquidation event.

# Reserved for future issuance

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

	As of De	As of March 31,	
	2012	2013	2014 (unaudited)
Conversion of Series A Preferred	28,602,031	28,602,031	28,602,031
Conversion of Series A-1 Preferred	_	10,323,988	10,323,988
Vesting of restricted stock	61,095	127,444	127,444
Options to purchase common stock	2,797,253	5,287,144	2,981,190
Common stock warrant (equity)	1,750,000	1,750,000	1,750,000
Common stock warrants (liability)	516,841	516,841	516,841
Total	33,727,220	46,607,448	44,301,494

# **Convertible Redeemable Preferred Stock**

Since inception, the Company has issued several series of convertible redeemable preferred stock. From and after the date of issuance of any shares of convertible preferred stock, dividends accrue at a rate of eight percent (8.0%) per annum payable in cash or shares at the option of the holder, when and as declared by the Company's board of directors, but in no event later than upon the earliest to occur of (a) a voluntary or involuntary liquidation, dissolution or winding up of the Company, (b) a deemed liquidation event, or (c) a redemption. The holders of shares of the convertible preferred stock are entitled to receive dividends, if and when declared by the board of directors on a pari passu basis, out of any funds legally available and prior and in preference to dividends to any other holder of capital stock. Dividends payable on each share of convertible preferred stock is determined as if such share had been converted into shares of common stock. As of December 31, 2013, no dividends have been declared or paid since the Company's inception. The Company has recorded cumulative accrued dividends for the convertible preferred stock of \$1,742 as of December 31, 2012 and \$3,307 as of December 31, 2013 and March 31, 2014. The following describes each series of convertible redeemable preferred stock issued.

# Histogenics Corporation (A Development Stage Company)

Notes to Consolidated Financial Statements (In thousands, except share and per share data)

# 2005 Series A Convertible Redeemable Preferred Stock

On August 1, 2005, the Company exchanged 500 shares of common stock into 500 shares of Series A junior convertible preferred stock at \$15,000.00 ("2005 Series A"). On various dates in 2005, the Company sold 167 shares of 2005 Series A to an investor for aggregate proceeds of \$2,500. In 2006, upon the filing of the Certificate of Incorporation in Delaware, the Company extinguished the existing shares and reissued them deeming all accrued dividends no longer payable. Upon this transaction, the Company recalculated the fair value of the 2005 Series A to \$4,947.53. The 2005 Series A was recorded at this new value. On July 23, 2008, the 2005 Series A was converted to common stock as a part of the 2008 Series B Preferred issuance. All cumulative dividends in arrears were reduced to zero and liquidation preferences were extinguished.

## 2006 Series A-1 Convertible Redeemable Preferred Stock

On July 19, 2006, the Company issued 2,345 shares of 2006 Series A-1 Preferred at a purchase price of \$6,375.27 per share, resulting in proceeds of \$13,376, net of issuance costs of \$1,574. This issuance effected the conversion of the \$1,100 in promissory notes to 2006 Series A-1 Preferred. On July 19, 2008, in conjunction with the issuance of the 2008 Series B Preferred, the holders of 2006 Series A-1 Preferred received the right to the liquidation value of 1.5 times the invested total. In conjunction with this additional benefit, the Company recalculated the fair value per share of the 2006 Series A-1 Preferred as \$3,599.99. The 2006 Series A-1 Preferred was reissued to reflect this new value. In 2009, a holder of 2006 Series A-1 Preferred elected not to participate in a qualified financing round following the 2008 Series B financing, as required by the agreement, and was forced to convert their outstanding 2006 Series A-1 Preferred into common at approximately a 4:1 ratio. All cumulative dividends were reduced to zero and liquidation preferences were extinguished. On May 13, 2011, as part of the Company's recapitalization (described above), all outstanding shares of 2006 Series A-1 Preferred were converted to common stock. All cumulative dividends were reduced to zero and liquidation preferences were extinguished.

## 2008 Series B Convertible Redeemable Preferred Stock

On July 19, 2008, the Company issued 6,480 shares of 2008 Series B Preferred at a purchase price of \$1,390.12 per share, resulting in proceeds of \$8,129, net of issuance costs of \$879. This issuance effected the conversion of the \$3,010 in promissory notes to 2008 Series B Preferred. In 2009, a holder of 2008 Series B Preferred elected not to participate in a qualified financing round following the 2008 Series B financing, as required by the agreement, and was forced to convert their outstanding 2008 Series B Preferred into common at approximately a 4:1 ratio. All cumulative dividends were reduced to zero and liquidation preferences were extinguished. On May 13, 2011, as part of the Company's recapitalization (described above), the 2008 Series B was converted to common stock. All cumulative dividends were reduced to zero and liquidation preferences were extinguished.

## 2011 Series A Convertible Redeemable Preferred Stock

On May 13, 2011, in connection with and prior to the acquisition of ProChon, the Company consummated a recapitalization in which it, among other actions, converted the principal amount of \$14,387 of its outstanding convertible notes and accrued interest of \$1,584 into 10,724,321 shares of 2011 Series A Preferred, \$0.001 par value per share, net of issuance costs of \$441. Subsequent to the recapitalization, in connection with the acquisition of ProChon, the Company issued 5,362,172 shares of 2011 Series A Preferred with a fair value of \$0.2933 per share. On July 20, 2012, as part of the Company's 2012 recapitalization described above), the 2011 Series A Preferred was cancelled. All cumulative dividends were reduced to zero and liquidation preferences were extinguished.

# Histogenics Corporation (A Development Stage Company)

Notes to Consolidated Financial Statements (In thousands, except share and per share data)

# Series A Convertible Redeemable Preferred Stock

On July 20, 2012, the Company entered into a stock purchase agreement to raise up to \$49,000 through the sale of shares of a Series A Preferred, \$0.001 par value per share, at a purchase price per share of \$1.00 per share. In conjunction with the closing of the financing, the Company sold 22,652,031 shares for net proceeds of \$20,679. The stock purchase agreement contains a commitment by the purchasers to purchase the remaining available shares of the Series A Preferred upon the achievement of certain milestones ("Milestone") or the vote of at least a majority of the holders of the outstanding shares of Series A Preferred to waive the milestone conditions if not achieved prior to March 2015.

# Series A-1 Convertible Redeemable Preferred Stock

On December 18, 2013, the Company entered into an Amended and Restated Series A and A-1 Preferred Stock Purchase Agreement (the "Stock Purchase Agreement"), whereby the Company sold 10,323,988 shares of Series A-1 Preferred, par value \$0.001, at a price of \$1.00 per share, resulting in aggregate proceeds of \$10,324.

The general rights, preferences and privileges of the Series A Preferred and Series A-1 Preferred (collectively, the "Preferred Stock") are as follows:

## Voting

The holders of shares of Preferred Stock are entitled to the number of votes equal to the number of whole shares of common stock into which the shares of the applicable series of Preferred Stock held by such holder are convertible on any matter presented to the stockholders of the Company for their action or consideration at any meeting of stockholders of the Company or by written consent of stockholders in lieu of meetings. Except as provided by law or otherwise, the holders of shares of Preferred Stock vote together with the holders of shares of common stock as a single class.

#### Protective Provision

At any time when at least 9,700,000 shares of Preferred Stock are outstanding, a majority of preferred stockholders must approve any of a list of significant changes to the existing Company's structure and business, including (a) the liquidation, dissolution or winding up of the business or affairs of the Company, (b) any amendment to the Company's certificate of incorporation, (c) altering any existing security that is pari passu with the Preferred Stock, (d) incurring indebtedness outside the ordinary course of business, (e) granting any exclusive license relating to the Company's material technology or intellectual property other than in the ordinary course of business, (f) any increase or decrease in the number of directors or (g) any amendment to the Company's equity incentive plans.

# Dividends

From and after the date of issuance of any shares of Preferred Stock, dividends accrue at a rate per annum of eight percent (8.0%), payable in cash or in shares at the option of the holder, when and as declared by the board of directors but in no event later than upon the earliest to occur of (a) a voluntary or involuntary liquidation, dissolution or winding up of the Company, (b) a deemed liquidation event, or (c) a redemption. The holders of shares of Preferred Stock are entitled to receive dividends, if and when declared by the board of directors on a pari passu basis. Dividends payable on each share of preferred stock is determined as if such share had been converted into shares of common stock. As of December 31, 2013, no dividends have been declared or paid since the Company's inception.

# Histogenics Corporation (A Development Stage Company)

# Notes to Consolidated Financial Statements (In thousands, except share and per share data)

## Liquidation

In the event of any voluntary or involuntary liquidation, dissolution or winding up of the Company, the holders of the Preferred Stock then outstanding are entitled to be paid out of the assets of the Company available for distribution to stockholders an amount per share equal to \$1.00, plus any accrued but unpaid dividends.

#### Conversion

Each share of Preferred Stock is convertible at the option of the holder, at any time and from time to time, into fully paid and nonassessable shares of common stock as is determined by dividing the original issuance price, or \$1.00 by the then applicable conversion price.

Each share of Preferred Stock is automatically convertible into fully paid and nonassessable shares of common stock upon either: (a) the closing of the sale of shares of the Company's common stock to the public in an underwritten public offering resulting in at least \$30,000 of gross proceeds to the Company or (b) the date and time, or the occurrence of an event, specified by vote or written consent of the holders of shares constituting a majority of the then outstanding shares of Preferred Stock and the holders of shares constituting a majority of the then outstanding shares of Preferred Stock.

## Redemption

Shares of Preferred Stock shall be redeemed by the Company out of funds lawfully available at a price per share equal to the original issue price, plus any accrued but unpaid dividends, whether or not declared, and any accrued unpaid net sales distribution payments, described below, in three equal annual installments commencing at any time on or after July 20, 2016. If the Company does not have sufficient funds legally available to redeem all shares on the redemption date, the Company shall redeem a pro rata portion of each stockholder's Preferred Shares out of funds legally available, based on the respective amounts which would otherwise be payable if sufficient funds were available to redeem all shares.

#### 3% Net Sales Distribution Payment

Within 45 days of the end of each calendar year, the Company shall pay the Royalty Recipients a payment equal to, in the aggregate, 3% of net sales during such calendar year, which is the Net Sales Distribution Payment. The Net Sales Distribution Payment shall be distributed pro rata based on the percentages set forth in the freestanding royalty agreement entered into in connection with the closing of the December 18, 2013 financing previously discussed.

Net sales shall mean the gross amount received by the Company, its affiliates and their sub-licensees for sales of the Company's products less (a) intercompany sales, (b) amounts repaid or credited by reason of actual rejection or return of applicable products, (c) reasonable and customary trade, quantity or cash rebates or discounts to the extent allowed, (d) amounts for outbound transportation, insurance, handling or shipping, and (e) taxes, customs duties and other governmental charges levied on or measured by sales of products, as adjusted for rebates and refunds. If any product is sold for non-cash consideration, net sales shall be calculated based on the average non-discounted cash amount charged to independent third parties for the product during the same period in the same country or based upon the fair value of the product.

At the election of the Royalty Recipients, all or a portion of the net sales payments may be redeemed by the Company. The Royalty Recipients can elect to have each net sales percentage point redeemed for

# Histogenics Corporation (A Development Stage Company)

Notes to Consolidated Financial Statements (In thousands, except share and per share data)

\$10,000 payable in cash or the Company's common stock. If the Royalty Recipients choose to elect common stock, the fair value per share will be determined as follows: (a) if the Company is publicly-traded, the average of the 10-day trailing closing price, or (b) if not publicly-traded, the fair market value as determined by board of directors. The Royalty Recipients may exercise their redemption right any time after January 1, 2017 and prior to January 1, 2019, provided, however, that each election must be at least six months apart.

## 11. STOCK-BASED COMPENSATION

## **Restricted Stock Awards and Stock Options**

Until the Company's plan of recapitalization was executed in 2012, the Company operated two equity incentive plans: the 2001 Stock Option Plan and the 2006 Equity Incentive Plan. Both equity incentive plans provided for the grant of nonqualified stock options and restricted equity interests to employees, directors, consultants and advisors. In connection with the recapitalization of the Company's equity in 2011 (as discussed in Note 10), both plans were suspended and all options and restricted stock granted under the plans were cancelled or forfeited.

The Company adopted the 2012 Equity Incentive Plan, as amended ("2012 Plan") in July 2012 pursuant to which 5,883,847 shares of common stock are authorized for issuance to employees, officers, directors, consultants and advisors of the Company as of March 31, 2014, of which 2,734,625 are available for future issuance. The 2012 Plan provides for the grant of incentive stock options, nonstatutory 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, 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, 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 Equity Incentive Plan ("2013 Plan") in November 2013 and the Company expects its stockholders to approve the 2013 Plan prior to the completion of this offering. The 2013 Plan became effective immediately on adoption, although no awards will be made under it until the effective date of the registration statement. The 2013 Plan will replace the Company's 2012 Equity Incentive Plan ("2012 Plan"), and no further grants will be made under the 2012 Plan following completion of this offering. However, awards outstanding under the 2012 Plan will continue to be governed by their existing terms.

# Histogenics Corporation (A Development Stage Company)

# Notes to Consolidated Financial Statements (In thousands, except share and per share data)

Stock option activity under the 2001, 2006, and 2012 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 Inception (June 28, 2000)		<del>\$</del> —		<u></u>
Granted	140	5,400.00		
Exercised	_	_		
Cancelled	(140)	5,400.00		
Outstanding at December 31, 2011	_	_		
Granted	2,797,253	0.07		
Exercised	_	_		
Cancelled				
Outstanding at December 31, 2012	2,797,253	0.07	9.6	\$ 168
Granted	4,882,675	0.23		
Exercised	(25,314)	0.07		1
Cancelled	(2,367,470)	0.07		
Outstanding at December 31, 2013	5,287,144	0.28	9.4	2,844
Granted	_	_		
Exercised	_	_		
Cancelled	(2,305,954)	0.12		
Outstanding at March 31, 2014 (unaudited)	2,981,190	\$ 0.30	9.1	\$ 1,032
Vested and expected to vest at December 31, 2013	4,856,238	\$ 0.23	9.4	\$ 2,844
Vested and expected to vest at March 31, 2014 (unaudited)	2,153,691	\$ 0.30	9.0	\$ 948
Exercisable at December 31, 2013	1,038,950	\$ 0.07	9.0	\$ 779
Exercisable at March 31, 2014 (unaudited)	973,438	\$ 0.07	8.6	\$ 652

As of December 31, 2012, December 31, 2013 and March 31, 2014, the unrecognized compensation cost related to outstanding options was \$130, \$1,002 and \$939, respectively, and is expected to be recognized as expense over approximately 3.28 years, 3.21 years and 2.77 years, respectively.

As of March 31, 2014, the weighted average fair value of vested options was \$0.07.

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# Notes to Consolidated Financial Statements (In thousands, except share and per share data)

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

	As of Dec	As of		
	2012	2013	20	March 31, 2014 (unaudited)
Weighted-average grant date fair value per share of employee option grants	\$ 0.05	\$ 0.23	\$	0.16
Cash received upon exercise of options	_	2		_

Restricted stock awards under the 2001, 2006, and 2012 plans are summarized as follows:

	Number of Shares	Weighted-Average Grant Date Fair Value
Unvested at Inception (June 28, 2000)	<del></del>	\$ —
Sale of restricted stock	598	1,050.00
Vesting of restricted stock	(440)	1,050.00
Repurchase of restricted stock	(98)	1,050.00
Recapitalization of equity	(60)	1,050.00
Unvested at December 31, 2011		
Sale of restricted stock	61,095	0.07
Repurchase of restricted stock	<del>_</del>	_
Unvested at December 31, 2012	61,095	0.07
Sale of restricted stock	81,623	0.11
Vesting of restricted stock	(15,274)	0.05
Repurchase of restricted stock	<del>_</del>	_
Unvested at December 31, 2013	127,444	0.10
Sale of restricted stock	<u> </u>	_
Vesting of restricted stock	<del>_</del>	_
Repurchase of restricted stock	<del>_</del>	_
Unvested at March 31, 2014 (unaudited)	127,444	\$ 0.10

As of December 31, 2012, December 31, 2013 and March 31, 2014, the unrecognized compensation cost related to restricted stock awards was \$4, \$14 and \$10, respectively, and is expected to be recognized as expense over approximately 3.84 years, 3.14 years and 2.94 years, respectively.

# **Stock-Based Compensation Expense**

The Company granted stock options to employees for the years ended December 31, 2012 and 2013 and for the three months ended March 31, 2013. The Company did not grant any stock options for the three months ended March 31, 2014. 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.

# Histogenics Corporation (A Development Stage Company)

# Notes to Consolidated Financial Statements (In thousands, except share and per share data)

For all periods from inception to date, stock-based compensation for all options granted and restricted stock awards are classified as selling, general and administrative expense. Stock compensation expense amounted to \$14, \$158, \$10, \$76, \$593 and \$669 for the years ended December 31, 2012 and 2013, three months ended March 31, 2013 and 2014 and the period from June 28, 2000 (inception) to December 31, 2013 and March 31, 2014, respectively.

Stock-based compensation by award type is as follows:

		Ended ber 31,	 Three Mo Mar	nths Ende ch 31,	d	June (Ince	od from 28, 2000 ption) to mber 31,	June (Ince	od from 28, 2000 eption) to erch 31,
	2012	2013	 013 udited)		)14 ıdited)		2013	2	2014 audited)
Stock options	\$ 14	\$155	\$ 10	\$	7 <b>5</b>	\$	225	\$	300
Restricted stock	_	3	_		1		368		369
Total stock-based compensation expense	\$ 14	\$158	\$ 10	\$	76	\$	593	\$	669

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:

	Years ended Dec	Years ended December 31,		ded March 31,
	2012	2013	2013	2014
			(unaudited)	(unaudited)
Risk-free interest rate	0.93%	1.01%	0.89%	1.01%
Expected volatility	89.0%	87.9%	88.3%	87.9%
Expected term (in years)	6.08	5.36	5.92	5.36
Expected dividend yield	0.0%	0.0%	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, noting the Company had no non-employee stock options granted for the year ended December 31, 2012:

	Years ended D	Years ended December 31,		ded March 31,
	2012	2013	2013	2014
			(unaudited)	(unaudited)
Risk-free interest rate	_	0.23%	0.28%	0.57%
Expected volatility	_	145.2%	82.0%	109.9%
Expected term (in years)	_	0.98	1.73	2.13
Expected dividend yield	_	0.0%	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.

# Histogenics Corporation (A Development Stage Company)

# Notes to Consolidated Financial Statements (In thousands, except share and per share data)

**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 March 31, 2014 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. In 2013, some of the stock option grants were in-the-money, based on the retrospective fair value determinations, so the Company determined the expected life assumption using a risk-adjusted method, which adjusts the average of the contractual term of the option and its vesting period for risk, reducing the expected life.

**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.

## 12. INCOME TAXES

For the years ended December 31, 2012 and 2013, 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 D	December 31,
	2012	2013
U.S.	\$(15,607)	\$(24,930)
Foreign	(1,328)	(782)
Total	\$(16,935)	\$(25,712)

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 Decem	ber 31,
	2012	2013
Federal income tax (benefit) at statutory rate	34.0%	34.0%
(Increase) decrease income tax benefit resulting from:		
Limitations on utilization of net operating losses	(13.9%)	0.0%
Permanent differences	(13.2%)	(0.9%)
Change in valuation allowance	(6.2%)	(32.8%)
Other	(0.7%)	(0.3%)
Income tax expense (benefit)	(0.0%)	0.0%

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# Notes to Consolidated Financial Statements (In thousands, except share and per share data)

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 Dece	mber 31,
	2012	2013
Deferred tax assets:		
Net operating loss carryforwards	\$ 12,832	\$ 13,369
Depreciation and amortization	3,234	2,926
Capitalized license agreement	216	221
Accrued expenses	2,202	5,346
Capitalized start-up costs	_	5,576
Capitalized R&D	362	155
Other	_	39
Deferred tax assets before valuation allowance	18,846	27,632
Valuation allowance	(14,304)	(24,265)
	4,542	3,367
Deferred tax liabilities		
IPR&D	(149)	(144)
Cancellation of indebtedness income	(4,390)	_
Change in accounting method	_	(3,223)
Other	(3)	
	(4,542)	(3,367)
Net deferred tax assets	<u>\$ —</u>	<u>\$</u>

The Company has evaluated the positive and negative evidence bearing upon the realizability of its deferred tax assets. As of December 31, 2012 and 2013, 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, 2012 and 2013. The valuation allowance increased \$9,961 during the year ended December 31, 2013, due primarily to net operating losses generated and capitalized expenses. The valuation allowance increased by \$1,151 during the year ended December 31, 2012, due primarily to deductible temporary differences generated during the period partially offset by restrictions on the use of net operating loss ("NOL") carryforwards under Section 382 of the Code.

The Company has recorded a current net deferred tax liability of \$1,058 and a noncurrent net deferred tax asset of \$1,058 on its consolidated balance sheet as of December 31, 2013, and a current net deferred tax liability of \$2,480 and a noncurrent net deferred tax asset of \$2,480 as of December 31, 2012. The classification of deferred tax assets and liabilities is primarily related to the timing of the reversal of the deferred tax liability related to a change of accounting method in 2013 and income from intercompany debt forgiveness in Israel for 2012.

As of December 31, 2012 and 2013, the Company had U.S. federal NOL carryforwards of \$5,294 and \$17,116, respectively, which may be available to offset future income tax liabilities and expire at various dates through 2033. As of December 31, 2012 and 2013, the Company also had U.S. state NOL carryforwards of \$5,270 and \$17,078, respectively, which may be available to offset future income tax liabilities and expire at various dates

# Histogenics Corporation (A Development Stage Company)

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through 2033. At December 31, 2012 and 2013, the Company also had \$43,015 and \$26,586, 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, will expire unused. Accordingly, the Company has recorded NOL carryforwards net of these limitations, which are approximately \$3,872, \$30,471, \$36,726 and \$49,655 in 2010, 2011, 2012 and 2013 respectively.

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

	As of E	As of December 31,	
	2012	2013	
Unrecognized tax benefit, beginning of year	\$5,253	\$ 5,577	
Increase (decrease) related to current year positions	324	(46)	
Settlements		(4,596)	
Unrecognized tax benefit, end of year	\$5,577	\$ 935	

As of December 31, 2012 and 2013, the total amount of unrecognized tax benefits was \$5,577 and \$935, respectively. The uncertain tax positions giving rise to the unrecognized tax benefits relate primarily to methods of accounting, used in the Company's tax returns, which accelerated certain deductions for federal income tax purposes. The reversal of the unrecognized tax benefits would not have any impact on effective tax rates in future periods and are not expected to create cash tax liabilities upon settlement due to the Company's ability to utilize both pre-change and post-change NOLs. The Company believes that it is reasonably possible that \$136 of its unrecognized tax benefits may be recognized by the end of 2014.

The Company will recognize interest and penalties related to uncertain tax positions in income tax expense. As of December 31, 2012 and 2013, the Company had no accrued interest or penalties related to uncertain tax positions and no amounts have been recognized in the Company's consolidated statements of operations.

The Company files income tax returns in the United States, and various state and foreign jurisdictions. The federal, state and foreign income tax returns are generally subject to tax examinations for the tax years ended December 31, 2010 through December 31, 2013. To the extent the Company has tax attribute carryforwards, the tax years in which the attribute was generated may still be adjusted upon examination by the Internal Revenue Service, state or foreign tax authorities to the extent utilized in a future period.

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# Notes to Consolidated Financial Statements (In thousands, except share and per share data)

# 13. EMPLOYEE BENEFITS

Effective January 1, 2009, the Company adopted 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

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 made 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 \$250 of development costs on a next generation tissue processer. Refer to the discussion under *Tissue Processor Sub-License* in Note 7.

The amounts that have been paid to Purpose, Co. under this agreement were \$410, \$154, \$57, \$49, \$584 and \$633 for the years ended December 31, 2012 and 2013, the three months ended March 31, 2013 and 2014 and the period from June 28, 2000 (inception) to December 31, 2013 and March 31, 2014, respectively. At March 31, 2014, \$0 is due to Purpose, Co. for various maintenance services.

# Receivables due from stockholders

On various dates beginning in May 13, 2011, the Company issued promissory notes totaling \$12,000 to existing stockholders. The promissory notes bore interest of 8.0% per annum and converted upon the earliest of the consummation of the next round of financing for which proceeds are greater than \$27,000, the consummation of a deemed liquidation event, or May 1, 2012. Inflection Point Ventures II, LP, also a stockholder, participated in the purchase of \$59 these promissory notes. At December 31, 2011, it had executed its note purchase agreement, but had not remitted its funds. The funds were received by the Company on March 6, 2012.

On May 9, 2008, the Company terminated the employment of its Chief Executive Officer, who was also a stockholder. The Company was owed \$100 from this individual at the time of his termination from a promissory note that was accruing interest at 4.69% per annum. The terms of the former CEO's separation agreement forgave all outstanding principal and interest due under the promissory note.

# Histogenics Corporation (A Development Stage Company)

# Notes to Consolidated Financial Statements (In thousands, except share and per share data)

# 15. SUBSEQUENT EVENTS—ANNUAL

For the purposes of annual financial statements, the Company has completed an evaluation of all subsequent events through April 11, 2014, the date these consolidated financial statements are available to be issued.

#### Sublease

In January 2014, the Company entered into an agreement with a third party to sublease an additional facility in Waltham, Massachusetts. The term of the sublease extends from February 1, 2014 through July 30, 2015. The Company expects to make fixed rent payments of \$163 over the term of the sublease.

# Resignation of President, Chief Executive Officer and Director

Effective February 28, 2014, Peter Greenleaf resigned as the Company's president, chief executive officer and one of the Company's directors. His decision to resign did not involve any disagreement with the Company, its management or its board of directors. The Company is in the process of identifying and hiring a president and chief executive officer to succeed Mr. Greenleaf. The Company expects that any successor to Mr. Greenleaf will be appointed to the board as a Class II director. Mr. Greenleaf has agreed to continue as a consultant of the Company following his resignation to provide support during the transition period.

# 16. SUBSEQUENT EVENTS—INTERIM (UNAUDITED)

For the purposes of the unaudited interim financial statements, the Company has completed an evaluation of all subsequent events through July 11, 2014, the date these consolidated financial statements are available to be issued. The Company has concluded that no subsequent event has occurred that requires disclosure, except as noted below:

# Hiring of President, Chief Executive Officer and Director

Effective April 26, 2014, the Company hired a new president and chief executive officer, Adam Gridley, who will also serve as a member of the Company's board of directors. Mr. Gridley's commencement date of full time employment was May 12, 2014.

# **Technology Transfer Agreement**

On April 15, 2014, the Company entered into a technology transfer agreement for a non-transferrable, nonexclusive, non-sub-licensable, worldwide royalty free right and license to make Type 1 bovine collagen using a proprietary process. This agreement may only be terminated upon material breach of either party.

## **Issuance of Series A-1 Preferred Stock**

On May 27, 2014, the Company closed the third and final closing of the Amended and Restated Series A and A-1 Preferred Stock Purchase Agreement as the conditions required for this closing were met. As a result of this third closing, the Company issued 10,323,980 shares of Series A-1 preferred stock at a purchase price of \$1.00 per share, resulting in aggregate proceeds of \$10,324. The terms for this closing are the same as those described in Note 10, "Capital and Convertible Redeemable Preferred Stock" under the Series A-1 Convertible Redeemable Preferred Stock section.

# Lexington, Massachusetts Lease

In June 2014, the Company entered into a lease agreement to rent a facility in Lexington, Massachusetts. The commencement date of the lease is July 1, 2014 with a term that extends through May 30, 2023. Terms of the lease agreement 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 operating expenses.

# Histogenics Corporation (A Development Stage Company)

Notes to Consolidated Financial Statements (In thousands, except share and per share data)

# **Equipment Loan**

In July 2014, the Company entered into a loan and security agreement with Silicon Valley Bank for a loan to purchase equipment. The amount of the loan is \$1,750 and the equipment loan draw period extends from July 1, 2014 through the earlier to occur of (a) March 31, 2015, or (b) an event of default. The loan is payable in equal monthly installments of principal plus interest over 36 months beginning six months after the funding date. The interest rate is 2.75% above the prime rate, fixed at the time of the advance for the loan. In accordance with the terms of the loan, the Company granted Silicon Valley Bank a warrant to purchase 70,946 shares of common stock in connection with entering into the loan and security agreement.

# **Shares**



# Common Stock PROSPECTUS

Until , 2014, all dealers that effect transactions in these securities, whether or not participating in this offering, may be required to deliver a prospectus. This is in addition to the dealers' obligation to deliver a prospectus when acting as underwriters and with respect to their unsold allotments or subscriptions.

**Cowen and Company** 

**Needham & Company** 

**Roth Capital Partners** 

, 2014

#### PART II

## INFORMATION NOT REQUIRED IN THE PROSPECTUS

## Item 13. Other Expenses of Issuance and Distribution.

The following table presents the costs and expenses, other than underwriting discounts and commissions, payable in connection with the sale of common stock being registered. All amounts are estimates except the SEC registration fee, the FINRA filing fee and the exchange listing fee. Except as otherwise noted, all the expenses below will be paid by us.

SEC registration fee	*
FINRA filing fee	*
Exchange listing fee	*
Printing and engraving expenses	*
Legal fees and expenses	*
Accounting fees and expenses	*
Blue sky fees and expenses	*
Transfer agent and registrar fees	*
Miscellaneous fees and expenses	*
Total	*
	<del></del>

To be completed by amendment

## Item 14. Indemnification of Directors and Officers.

Sections 145 and 102(b)(7) of the General Corporation Law of the State of Delaware provide that a corporation may indemnify any person made a party to an action by reason of the fact that he or she was a director, officer, employee or agent of the corporation or is or was serving at the request of a corporation against expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by him or her in connection with such action if he or she acted in good faith and in a manner he or she reasonably believed to be in, or not opposed to, the best interests of the corporation and, with respect to any criminal action or proceeding, had no reasonable cause to believe his or her conduct was unlawful, except that, in the case of an action by or in right of the corporation, no indemnification may generally be made in respect of any claim as to which such person is adjudged to be liable to the corporation.

In connection with the completion of this offering, the Registrant's amended and restated certificate of incorporation will contain provisions that eliminate, to the maximum extent permitted by the General Corporation Law of the State of Delaware, the personal liability of the Registrant's directors for monetary damages for breach of their fiduciary duties as directors. The Registrant's amended and restated bylaws to be in effect immediately prior to the completion of this offering provide that the Registrant must indemnify its directors and officers and may indemnify its employees and other agents to the fullest extent permitted by the General Corporation Law of the State of Delaware.

The Registrant has entered into indemnification agreements with its directors and executive officers, in addition to the indemnification provided for in its amended and restated bylaws, and intends to enter into indemnification agreements with any new directors and executive officers in the future.

The Registrant has purchased and intends to maintain insurance on behalf of any person who is or was a director or officer of the Registrant against any loss arising from any claim asserted against him or her and incurred by him or her in any such capacity, subject to certain exclusions.

The Underwriting Agreement, the form of which is attached as Exhibit 1.1 hereto, provides for indemnification by the underwriters of the Registrant and its executive officers and directors, and by the Registrant of the

underwriters, for certain liabilities, including liabilities arising under the Securities Act and affords certain rights of contribution with respect thereto.

See also "Undertakings" set out in response to Item 17 herein.

# Item 15. Recent Sales of Unregistered Securities.

Set forth below is information regarding the shares of common stock and preferred stock and the warrant issued, and options granted, by us since July 11, 2011 that were not registered under the Securities Act of 1933.

- (1) Under the 2012 Equity Incentive Plan, we granted stock options to purchase shares of our common stock to certain of our employees, officers, consultants and advisors, as follows: (a) from August 15, 2012 to July 16, 2013, we granted stock options to purchase an aggregate of 5,391,806 shares of our common stock at an exercise price of \$0.07 per share; (b) on October 31, 2012, we issued 61,095 shares of restricted common stock at a price of \$0.001 per share; (c) on April 23, 2013, we issued 81,623 shares of restricted common stock at a price of \$0.001 per share; (d) on December 11, 2013, we granted stock options to purchase an aggregate of 1,353,211 shares of our common stock at an exercise price of \$0.66 per share; and (e) on April 30, 2014, we granted stock options to purchase an aggregate of 2,311,460 shares of our common stock at an exercise price of \$0.74 per share.
- (2) In 2012, we issued and sold an aggregate of 28,602,031 shares of Series A convertible preferred stock to investors for an aggregate purchase price of \$26.5 million, net of issuance costs.
- (3) In 2012, in connection with our Series A Financing, we issued warrants to investors and advisors exercisable for an aggregate of 2,266,841 shares of our common stock at a weighted average exercise price of \$0.0167 per share. These warrants are or will be exercisable upon the occurrence of certain defined events for an aggregate of up 2,266,841 shares of our common stock. These warrants terminate ten years after the date issued.
- (4) In December 2013, we issued and sold an aggregate of 10,323,988 shares of Series A-1 convertible preferred stock to investors for an aggregate purchase price of \$10.3 million.
- (5) In May 2014, we issued and sold an aggregate of 10,323,980 shares of Series A-1 convertible preferred stock for an aggregate purchase price of \$10.3 million.
- (6) In July 2014, in connection with entering into a loan and security agreement with Silicon Valley Bank, we issued a warrant to Silicon Valley Bank exercisable for an aggregate of 70,946 shares of our common stock, subject to certain adjustments, at an exercise price of \$0.74 per share. The warrant is immediately exercisable and terminates ten years after the date issued.

The offers, sales, grants and issuances of the securities described in paragraph (1) were deemed to be exempt from registration under the Securities Act in reliance on Rule 701. The recipients of such securities were our employees, officers, bona fide consultants and advisors and received the securities under our 2012 Equity Incentive Plan. Appropriate legends were affixed to the securities issued in these transactions. Each of the recipients of securities in these transactions had adequate access, through employment, business or other relationships, to information about us.

The offer, sale and issuance of the securities described in paragraphs (2) through (6) were deemed to be exempt from registration under the Securities Act in reliance on Section 4(a)(2) of the Securities Act in that the issuance of the securities to the accredited investors did not involve a public offering. The recipients of the securities in this transaction acquired the securities for investment only and not with a view to or for sale in connection with any distribution thereof, and appropriate legends were affixed to the securities issued in this transaction. The recipients of the securities in this transaction were accredited investors under Rule 501 of Regulation D.

# Item 16. Exhibits and Financial Statement Schedules.

<u>Exhibit</u>	<u>Description</u>
1.1*	Form of Underwriting Agreement
3.1‡	Fifth Amended and Restated Certificate of Incorporation, as amended (currently in effect)
3.2‡	Bylaws (currently in effect)
3.3‡	Form of Sixth Amended and Restated Certificate of Incorporation (to be effective immediately prior to the closing of this offering)
3.4‡	Form of Amended and Restated Bylaws (to be effective immediately prior to the closing of this offering)
4.1*	Specimen stock certificate evidencing the shares of common stock
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10.5+‡	Offer letter effective as of August 5, 2013 between the Registrant and Stephen Kennedy
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23.1*	Consent of Grant Thornton LLP, independent registered public accounting firm	
23.2*	Consent of Gunderson Dettmer Stough Villeneuve Franklin & Hachigian, LLP (included in Exhibit 5.1)	
24.1*	Power of Attorney (included on signature page)	

- \* To be filed by amendment.
- + Indicates management contract or compensatory plan.
- Portions of this exhibit (indicated by asterisks) have been omitted pursuant to a request for confidential treatment. The omitted portions of this exhibit have been filed with the SEC.
- ‡ Previously submitted.

# (b) Financial Statement Schedules

Schedules not listed above have been omitted because the information required to be set forth therein is not applicable or is shown in the financial statements or notes thereto.

## Item 17. Undertakings.

Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that, in the opinion of the SEC, such indemnification is against public policy as expressed in the Securities Act of 1933, and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act of 1933, and will be governed by the final adjudication of such issue.

The undersigned Registrant hereby undertakes to provide the underwriters, at the closing specified in the underwriting agreement, certificates in such denominations and registered in such names as required by the underwriters to permit prompt delivery to each purchaser.

The undersigned registrant hereby undertakes that:

- 1. For purposes of determining any liability under the Securities Act of 1933, the information omitted from a form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in the form of prospectus filed by the Registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act of 1933 shall be deemed to be part of this registration statement as of the time it was declared effective.
- 2. For the purpose of determining any liability under the Securities Act of 1933, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial *bona fide* offering thereof.
- 3. For the purpose of determining liability under the Securities Act to any purchaser, each prospectus filed pursuant to Rule 424(b) as part of a registration statement relating to an offering, other than registration statements relying on Rule 430B or other than prospectuses filed in reliance on Rule 430A, shall be deemed to be part of and included in the registration statement as of the date it is first used after effectiveness. Provided, however, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such first use, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such date of first use.
- 4. In a primary offering of securities of the undersigned registrant pursuant to this registration statement, regardless of the underwriting method used to sell the securities to the purchaser, if the securities are offered or sold to such purchaser by means of any of the following communications, the undersigned registrant will be a seller to the purchaser and will be considered to offer or sell such securities to such purchaser:
  - (1) Any preliminary prospectus or prospectus of the undersigned registrant relating to the offering required to be filed pursuant to Rule 424;
  - (2) Any free writing prospectus relating to the offering prepared by or on behalf of the undersigned registrant or used or referred to by the undersigned registrant;
  - (3) The portion of any other free writing prospectus relating to the offering containing material information about the undersigned registrant or its securities provided by or on behalf of the undersigned registrant; and
  - (4) Any other communication that is an offer in the offering made by the undersigned registrant to the purchaser.

### **SIGNATURES**

Pursuant to the requirements of the Securities Act of 1933, as amended, the registrant has duly caused this Registration Statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Waltham, Commonwealth of Massachusetts, on this day of , 2014.

### HISTOGENICS CORPORATION

By:	
Adam Gridley,	
Precident and Chief Executive Officer	

### SIGNATURES AND POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below hereby constitutes and appoints Adam Gridley and Kevin McArdle, and each of them, as his or her true and lawful attorney-in-fact and agent with full power of substitution, for him or her in any and all capacities, to sign any and all amendments to this registration statement (including post-effective amendments) and any registration statement related thereto filed pursuant to Rule 462(b) increasing the number of securities for which registration is sought, and to file the same, with all exhibits thereto and other documents in connection therewith, with the SEC, granting unto said attorney-in-fact and agent full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully for all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that said attorney-in-fact and agent, or his or her substitute, may lawfully do or cause to be done by virtue hereof.

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

<u>Signature</u>	Title	Date
Adam Gridley	Chief Executive Officer, President and Director (Principal Executive Officer)	
Kevin McArdle	Chief Financial Officer (Principal Financial and Accounting Officer)	
Garheng Kong, M.D., Ph.D.	Chairman of the Board	
Joshua Baltzell	Director	
John H. Johnson	Director	
Michael Lewis	Director	
Kevin Rakin	Director	

# EXHIBIT INDEX

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Portions of this exhibit (indicated by asterisks) have been omitted pursuant to a request for confidential treatment. The omitted portions of this exhibit have been filed with the SEC.

Previously submitted.

THIS WARRANT AND THE SHARES ISSUABLE HEREUNDER HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED (THE "ACT"), OR THE SECURITIES LAWS OF ANY STATE AND, EXCEPT AS SET FORTH IN SECTIONS 5.3 AND 5.4 BELOW, MAY NOT BE OFFERED, SOLD, PLEDGED OR OTHERWISE TRANSFERRED UNLESS AND UNTIL REGISTERED UNDER SAID ACT AND LAWS OR, IN THE OPINION OF LEGAL COUNSEL IN FORM AND SUBSTANCE SATISFACTORY TO THE ISSUER, SUCH OFFER, SALE, PLEDGE OR OTHER TRANSFER IS EXEMPT FROM SUCH REGISTRATION.

#### WARRANT TO PURCHASE STOCK

Company: Histogenics Corporation, a Delaware corporation

Number of Shares: 70,946, subject to adjustment

Type/Series of Stock: Common Stock, \$0.001 par value per share

**Warrant Price:** \$0.74 per Share, subject to adjustment

Issue Date: July 9, 2014

**Expiration Date:** July 8, 2024 **See also Section 5.1(b).** 

**Credit Facility:** This Warrant to Purchase Stock ("<u>Warrant</u>") is issued in connection with that certain Loan and Security Agreement of even date herewith between Silicon Valley Bank and the Company (as amended and/or modified and in effect from time to time, the "Loan Agreement").

THIS WARRANT CERTIFIES THAT, for good and valuable consideration, SILICON VALLEY BANK (together with any successor or permitted assignee or transferee of this Warrant or of any shares issued upon exercise hereof, "Holder") is entitled to purchase the number of fully paid and non-assessable shares (the "Shares") of the above-stated Type/Series of Stock (the "Class") of the above-named company (the "Company") at the above-stated Warrant Price, all as set forth above and as adjusted pursuant to Section 2 of this Warrant, subject to the provisions and upon the terms and conditions set forth in this Warrant. Reference is made to Section 5.4 of this Warrant whereby Silicon Valley Bank shall transfer this Warrant to its parent company, SVB Financial Group.

### SECTION 1. EXERCISE.

- 1.1 <u>Method of Exercise</u>. Holder may at any time and from time to time exercise this Warrant, in whole or in part, by delivering to the Company the original of this Warrant together with a duly executed Notice of Exercise in substantially the form attached hereto as Appendix 1 and, unless Holder is exercising this Warrant pursuant to a cashless exercise set forth in Section 1.2, a check, wire transfer of same-day funds (to an account designated by the Company), or other form of payment acceptable to the Company for the aggregate Warrant Price for the Shares being purchased.
- 1.2 <u>Cashless Exercise</u>. On any exercise of this Warrant, in lieu of payment of the aggregate Warrant Price in the manner as specified in Section 1.1 above, but otherwise in accordance with the requirements of Section 1.1, Holder may elect to receive Shares equal to the value of this Warrant, or portion hereof as to which this Warrant is being exercised. Thereupon, the Company shall issue to the Holder such number of fully paid and non-assessable Shares as are computed using the following formula:

X = Y(A-B)/A

#### where:

- X = the number of Shares to be issued to the Holder;
- Y = the number of Shares with respect to which this Warrant is being exercised (inclusive of the Shares surrendered to the Company in payment of the aggregate Warrant Price);
- A = the Fair Market Value (as determined pursuant to Section 1.3 below) of one Share; and
- B = the Warrant Price.
- 1.3 <u>Fair Market Value</u>. If shares of the Class are then traded or quoted on a nationally recognized securities exchange, inter-dealer quotation system or over-the-counter market (a "<u>Trading Market</u>"), the fair market value of a Share shall be the closing price or last sale price of a share of the Class reported for the Business Day immediately before the date on which Holder delivers this Warrant together with its Notice of Exercise to the Company. If shares of the Class are not then traded in a Trading Market, the Board of Directors of the Company shall determine the fair market value of a Share in its reasonable good faith judgment.
- 1.4 <u>Delivery of Certificate and New Warrant</u>. Within a reasonable time after Holder exercises this Warrant in the manner set forth in Section 1.1 or 1.2 above, the Company shall deliver to Holder a certificate representing the Shares issued to Holder upon such exercise and, if this Warrant has not been fully exercised and has not expired, a new warrant of like tenor representing the Shares not so acquired.
- 1.5 <u>Replacement of Warrant</u>. On receipt of evidence reasonably satisfactory to the Company of the loss, theft, destruction or mutilation of this Warrant and, in the case of loss, theft or destruction, on delivery of an indemnity agreement reasonably satisfactory in form, substance and amount to the Company or, in the case of mutilation, on surrender of this Warrant to the Company for cancellation, the Company shall, within a reasonable time, execute and deliver to Holder, in lieu of this Warrant, a new warrant of like tenor and amount.
  - 1.6 Treatment of Warrant Upon Acquisition of Company.
- (a) <u>Acquisition</u>. For the purpose of this Warrant, "<u>Acquisition</u>" means any transaction or series of related transactions involving: (i) the sale, lease, exclusive license, or other disposition of all or substantially all of the assets of the Company (ii) any merger or consolidation of the Company into or with another person or entity (other than a merger or consolidation effected exclusively to change the Company's domicile), or any other corporate reorganization, in which the stockholders of the Company in their capacity as such immediately prior to such merger, consolidation or reorganization, own less than a majority of the Company's (or the surviving or successor entity's) outstanding voting power immediately after such merger, consolidation or reorganization (or, if such Company stockholders beneficially own a majority of the outstanding voting power of the surviving or successor entity as of immediately after such merger, consolidation or reorganization, such surviving or successor entity is not the Company); or (iii) any sale or other transfer by the stockholders of the Company of shares representing at least a majority of the Company's then-total outstanding combined voting power.

- (b) Treatment of Warrant at Acquisition. In the event of an Acquisition in which the consideration to be received by the Company's stockholders consists solely of cash, solely of Marketable Securities or a combination of cash and Marketable Securities (a "Cash/Public Acquisition"), and the fair market value of one Share as determined in accordance with Section 1.3 above would be greater than the Warrant Price in effect on such date immediately prior to such Cash/Public Acquisition, and Holder has not exercised this Warrant pursuant to Section 1.1 above as to all Shares, then this Warrant shall automatically be deemed to be Cashless Exercised pursuant to Section 1.2 above as to all Shares effective immediately prior to and contingent upon the consummation of a Cash/Public Acquisition. In connection with such Cashless Exercise, Holder shall be deemed to have restated each of the representations and warranties in Section 4 of the Warrant as the date thereof and the Company shall promptly notify the Holder of the number of Shares (or such other securities) issued upon exercise. In the event of a Cash/Public Acquisition where the fair market value of one Share as determined in accordance with Section 1.3 above would be less than the Warrant Price in effect immediately prior to such Cash/Public Acquisition, then this Warrant will expire immediately prior to the consummation of such Cash/Public Acquisition.
- (c) Upon the closing of any Acquisition other than a Cash/Public Acquisition, the acquiring, surviving or successor entity shall assume the obligations of this Warrant, and this Warrant shall thereafter be exercisable for the same securities and/or other property as would have been paid for the Shares issuable upon exercise of the unexercised portion of this Warrant as if such Shares were outstanding on and as of the closing of such Acquisition, subject to further adjustment from time to time in accordance with the provisions of this Warrant.
- (d) As used in this Warrant, "Marketable Securities" means securities meeting all of the following requirements: (i) the issuer thereof is then subject to the reporting requirements of Section 13 or Section 15(d) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and is then current in its filing of all required reports and other information under the Act and the Exchange Act; (ii) the class and series of shares or other security of the issuer that would be received by Holder in connection with the Acquisition were Holder to exercise this Warrant on or prior to the closing thereof is then traded in Trading Market, and (iii) following the closing of such Acquisition, Holder would not be restricted from publicly re-selling all of the issuer's shares and/or other securities that would be received by Holder in such Acquisition were Holder to exercise this Warrant in full on or prior to the closing of such Acquisition, except to the extent that any such restriction (x) arises solely under federal or state securities laws, rules or regulations, and (y) does not extend beyond six (6) months from the closing of such Acquisition.

### SECTION 2. ADJUSTMENTS TO THE SHARES AND WARRANT PRICE.

2.1 <u>Stock Dividends, Splits, Etc.</u> If the Company declares or pays a dividend or distribution on the outstanding shares of the Class payable in additional shares of the Class or other securities or property (other than cash), then upon exercise of this Warrant, for each Share acquired, Holder shall receive, without additional cost to Holder, the total number and kind of securities and property which Holder would have received had Holder owned the Shares of record as of the date the dividend or distribution occurred. If the Company subdivides the outstanding shares of the Class by reclassification or otherwise into a greater number of shares, the number of Shares purchasable hereunder shall be proportionately increased and the Warrant Price shall be proportionately decreased. If the outstanding shares of the Class are combined or consolidated, by reclassification or otherwise, into

a lesser number of shares, the Warrant Price shall be proportionately increased and the number of Shares shall be proportionately decreased.

- 2.2 <u>Reclassification, Exchange, Combinations or Substitution</u>. Upon any event whereby all of the outstanding shares of the Class are reclassified, exchanged, combined, substituted, or replaced for, into, with or by Company securities of a different class and/or series, then from and after the consummation of such event, this Warrant will be exercisable for the number, class and series of Company securities that Holder would have received had the Shares been outstanding on and as of the consummation of such event, and subject to further adjustment thereafter from time to time in accordance with the provisions of this Warrant. The provisions of this Section 2.2 shall similarly apply to successive reclassifications, exchanges, combinations, substitutions, replacements or other similar events.
- 2.3 No Fractional Share. No fractional Share shall be issuable upon exercise of this Warrant and the number of Shares to be issued shall be rounded down to the nearest whole Share. If a fractional Share interest arises upon any exercise of the Warrant, the Company shall eliminate such fractional Share interest by paying Holder in cash the amount computed by multiplying the fractional interest by (i) the fair market value (as determined in accordance with Section 1.3 above) of a full Share, less (ii) the then-effective Warrant Price.
- 2.4 Notice/Certificate as to Adjustments. Upon each adjustment of the Warrant Price, Class and/or number of Shares, the Company, at the Company's expense, shall notify Holder in writing within a reasonable time setting forth the adjustments to the Warrant Price, Class and/or number of Shares and facts upon which such adjustment is based. The Company shall, upon written request from Holder, furnish Holder with a certificate of its Chief Financial Officer, including computations of such adjustment and the Warrant Price, Class and number of Shares in effect upon the date of such adjustment.

### SECTION 3. REPRESENTATIONS AND COVENANTS OF THE COMPANY.

- 3.1 <u>Representations and Warranties</u>. The Company represents and warrants to, and agrees with, the Holder as follows:
- (a) The initial Warrant Price referenced on the first page of this Warrant is not greater than the fair market value of a share of the Class as determined by the most recent to have occurred of (i) a valuation of the Company's stock for purposes of its compliance with Section 409A of the Internal Revenue Code of 1986, as amended, and (ii) a determination by the Company's Board of Directors in connection with the Company's grant of employee incentive stock options.
- (b) All Shares which may be issued upon the exercise of this Warrant shall, upon issuance, be duly authorized, validly issued, fully paid and non-assessable, and free of any liens and encumbrances except for restrictions on transfer provided for herein or under applicable federal and state securities laws. The Company covenants that it shall at all times cause to be reserved and kept available out of its authorized and unissued capital stock such number of shares of the Class and other securities as will be sufficient to permit the exercise in full of this Warrant.
  - (c) The Company's capitalization table attached hereto as Schedule 1 is true and complete, in all material respects, as of the Issue Date.

- 3.2 Notice of Certain Events. If the Company proposes at any time to:
- (a) declare any dividend or distribution upon the outstanding shares of the Class, whether in cash, property, stock, or other securities and whether or not a regular cash dividend;
- (b) offer for subscription or sale pro rata to the holders of the outstanding shares of the Class any additional shares of any class or series of the Company's stock (other than pursuant to contractual pre-emptive rights);
- (c) effect any reclassification, exchange, combination, substitution, reorganization or recapitalization of the outstanding shares of the Class:
  - (d) effect an Acquisition or to liquidate, dissolve or wind up; or
- (e) effect its initial, underwritten offering and sale of its securities to the public pursuant to an effective registration statement under the Act (the "IPO");

then, in connection with each such event, the Company shall give Holder:

- (1) in the case of the matters referred to in (a) and (b) above, at least seven (7) Business Days prior written notice of the earlier to occur of the effective date thereof or the date on which a record will be taken for such dividend, distribution, or subscription rights (and specifying the date on which the holders of outstanding shares of the Class will be entitled thereto) or for determining rights to vote, if any;
- (2) in the case of the matters referred to in (c) and (d) above at least seven (7) Business Days prior written notice of the date when the same will take place (and specifying the date on which the holders of outstanding shares of the Class will be entitled to exchange their shares for the securities or other property deliverable upon the occurrence of such event and such reasonable information as Holder may reasonably require regarding the treatment of this Warrant in connection with such event giving rise to the notice); and
- (3) with respect to the IPO, at least seven (7) Business Days prior written notice of the date on which the Company proposes to file its registration statement in connection therewith.

The Company will also provide information requested by Holder that is reasonably necessary to enable Holder to comply with Holder's accounting or reporting requirements.

### SECTION 4. REPRESENTATIONS, WARRANTIES OF THE HOLDER.

The Holder represents and warrants to the Company as follows:

4.1 <u>Purchase for Own Account</u>. This Warrant and the Shares to be acquired upon exercise of this Warrant by Holder are being acquired for investment for Holder's account, not as a nominee or agent, and not with a view to the public resale or distribution within the meaning of the Act. Holder also represents that it has not been formed for the specific purpose of acquiring this Warrant or the Shares.

- 4.2 <u>Disclosure of Information</u>. Holder is aware of the Company's business affairs and financial condition and has received or has had full access to all the information it considers necessary or appropriate to make an informed investment decision with respect to the acquisition of this Warrant and its underlying securities. Holder further has had an opportunity to ask questions and receive answers from the Company regarding the terms and conditions of the offering of this Warrant and its underlying securities and to obtain additional information (to the extent the Company possessed such information or could acquire it without unreasonable effort or expense) necessary to verify any information furnished to Holder or to which Holder has access.
- 4.3 <u>Investment Experience</u>. Holder understands that the purchase of this Warrant and its underlying securities involves substantial risk. Holder has experience as an investor in securities of companies in the development stage and acknowledges that Holder can bear the economic risk of such Holder's investment in this Warrant and its underlying securities and has such knowledge and experience in financial or business matters that Holder is capable of evaluating the merits and risks of its investment in this Warrant and its underlying securities and/or has a preexisting personal or business relationship with the Company and certain of its officers, directors or controlling persons of a nature and duration that enables Holder to be aware of the character, business acumen and financial circumstances of such persons.
  - 4.4 Accredited Investor Status. Holder is an "accredited investor" within the meaning of Regulation D promulgated under the Act.
- 4.5 The Act. Holder understands that this Warrant and the Shares issuable upon exercise hereof have not been registered under the Act in reliance upon a specific exemption therefrom, which exemption depends upon, among other things, the bona fide nature of the Holder's investment intent as expressed herein. Holder understands that this Warrant and the Shares issued upon any exercise hereof must be held indefinitely unless subsequently registered under the Act and qualified under applicable state securities laws, or unless exemption from such registration and qualification are otherwise available. Holder is aware of the provisions of Rule 144 promulgated under the Act.
  - 4.6 No Voting Rights. Holder, as a Holder of this Warrant, will not have any voting rights until the exercise of this Warrant.

### SECTION 5. MISCELLANEOUS.

- 5.1 Term; Automatic Cashless Exercise Upon Expiration.
- (a) <u>Term</u>. Subject to the provisions of Section 1.6 above, this Warrant is exercisable in whole or in part at any time and from time to time on or before 6:00 PM, Pacific time, on the Expiration Date and shall be void thereafter.
- (b) <u>Automatic Cashless Exercise upon Expiration</u>. In the event that, upon the Expiration Date, the fair market value of one Share as determined in accordance with Section 1.3 above is greater than the Warrant Price in effect on such date, then this Warrant shall automatically be deemed on and as of such date to be exercised pursuant to Section 1.2 above as to all Shares for which it shall not previously have been exercised, and the Company shall, within a reasonable time, deliver a certificate representing the Shares issued upon such exercise to Holder.

5.2 Legends. Each certificate evidencing Shares shall be imprinted with a legend in substantially the following form:

THE SHARES EVIDENCED BY THIS CERTIFICATE HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED (THE "ACT"), OR THE SECURITIES LAWS OF ANY STATE AND, EXCEPT AS SET FORTH IN THAT CERTAIN WARRANT TO PURCHASE STOCK ISSUED BY THE ISSUER TO SILICON VALLEY BANK DATED JULY \_\_, 2014, MAY NOT BE OFFERED, SOLD, PLEDGED OR OTHERWISE TRANSFERRED UNLESS AND UNTIL REGISTERED UNDER SAID ACT AND LAWS OR, IN THE OPINION OF LEGAL COUNSEL IN FORM AND SUBSTANCE SATISFACTORY TO THE ISSUER, SUCH OFFER, SALE, PLEDGE OR OTHER TRANSFER IS EXEMPT FROM SUCH REGISTRATION.

- 5.3 <u>Compliance with Securities Laws on Transfer</u>. This Warrant and the Shares issued upon exercise of this Warrant may not be transferred or assigned in whole or in part except in compliance with applicable federal and state securities laws by the transferor and the transferee (including, without limitation, the delivery of investment representation letters and legal opinions reasonably satisfactory to the Company, as reasonably requested by the Company). The Company shall not require Holder to provide an opinion of counsel if the transfer is to SVB Financial Group (Silicon Valley Bank's parent company) or any other affiliate of Holder, provided that any such transferee is an "accredited investor" as defined in Regulation D promulgated under the Act. Additionally, the Company shall also not require an opinion of counsel if there is no material question as to the availability of Rule 144 promulgated under the Act.
- 5.4 <u>Transfer Procedure</u>. After receipt by Silicon Valley Bank of the executed Warrant, Silicon Valley Bank will transfer all of this Warrant to its parent company, SVB Financial Group. By its acceptance of this Warrant, SVB Financial Group hereby makes to the Company each of the representations and warranties set forth in Section 4 hereof and agrees to be bound by all of the terms and conditions of this Warrant as if the original Holder hereof. Subject to the provisions of Section 5.3 and upon providing the Company with written notice, SVB Financial Group and any subsequent Holder may transfer all or part of this Warrant or the Shares issued upon exercise of this Warrant to any transferee, provided, however, in connection with any such transfer, SVB Financial Group or any subsequent Holder will give the Company notice of the portion of the Warrant and/or Shares being transferred with the name, address and taxpayer identification number of the transferee and Holder will surrender this Warrant to the Company for reissuance to the transferee(s) (and Holder if applicable); and provided further, that any subsequent transferee other than SVB Financial Group shall agree in writing with the Company to be bound by all of the terms and conditions of this Warrant. Notwithstanding any contrary provision herein, at all times prior to the IPO, Holder may not, without the Company's prior written consent, transfer this Warrant or any portion hereof, or any Shares issued upon any exercise hereof, to any person or entity who directly competes with the Company, except in connection with an Acquisition of the Company by such a direct competitor.
- 5.5 <u>Notices</u>. All notices and other communications hereunder from the Company to the Holder, or vice versa, shall be deemed delivered and effective (i) when given personally, (ii) on the third (3<sup>rd</sup>) Business Day after being mailed by first-class registered or certified mail, postage prepaid, (iii) upon actual receipt if given by facsimile or electronic mail and such receipt is confirmed in writing by the recipient, or (iv) on the first Business Day following delivery to a reliable overnight courier

service, courier fee prepaid, in any case at such address as may have been furnished to the Company or Holder, as the case may be, in writing by the Company or such Holder from time to time in accordance with the provisions of this Section 5.5. All notices to Holder shall be addressed as follows until the Company receives notice of a change of address in connection with a transfer or otherwise:

SVB Financial Group Attn: Treasury Department 3003 Tasman Drive, HC 215 Santa Clara, CA 95054 Telephone: (408) 654-7400 Facsimile: (408) 988-8317

Email address: <a href="mailto:derivatives@svb.com">derivatives@svb.com</a>

Notice to the Company shall be addressed as follows until Holder receives notice of a change in address:

Histogenics Corporation Attn: Chief Financial Officer 830 Winter Street, 3<sup>rd</sup> Floor Waltham, MA 02451 Telephone: Facsimile:

Email:

With a copy (which shall not constitute notice) to:

Gunderson Dettmer Stough Villeneuve Franklin & Hachigian, LLP Attn: Marc Dupre
One Marina Park Drive, Suite 900
Boston, MA 02210
Telephone:
Facsimile:
Email:

- 5.6 <u>Waiver</u>. This Warrant and any term hereof may be changed, waived, discharged or terminated (either generally or in a particular instance and either retroactively or prospectively) only by an instrument in writing signed by the party against which enforcement of such change, waiver, discharge or termination is sought.
- 5.7 <u>Attorneys' Fees</u>. In the event of any dispute between the parties concerning the terms and provisions of this Warrant, the party prevailing in such dispute shall be entitled to collect from the other party all costs incurred in such dispute, including reasonable attorneys' fees.
- 5.8 <u>Counterparts</u>; <u>Facsimile/Electronic Signatures</u>. This Warrant may be executed in counterparts, all of which together shall constitute one and the same agreement. Any signature page delivered electronically or by facsimile shall be binding to the same extent as an original signature page with regards to any agreement subject to the terms hereof or any amendment thereto.

- 5.9 <u>Governing Law</u>. This Warrant shall be governed by and construed in accordance with the laws of the State of California, without giving effect to its principles regarding conflicts of law.
- 5.10 <u>Headings</u>. The headings in this Warrant are for purposes of reference only and shall not limit or otherwise affect the meaning of any provision of this Warrant.
  - 5.11 Business Days. "Business Day" is any day that is not a Saturday, Sunday or a day on which Silicon Valley Bank is closed.

[Remainder of page left blank intentionally]
[Signature page follows]

IN WITNESS WHEREOF, the parties have caused this Warrant to Purchase Stock to be executed by their duly authorized representatives effective as of the Issue Date written above.

## "COMPANY"

# HISTOGENICS CORPORATION

By: /s/ Kevin McArdle

Name: Kevin McArdle

(Print)

Title: Chief Financial Officer

"HOLDER"

SILICON VALLEY BANK

By: /s/ Matthew Griffiths

Name: Matthew Griffiths

(Print)

Title: Vice President

## APPENDIX 1

# NOTICE OF EXERCISE

	The undersigned Holder hereby exercises its right to purchase shares of apany") in accordance with the attached Warrant To Purchase Stock, and tender				
	□ check in the amount of \$ payable to order of the Company enclosed herewith				
	Wire transfer of immediately available funds to the Company's account				
	Cashless Exercise pursuant to Section 1.2 of the Warrant				
	Other [Describe]				
2. P	lease issue a certificate or certificates representing the Shares in the name speci	rified below:			
	Holder's Name				
	Holder 5 Name				
	(Address)				
3. By its execution below and for the benefit of the Company, Holder hereby restates each of the representations and warranties in Section 4 of the Warrant to Purchase Stock as of the date hereof.					
		HOLDER:			
		By:			
		Name:			
		(Date):			

Appendix 1

SCHEDULE 1

# **Company Capitalization Table**

See attached

Schedule 1

# HISTOGENICS CORPORATION

# 2013 EQUITY INCENTIVE PLAN

(AS ADOPTED ON NOVEMBER 13, 2013)

# HISTOGENICS CORPORATION 2013 EQUITY INCENTIVE PLAN

### ARTICLE 1. INTRODUCTION.

The Board adopted the Plan to become effective immediately, although no Awards may be granted prior to the Registration Date. The purpose of the Plan is to promote the long-term success of the Company and the creation of stockholder value by (a) encouraging Service Providers to focus on critical long-range corporate objectives, (b) encouraging the attraction and retention of Service Providers with exceptional qualifications and (c) linking Service Providers directly to stockholder interests through increased stock ownership. The Plan seeks to achieve this purpose by providing for Awards in the form of Options (which may constitute ISOs or NSOs), SARs, Restricted Shares, Stock Units and Performance Cash Awards.

### ARTICLE 2. ADMINISTRATION.

- **2.1 General**. The Plan may be administered by the Board or one or more Committees. Each Committee shall have the authority and be responsible for such functions as have been assigned to it.
- **2.2 Section 162(m)**. To the extent an Award is intended to qualify as "performance-based compensation" within the meaning of Code Section 162(m), the Plan will be administered by a Committee of two or more "outside directors" within the meaning of Code Section 162(m).
- **2.3 Section 16.** To the extent desirable to qualify transactions hereunder as exempt under Exchange Act Rule 16b-3, the transactions contemplated hereunder will be approved by the entire Board or a Committee of two or more "non-employee directors" within the meaning of Exchange Act Rule 16b-3.
- **2.4 Powers of Administrator**. Subject to the terms of the Plan, and in the case of a Committee, subject to the specific duties delegated to the Committee, the Administrator shall have the authority to (a) select the Service Providers who are to receive Awards under the Plan, (b) determine the type, number, vesting requirements and other features and conditions of such Awards, (c) determine whether and to what extent any Performance Goals have been attained, (d) interpret the Plan and Awards granted under the Plan, (e) make, amend and rescind rules relating to the Plan and Awards granted under the Plan, including rules relating to sub-plans established for the purposes of satisfying applicable foreign laws or for qualifying for favorable tax treatment under applicable foreign laws, (f) impose such restrictions, conditions or limitations as it determines appropriate as to the timing and manner of any resales by a Participant of any Common Shares issued pursuant to an Award, including restrictions under an insider trading policy and restrictions as to the use of a specified brokerage firm for such resales, and (g) make all other decisions relating to the operation of the Plan and Awards granted under the Plan.

- **2.5 Effect of Administrator's Decisions**. The Administrator's decisions, determinations and interpretations shall be final and binding on all Participants and any other holders of Awards.
- **2.6 Governing Law**. The Plan shall be governed by, and construed in accordance with, the laws of the State of Delaware (except its choice-of-law provisions).

### ARTICLE 3. SHARES AVAILABLE FOR GRANTS.

- **3.1 Basic Limitation**. Common Shares issued pursuant to the Plan may be authorized but unissued shares or treasury shares. The aggregate number of Common Shares issued under the Plan shall not exceed the sum of (a) 5,600,000 Common Shares (subject to adjustment pursuant to a stock split to be effected prior to the IPO Date), (b) the number of Common Shares reserved under the Predecessor Plan that are not issued or subject to outstanding awards under the Predecessor Plan on the Registration Date, (c) any Common Shares subject to outstanding options under the Predecessor Plan on the Registration Date that subsequently expire or lapse unexercised and Common Shares issued pursuant to awards granted under the Predecessor Plans that are outstanding on the Registration Date and that are subsequently forfeited to or repurchased by the Company and (d) the additional Common Shares described in Articles 3.2 and 3.3; provided, however, that no more than 5,460,682 Common Shares (subject to adjustment pursuant to a stock split to be effected prior to the IPO Date), in the aggregate, shall be added to the Plan pursuant to clauses (b) and (c). The number of Common Shares that are subject to Stock Awards outstanding at any time under the Plan may not exceed the number of Common Shares that then remain available for issuance under the Plan. The numerical limitations in this Article 3.1 shall be subject to adjustment pursuant to Article 9.
- **3.2 Annual Increase in Shares**. As of the first business day of each fiscal year of the Company during the term of the Plan, commencing on January 1, 2015, the aggregate number of Common Shares that may be issued under the Plan shall automatically increase by a number equal to the least of (a) 3.5% of the total number of Common Shares outstanding on December 31 of the prior year, (b) subject to adjustment under Article 9, 1,960,000 Common Shares (subject to adjustment pursuant to a stock split to be effected prior to the IPO Date), or (c) a number of Common Shares determined by the Board.
- **3.3 Shares Returned to Reserve.** To the extent that Options, SARs or Stock Units granted under this Plan are forfeited or expire for any other reason before being exercised or settled in full, the Common Shares subject to such Options, SARs or Stock Units shall again become available for issuance under the Plan. If SARs are exercised, then only the number of Common Shares (if any) actually issued to the Participant in settlement of such SARs shall reduce the number available under Article 3.1 and the balance shall again become available for issuance under the Plan. If Stock Units are settled, then only the number of Common Shares (if any) actually issued to the Participant in settlement of such Stock Units shall reduce the number available under Article 3.1 and the balance shall again become available for issuance under the Plan. If Restricted Shares or Common Shares issued upon the exercise of Options or otherwise under the Plan are reacquired by the Company pursuant to a forfeiture provision, repurchase right or for any other reason prior to the shares having become vested, then such Common Shares shall again become available for issuance under the Plan. Common Shares applied to pay

the Exercise Price of Options or to satisfy tax withholding obligations related to any Award shall again become available for issuance under the Plan. To the extent that an Award is settled in cash rather than Common Shares, the cash settlement shall not reduce the number of Shares available for issuance under the Plan.

**3.4 Awards Not Reducing Share Reserve in Article 3.1.** Any dividend equivalents paid or credited under the Plan with respect to Stock Units shall not be applied against the number of Common Shares that may be issued under the Plan, whether or not such dividend equivalents are converted into Stock Units. In addition, Common Shares subject to Substitute Awards granted by the Company shall not reduce the number of Common Shares that may be issued under Article 3.1, nor shall shares subject to Substitute Awards again be available for Awards under the Plan in the event of any forfeiture, expiration or cash settlement of such Substitute Awards.

### **3.5 Code Section 162(m) and 422 Limits**. Subject to adjustment in accordance with Article 9:

- (a) The aggregate number of Common Shares subject to Options and SARs that may be granted under this Plan during any calendar year to any one Participant shall not exceed 500,000 Common Shares (subject to adjustment pursuant to a stock split to be effected prior to the IPO Date), except that the Company may grant to a new Employee in the calendar year in which his or her Service as an Employee first commences Options and/or SARs that cover (in the aggregate) up to an additional 500,000 Common Shares (subject to adjustment pursuant to a stock split to be effected prior to the IPO Date);
- (b) The aggregate number of Common Shares subject to Restricted Share awards and Stock Units that may be granted under this Plan during any calendar year to any one Participant shall not exceed 500,000 Shares (subject to adjustment pursuant to a stock split to be effected prior to the IPO Date), except that the Company may grant to a new Employee in the calendar year in which his or her Service as an Employee first commences Restricted Share awards and Stock Units that cover (in the aggregate) up to an additional 500,000 Common Shares (subject to adjustment pursuant to a stock split to be effected prior to the IPO Date);
- (c) No Participant shall be paid more than \$1 million in cash in any calendar year pursuant to Performance Cash Awards granted under the Plan; and
- (d) No more than 11,060,682 Common Shares (subject to adjustment pursuant to a stock split to be effected prior to the IPO Date) plus the additional Common Shares described in Article 3.2 may be issued under the Plan upon the exercise of ISOs.

### **ARTICLE 4. ELIGIBILITY.**

**4.1 Incentive Stock Options**. Only Employees who are common-law employees of the Company, a Parent or a Subsidiary shall be eligible for the grant of ISOs. In addition, an Employee who owns more than 10% of the total combined voting power of all classes of outstanding stock of the Company or any of its Parents or Subsidiaries shall not be eligible for the grant of an ISO unless the additional requirements set forth in Code Section 422(c)(5) are satisfied.

**4.2 Other Awards**. Awards other than ISOs may only be granted to Service Providers.

### ARTICLE 5. OPTIONS.

- **5.1 Stock Option Agreement**. Each grant of an Option under the Plan shall be evidenced by a Stock Option Agreement between the Optionee and the Company. Such Option shall be subject to all applicable terms of the Plan and may be subject to any other terms that are not inconsistent with the Plan. The Stock Option Agreement shall specify whether the Option is intended to be an ISO or an NSO. The provisions of the various Stock Option Agreements entered into under the Plan need not be identical.
- **5.2 Number of Shares**. Each Stock Option Agreement shall specify the number of Common Shares subject to the Option, which number shall adjust in accordance with Article 9.
- **5.3 Exercise Price**. Each Stock Option Agreement shall specify the Exercise Price, which shall not be less than 100% of the Fair Market Value of a Common Share on the date of grant. The preceding sentence shall not apply to an Option that is a Substitute Award granted in a manner that would satisfy the requirements of Code Section 409A and, if applicable, Code Section 424(a).
- **5.4 Exercisability and Term.** Each Stock Option Agreement shall specify the date or event when all or any installment of the Option is to become vested and/or exercisable. The Stock Option Agreement shall also specify the term of the Option; provided that, except to the extent necessary to comply with applicable foreign law, the term of an Option shall in no event exceed 10 years from the date of grant. A Stock Option Agreement may provide for accelerated vesting and/or exercisability upon certain specified events and may provide for expiration prior to the end of its term in the event of the termination of the Optionee's Service.
- **5.5 Death of Optionee**. After an Optionee's death, any vested and exercisable Options held by such Optionee may be exercised by his or her beneficiary or beneficiaries. Each Optionee may designate one or more beneficiaries for this purpose by filing the prescribed form with the Company. A beneficiary designation may be changed by filing the prescribed form with the Company at any time before the Optionee's death. If no beneficiary was designated or if no designated beneficiary survives the Optionee, then any vested and exercisable Options held by the Optionee may be exercised by his or her estate.
- **5.6 Modification or Assumption of Options**. Within the limitations of the Plan, the Administrator may modify, reprice, extend or assume outstanding options or may accept the cancellation of outstanding options (whether granted by the Company or by another issuer) in return for the grant of new Options for the same or a different number of shares and at the same or a different exercise price or in return for the grant of a different type of Award. The foregoing notwithstanding, no modification of an Option shall, without the consent of the Optionee, impair his or her rights or obligations under such Option.
- **5.7 Buyout Provisions**. The Administrator may at any time (a) offer to buy out for a payment in cash or cash equivalents an Option previously granted or (b) authorize an Optionee to

elect to cash out an Option previously granted, in either case at such time and based upon such terms and conditions as the Administrator shall establish.

- **5.8 Payment for Option Shares**. The entire Exercise Price of Common Shares issued upon exercise of Options shall be payable in cash or cash equivalents at the time when such Common Shares are purchased. In addition, the Administrator may, in its sole discretion and to the extent permitted by applicable law, accept payment of all or a portion of the Exercise Price through any one or a combination of the following forms or methods:
- (a) Subject to any conditions or limitations established by the Administrator, by surrendering, or attesting to the ownership of, Common Shares that are already owned by the Optionee with a Fair Market Value on the date of surrender equal to the aggregate exercise price of the Common Shares as to which such Option will be exercised;
- (b) By delivering (on a form prescribed by the Company) an irrevocable direction to a securities broker approved by the Company to sell all or part of the Common Shares being purchased under the Plan and to deliver all or part of the sales proceeds to the Company;
  - (c) Subject to such conditions and requirements as the Administrator may impose from time to time, through a net exercise procedure;
  - (d) By delivering a full-recourse promissory note, on such terms approved by the Administrator; or
  - (e) Through any other form or method consistent with applicable laws, regulations and rules.

### ARTICLE 6. STOCK APPRECIATION RIGHTS.

- **6.1 SAR Agreement**. Each grant of a SAR under the Plan shall be evidenced by a SAR Agreement between the Optionee and the Company. Such SAR shall be subject to all applicable terms of the Plan and may be subject to any other terms that are not inconsistent with the Plan. The provisions of the various SAR Agreements entered into under the Plan need not be identical.
- **6.2 Number of Shares**. Each SAR Agreement shall specify the number of Common Shares to which the SAR pertains, which number shall adjust in accordance with Article 9.
- **6.3** Exercise Price. Each SAR Agreement shall specify the Exercise Price, which shall in no event be less than 100% of the Fair Market Value of a Common Share on the date of grant. The preceding sentence shall not apply to a SAR that is a Substitute Award granted in a manner that would satisfy the requirements of Code Section 409A.
- **6.4 Exercisability and Term**. Each SAR Agreement shall specify the date when all or any installment of the SAR is to become vested and exercisable. The SAR Agreement shall also specify the term of the SAR; provided that except to the extent necessary to comply with applicable foreign law, the term of a SAR shall not exceed 10 years from the date of grant. A

SAR Agreement may provide for accelerated vesting and exercisability upon certain specified events and may provide for expiration prior to the end of its term in the event of the termination of the Optionee's Service.

- **6.5 Exercise of SARs**. Upon exercise of a SAR, the Optionee (or any person having the right to exercise the SAR after his or her death) shall receive from the Company (a) Common Shares, (b) cash or (c) a combination of Common Shares and cash, as the Administrator shall determine. The amount of cash and/or the Fair Market Value of Common Shares received upon exercise of SARs shall, in the aggregate, not exceed the amount by which the Fair Market Value (on the date of surrender) of the Common Shares subject to the SARs exceeds the Exercise Price. If, on the date when a SAR expires, the Exercise Price is less than the Fair Market Value on such date but any portion of such SAR has not been exercised or surrendered, then such SAR shall automatically be deemed to be exercised as of such date with respect to such portion. A SAR Agreement may also provide for an automatic exercise of the SAR on an earlier date.
- **6.6 Death of Optionee**. After an Optionee's death, any vested and exercisable SARs held by such Optionee may be exercised by his or her beneficiary or beneficiaries. Each Optionee may designate one or more beneficiaries for this purpose by filing the prescribed form with the Company. A beneficiary designation may be changed by filing the prescribed form with the Company at any time before the Optionee's death. If no beneficiary was designated or if no designated beneficiary survives the Optionee, then any vested and exercisable SARs held by the Optionee at the time of his or her death may be exercised by his or her estate.
- **6.7 Modification or Assumption of SARs**. Within the limitations of the Plan, the Administrator may modify, reprice, extend or assume outstanding SARs or may accept the cancellation of outstanding SARs (whether granted by the Company or by another issuer) in return for the grant of new SARs for the same or a different number of shares and at the same or a different exercise price or in return for the grant of a different type of Award. The foregoing notwithstanding, no modification of a SAR shall, without the consent of the Optionee, impair his or her rights or obligations under such SAR.

### ARTICLE 7. RESTRICTED SHARES.

- **7.1 Restricted Stock Agreement**. Each grant of Restricted Shares under the Plan shall be evidenced by a Restricted Stock Agreement between the recipient and the Company. Such Restricted Shares shall be subject to all applicable terms of the Plan and may be subject to any other terms that are not inconsistent with the Plan. The provisions of the various Restricted Stock Agreements entered into under the Plan need not be identical.
- **7.2 Payment for Awards**. Restricted Shares may be sold or awarded under the Plan for such consideration as the Administrator may determine, including (without limitation) cash, cash equivalents, property, cancellation of other equity awards, full-recourse promissory notes, past services and future services, and such other methods of payment as are permitted by applicable law.
- **7.3 Vesting Conditions**. Each Award of Restricted Shares may or may not be subject to vesting and/or other conditions as the Administrator may determine. Vesting shall occur, in

full or in installments, upon satisfaction of the conditions specified in the Restricted Stock Agreement. Such conditions, at the Administrator's discretion, may include one or more Performance Goals. A Restricted Stock Agreement may provide for accelerated vesting upon certain specified events.

**7.4 Voting and Dividend Rights**. The holders of Restricted Shares awarded under the Plan shall have the same voting, dividend and other rights as the Company's other stockholders, unless the Administrator otherwise provides. A Restricted Stock Agreement, however, may require that any cash dividends paid on Restricted Shares (a) be accumulated and paid when such Restricted Shares vest, or (b) be invested in additional Restricted Shares. Such additional Restricted Shares shall be subject to the same conditions and restrictions as the shares subject to the Stock Award with respect to which the dividends were paid. In addition, unless the Administrator provides otherwise, if any dividends or other distributions are paid in Common Shares, such Common Shares shall be subject to the same restrictions on transferability and forfeitability as the Restricted Shares with respect to which they were paid.

#### ARTICLE 8. STOCK UNITS.

- **8.1 Stock Unit Agreement.** Each grant of Stock Units under the Plan shall be evidenced by a Stock Unit Agreement between the recipient and the Company. Such Stock Units shall be subject to all applicable terms of the Plan and may be subject to any other terms that are not inconsistent with the Plan. The provisions of the various Stock Unit Agreements entered into under the Plan need not be identical.
- **8.2 Payment for Awards**. To the extent that an Award is granted in the form of Stock Units, no cash consideration shall be required of the Award recipients.
- **8.3 Vesting Conditions**. Each Award of Stock Units may or may not be subject to vesting, as determined by the Administrator. Vesting shall occur, in full or in installments, upon satisfaction of the conditions specified in the Stock Unit Agreement. Such conditions, at the Administrator's discretion, may include one or more Performance Goals. A Stock Unit Agreement may provide for accelerated vesting upon certain specified events.
- **8.4 Voting and Dividend Rights**. The holders of Stock Units shall have no voting rights. Prior to settlement or forfeiture, Stock Units awarded under the Plan may, at the Administrator's discretion, provide for a right to dividend equivalents. Such right entitles the holder to be credited with an amount equal to all cash dividends paid on one Common Share while the Stock Unit is outstanding. Dividend equivalents may be converted into additional Stock Units. Settlement of dividend equivalents may be made in the form of cash, in the form of Common Shares, or in a combination of both. Prior to distribution, any dividend equivalents shall be subject to the same conditions and restrictions as the Stock Units to which they attach.
- **8.5 Form and Time of Settlement of Stock Units.** Settlement of vested Stock Units may be made in the form of (a) cash, (b) Common Shares or (c) any combination of both, as determined by the Administrator. The actual number of Stock Units eligible for settlement may be larger or smaller than the number included in the original Award, based on predetermined performance factors, including Performance Goals. Methods of converting Stock Units into cash

may include (without limitation) a method based on the average Fair Market Value of Common Shares over a series of trading days. Vested Stock Units shall be settled in such manner and at such time(s) as specified in the Stock Unit Agreement. Until an Award of Stock Units is settled, the number of such Stock Units shall be subject to adjustment pursuant to Article 9.

- **8.6 Death of Recipient**. Any Stock Units that become payable after the recipient's death shall be distributed to the recipient's beneficiary or beneficiaries. Each recipient of Stock Units under the Plan may designate one or more beneficiaries for this purpose by filing the prescribed form with the Company. A beneficiary designation may be changed by filing the prescribed form with the Company at any time before the Award recipient's death. If no beneficiary was designated or if no designated beneficiary survives the Award recipient, then any Stock Units that become payable after the recipient's death shall be distributed to the recipient's estate.
- **8.7 Modification or Assumption of Stock Units.** Within the limitations of the Plan, the Administrator may modify or assume outstanding stock units or may accept the cancellation of outstanding stock units (whether granted by the Company or by another issuer) in return for the grant of new Stock Units for the same or a different number of shares or in return for the grant of a different type of Award. The foregoing notwithstanding, no modification of a Stock Unit shall, without the consent of the Participant, impair his or her rights or obligations under such Stock Unit.
- **8.8 Creditors' Rights**. A holder of Stock Units shall have no rights other than those of a general creditor of the Company. Stock Units represent an unfunded and unsecured obligation of the Company, subject to the terms and conditions of the applicable Stock Unit Agreement.

### ARTICLE 9. ADJUSTMENTS; DISSOLUTIONS AND LIQUIDATIONS; CORPORATE TRANSACTIONS.

- **9.1 Adjustments**. In the event of a subdivision of the outstanding Common Shares, a declaration of a dividend payable in Common Shares or a combination or consolidation of the outstanding Common Shares (by reclassification or otherwise) into a lesser number of Common Shares, corresponding proportionate adjustments shall automatically be made in each of the following:
  - (a) The number and kind of shares available for issuance under Article 3, including the numerical share limits in Articles 3.1, 3.2 and 3.5;
  - (b) The number and kind of shares covered by each outstanding Option, SAR and Stock Unit; and
  - (c) The Exercise Price applicable to each outstanding Option and SAR, and the repurchase price, if any, applicable to Restricted Shares.

In the event of a declaration of an extraordinary dividend payable in a form other than Common Shares in an amount that has a material effect on the price of Common Shares, a recapitalization, a spin-off or a similar occurrence, the Administrator shall make such adjustments as it, in its sole

discretion, deems appropriate in one or more of the foregoing. Any adjustment in the number of and kind of shares subject to an Award under this Article 9.1 shall be rounded down to the nearest whole share, although the Administrator in its sole discretion may make a cash payment in lieu of a fractional share. Except as provided in this Article 9, a Participant shall have no rights by reason of any issuance by the Company of stock of any class or securities convertible into stock of any class, any subdivision or consolidation of shares of stock of any class, the payment of any stock dividend or any other increase or decrease in the number of shares of stock of any class.

- **9.2 Dissolution or Liquidation**. To the extent not previously exercised or settled, Options, SARs and Stock Units shall terminate immediately prior to the dissolution or liquidation of the Company.
- **9.3 Corporate Transactions**. In the event that the Company is a party to a merger, consolidation, or a Change in Control (other than one described in Article 14.6(d)), all Common Shares acquired under the Plan and all Awards outstanding on the effective date of the transaction shall be treated in the manner described in the definitive transaction agreement (or, in the event the transaction does not entail a definitive agreement to which the Company is party, in the manner determined by the Administrator, with such determination having final and binding effect on all parties), which agreement or determination need not treat all Awards (or portions thereof) in an identical manner. Unless an Award Agreement provides otherwise, the treatment specified in the transaction agreement or by the Administrator shall include (without limitation) one or more of the following with respect to each outstanding Award:
  - (a) The continuation of such outstanding Awards by the Company (if the Company is the surviving entity);
- (b) The assumption of such outstanding Awards by the surviving entity or its parent, provided that the assumption of an Option or a SAR shall comply with applicable tax requirements;
- (c) The substitution by the surviving entity or its parent of an equivalent award for outstanding Awards (including, but not limited to, an award to acquire the same consideration paid to the holders of Common Shares in the transaction), provided that the substitution of an Option or a SAR shall comply with applicable tax requirements;
- (d) The cancellation of outstanding Options and SARs without payment of any consideration. The Optionees shall be able to exercise such Options and SARs (to the extent the Options and SARs are vested or become vested as of the effective date of the transaction) during a period of not less than five full business days preceding the closing date of the transaction, unless (i) a shorter period is required to permit a timely closing of the transaction and (ii) such shorter period still offers the Optionees a reasonable opportunity to exercise such Options and SARs. Any exercise of such Options and SARs during such period may be contingent on the closing of the transaction;
- (e) Full exercisability of outstanding Options and SARs and full vesting of the Common Shares subject to Options and SARs, followed by cancellation of such Options and

SARs. The full exercisability of such Options and SARs and full vesting of such Common Shares may be contingent on the closing of the transaction. The Optionees shall be able to exercise such Options and SARs during a period of not less than five full business days preceding the closing date of such merger or consolidation, unless (i) a shorter period is required to permit a timely closing of such merger or consolidation and (ii) such shorter period still offers the Optionees a reasonable opportunity to exercise such Options and SARs. Any exercise of such Options and SARs during such period may be contingent on the closing of such merger or consolidation;

- (f) The cancellation of the Options and SARs and a payment to the Optionee with respect to each Share subject to the portion of the Award that is vested as of the transaction date equal to the excess of (A) the value, as determined by the Administrator in its absolute discretion, of the property (including cash) received by the holder of a Common Share as a result of the transaction, over (B) the per-share Exercise Price of the Option or SAR (such excess, the "Spread"). Such payment shall be made in the form of cash, cash equivalents, or securities of the surviving entity or its parent having a value equal to the Spread. In addition, any escrow, holdback, earn-out or similar provisions in the transaction agreement may apply to such payment to the same extent and in the same manner as such provisions apply to the holders of Common Shares, but only to the extent the application of such provisions does not adversely affect the status of the Option or SAR as exempt from Code Section 409A. If the Spread applicable to an Option or SAR is zero or a negative number, then the Option or SAR may be cancelled without making a payment to the Optionee;
- (g) The cancellation of outstanding Stock Units and a payment to the holder thereof with respect to each Common Share subject to the Stock Unit (whether or not such Stock Unit is then vested) equal to the value, as determined by the Administrator in its absolute discretion, of the property (including cash) received by the holder of a Common Share as a result of the transaction (the "Transaction Value"). Such payment shall be made in the form of cash, cash equivalents, or securities of the surviving entity or its parent having a value equal to the Transaction Value. In addition, such payment may be subject to vesting based on the Participant's continuing Service, provided that the vesting schedule shall not be less favorable to the Participant than the schedule under which such Stock Units would have vested, and if required under applicable tax rules, such payment may be deferred until the settlement date specified in the Stock Unit Agreement. In addition, any escrow, holdback, earn-out or similar provisions in the transaction agreement may apply to such payment to the same extent and in the same manner as such provisions apply to the holders of Common Shares. In the event that a Stock Unit is subject to Code Section 409A, the payment described in this clause (g) shall be made on the settlement date specified in the applicable Stock Unit Agreement, provided that settlement may be accelerated in accordance with Treasury Regulation Section 1.409A-3(j)(4); or
- (h) The assignment of any reacquisition or repurchase rights held by the Company in respect of an Award of Restricted Shares to the surviving entity or its parent, with corresponding proportionate adjustments made to the price per share to be paid upon exercise of any such reacquisition or repurchase rights.

For avoidance of doubt, the Administrator shall have the discretion, exercisable either at the time an Award is granted or at any time while the Award remains outstanding, to provide for the acceleration of vesting upon the occurrence of a Change in Control, whether or not the Award is to be assumed or replaced in the transaction, or in connection with a termination of the Participant's Service following a transaction.

Any action taken under this Article 9.3 shall either preserve an Award's status as exempt from Code Section 409A or comply with Code Section 409A.

#### ARTICLE 10. OTHER AWARDS.

**10.1 Performance Cash Awards**. A Performance Cash Award is a cash award that may be granted subject to the attainment of specified Performance Goals during a Performance Period. A Performance Cash Award may also require the completion of a specified period of continuous Service. The length of the Performance Period, the Performance Goals to be attained during the Performance Period, and the degree to which the Performance Goals have been attained shall be determined conclusively by the Administrator. Each Performance Cash Award shall be set forth in a written agreement or in a resolution duly adopted by the Administrator which shall contain provisions determined by the Administrator and not inconsistent with the Plan. The terms of various Performance Cash Awards need not be identical.

**10.2 Awards Under Other Plans**. The Company may grant awards under other plans or programs. Such awards may be settled in the form of Common Shares issued under this Plan. Such Common Shares shall be treated for all purposes under the Plan like Common Shares issued in settlement of Stock Units and shall, when issued, reduce the number of Common Shares available under Article 3.

#### ARTICLE 11. LIMITATION ON RIGHTS.

- **11.1 Retention Rights**. Neither the Plan nor any Award granted under the Plan shall be deemed to give any individual a right to remain a Service Provider. The Company and its Parents, Subsidiaries and Affiliates reserve the right to terminate the Service of any Service Provider at any time, with or without cause, subject to applicable laws, the Company's certificate of incorporation and by-laws and a written employment agreement (if any).
- 11.2 Stockholders' Rights. Except as set forth in Article 7.4 or 8.4 above, a Participant shall have no dividend rights, voting rights or other rights as a stockholder with respect to any Common Shares covered by his or her Award prior to the time when a stock certificate for such Common Shares is issued or, if applicable, the time when he or she becomes entitled to receive such Common Shares by filing any required notice of exercise and paying any required Exercise Price. No adjustment shall be made for cash dividends or other rights for which the record date is prior to such time, except as expressly provided in the Plan.
- **11.3 Regulatory Requirements**. Any other provision of the Plan notwithstanding, the obligation of the Company to issue Common Shares under the Plan shall be subject to all applicable laws, rules and regulations and such approval by any regulatory body as may be required. The Company reserves the right to restrict, in whole or in part, the delivery of Common Shares pursuant to any Award prior to the satisfaction of all legal requirements relating

to the issuance of such Common Shares, to their registration, qualification or listing or to an exemption from registration, qualification or listing. The inability of the Company to obtain authority from any regulatory body having jurisdiction, which authority is deemed necessary by the Company's counsel to be necessary to the lawful issuance and sale of any Common Shares hereunder, will relieve the Company of any liability in respect of the failure to issue or sell such Common Shares as to which such requisite authority will not have been obtained.

- 11.4 Transferability of Awards. The Administrator may, in its sole discretion, permit transfer of an Award in a manner consistent with applicable law. Unless otherwise determined by the Administrator, Awards shall be transferable by a Participant only by (a) beneficiary designation, (b) a will or (c) the laws of descent and distribution. An ISO may only be transferred by will or by the laws of descent and distribution and may be exercised during the lifetime of the Optionee only by the Optionee or by the Optionee's guardian or legal representative.
- 11.5 Other Conditions and Restrictions on Common Shares. Any Common Shares issued under the Plan shall be subject to such forfeiture conditions, rights of repurchase, rights of first refusal, other transfer restrictions and such other terms and conditions as the Administrator may determine. Such conditions and restrictions shall be set forth in the applicable Award Agreement and shall apply in addition to any restrictions that may apply to holders of Common Shares generally. In addition, Common Shares issued under the Plan shall be subject to such conditions and restrictions imposed either by applicable law or by Company policy, as adopted from time to time, designed to ensure compliance with applicable law or laws with which the Company determines in its sole discretion to comply including in order to maintain any statutory, regulatory or tax advantage.

#### ARTICLE 12. TAXES.

- **12.1 General**. As a condition to an Award under the Plan, a Participant or his or her successor shall make arrangements satisfactory to the Company for the satisfaction of any federal, state, local or foreign withholding tax obligations that arise in connection with any Award granted under the Plan. The Company shall not be required to issue any Common Shares or make any cash payment under the Plan until such obligations are satisfied.
- 12.2 Share Withholding. To the extent that applicable law subjects a Participant to tax withholding obligations, the Administrator may permit such Participant to satisfy all or part of such obligations by having the Company withhold all or a portion of any Common Shares that otherwise would be issued to him or her or by surrendering all or a portion of any Common Shares that he or she previously acquired. Such Common Shares shall be valued at their Fair Market Value on the date when they are withheld or surrendered. Any payment of taxes by assigning Common Shares to the Company may be subject to restrictions including any restrictions required by SEC, accounting or other rules.
- **12.3 Section 162(m) Matters**. The Administrator, in its sole discretion, may determine whether an Award is intended to qualify as "performance-based compensation" within the meaning of Code Section 162(m). The Administrator may grant Awards that are based on Performance Goals but that are not intended to qualify as performance-based compensation.

With respect to any Award that is intended to qualify as performance-based compensation, the Administrator shall designate the Performance Goal(s) applicable to, and the formula for calculating the amount payable under, an Award within 90 days following commencement of the applicable Performance Period (or such earlier time as may be required under Code Section 162(m)), and in any event at a time when achievement of the applicable Performance Goal(s) remains substantially uncertain. Prior to the payment of any Award that is intended to constitute performance-based compensation, the Administrator shall certify in writing whether and the extent to which the Performance Goal(s) were achieved for such Performance Period. The Administrator shall have the right to reduce or eliminate (but not to increase) the amount payable under an Award that is intended to constitute performance-based compensation.

12.4 Section 409A Matters. Except as otherwise expressly set forth in an Award Agreement, it is intended that Awards granted under the Plan either be exempt from, or comply with, the requirements of Code Section 409A. To the extent an Award is subject to Code Section 409A (a "409A Award"), the terms of the Plan, the Award and any written agreement governing the Award shall be interpreted to comply with the requirements of Code Section 409A so that the Award is not subject to additional tax or interest under Code Section 409A, unless the Administrator expressly provides otherwise. A 409A Award shall be subject to such additional rules and requirements as specified by the Administrator from time to time in order for it to comply with the requirements of Code Section 409A. In this regard, if any amount under a 409A Award is payable upon a "separation from service" to an individual who is considered a "specified employee" (as each term is defined under Code Section 409A), then no such payment shall be made prior to the date that is the earlier of (i) six months and one day after the Participant's separation from service or (ii) the Participant's death, but only to the extent such delay is necessary to prevent such payment from being subject to Code Section 409A(a)(1).

**12.5 Limitation on Liability**. Neither the Company nor any person serving as Administrator shall have any liability to a Participant in the event an Award held by the Participant fails to achieve its intended characterization under applicable tax law.

### ARTICLE 13. FUTURE OF THE PLAN.

- **13.1 Term of the Plan**. The Plan, as set forth herein, shall become effective on the Registration Date. The Plan shall remain in effect until the earlier of (a) the date when the Plan is terminated under Article 13.2 or (b) the 10th anniversary of the date when the Board adopted the Plan.
- **13.2 Amendment or Termination**. The Board may, at any time and for any reason, amend or terminate the Plan. No Awards shall be granted under the Plan after the termination thereof. The termination of the Plan, or any amendment thereof, shall not affect any Award previously granted under the Plan.
- **13.3 Stockholder Approval**. An amendment of the Plan shall be subject to the approval of the Company's stockholders only to the extent required by applicable laws, regulations or rules.

### **ARTICLE 14. DEFINITIONS.**

- 14.1 "Administrator" means the Board or any Committee administering the Plan in accordance with Article 2.
- 14.2 "Affiliate" means any entity other than a Subsidiary, if the Company and/or one or more Subsidiaries own not less than 50% of such entity.
- 14.3 "Award" means any award granted under the Plan, including as an Option, a SAR, a Restricted Share, a Stock Unit or a Performance Cash Award.
- 14.4 "Award Agreement" means a Stock Option Agreement, an SAR Agreement, a Restricted Stock Agreement, a Stock Unit Agreement or such other agreement evidencing an Award granted under the Plan.
  - 14.5 "Board" means the Company's Board of Directors, as constituted from time to time.

#### 14.6 "Change in Control" means:

- (a) Any "person" (as such term is used in Sections 13(d) and 14(d) of the Exchange Act) becomes the "beneficial owner" (as defined in Rule 13d-3 of the Exchange Act), directly or indirectly, of securities of the Company representing more than fifty percent (50%) of the total voting power represented by the Company's then-outstanding voting securities;
  - (b) The consummation of the sale or disposition by the Company of all or substantially all of the Company's assets;
- (c) The consummation of a merger or consolidation of the Company with or into any other entity, other than a merger or consolidation which would result in the voting securities of the Company outstanding immediately prior thereto continuing to represent (either by remaining outstanding or by being converted into voting securities of the surviving entity or its parent) more than fifty percent (50%) of the total voting power represented by the voting securities of the Company or such surviving entity or its parent outstanding immediately after such merger or consolidation; or
- (d) Individuals who are members of the Board (the "**Incumbent Board**") cease for any reason to constitute at least a majority of the members of the Board over a period of 12 months; provided, however, that if the appointment or election (or nomination for election) of any new Board member was approved or recommended by a majority vote of the members of the Incumbent Board then still in office, such new member shall, for purposes of this Plan, be considered as a member of the Incumbent Board.

A transaction shall not constitute a Change in Control if its sole purpose is to change the state of the Company's incorporation or to create a holding company that will be owned in substantially the same proportions by the persons who held the Company's securities immediately before such transaction. In addition, if a Change in Control constitutes a payment event with respect to any Award which provides for a deferral of compensation and is subject to Code Section 409A, then

notwithstanding anything to the contrary in the Plan or applicable Award Agreement the transaction with respect to such Award must also constitute a "change in control event" as defined in Treasury Regulation Section 1.409A-3(i)(5) to the extent required by Code Section 409A.

- 14.7 "Code" means the Internal Revenue Code of 1986, as amended.
- 14.8 "Committee" means a committee of one or more members of the Board, or of other individuals satisfying applicable laws, appointed by the Board to administer the Plan.
  - 14.9 "Common Share" means one share of the common stock of the Company.
  - 14.10 "Company" means Histogenics Corporation, a Delaware corporation.
- 14.11 "**Consultant**" means a consultant or adviser who provides *bona fide* services to the Company, a Parent, a Subsidiary or an Affiliate as an independent contractor and who qualifies as a consultant or advisor under Instruction A.1.(a)(1) of Form S-8 under the Securities Act of 1933, as amended.
  - 14.12 "Employee" means a common-law employee of the Company, a Parent, a Subsidiary or an Affiliate.
  - 14.13 "Exchange Act" means the Securities Exchange Act of 1934, as amended.
- 14.14 "Exercise Price," in the case of an Option, means the amount for which one Common Share may be purchased upon exercise of such Option, as specified in the applicable Stock Option Agreement. "Exercise Price," in the case of a SAR, means an amount, as specified in the applicable SAR Agreement, which is subtracted from the Fair Market Value of one Common Share in determining the amount payable upon exercise of such SAR.
- 14.15 "Fair Market Value" means the closing price of a Common Share on any established stock exchange or a national market system on the applicable date or, if the applicable date is not a trading day, on the last trading day prior to the applicable date, as reported in a source that the Administrator deems reliable. If Common Shares are no longer traded on an established stock exchange or a national market system, the Fair Market Value shall be determined by the Administrator in good faith on such basis as it deems appropriate. The Administrator's determination shall be conclusive and binding on all persons.
  - 14.16 "ISO" means an incentive stock option described in Code Section 422(b).
  - 14.17 "NSO" means a stock option not described in Code Sections 422 or 423.
  - 14.18 "Option" means an ISO or NSO granted under the Plan and entitling the holder to purchase Common Shares.
  - 14.19 "Optionee" means an individual or estate holding an Option or SAR.

- 14.20 "Outside Director" means a member of the Board who is not an Employee.
- 14.21 "Parent" means any corporation (other than the Company) in an unbroken chain of corporations ending with the Company, if each of the corporations other than the Company owns stock possessing 50% or more of the total combined voting power of all classes of stock in one of the other corporations in such chain. A corporation that attains the status of a Parent on a date after the adoption of the Plan shall be considered a Parent commencing as of such date.
  - 14.22 "Participant" means an individual or estate holding an Award.
  - 14.23 "Performance Cash Award" means an award of cash granted under Article 10.1 of the Plan.
- 14.24 "Performance Goal" means a goal established by the Administrator for the applicable Performance Period based on one or more of the performance criteria set forth in Appendix A. Depending on the performance criteria used, a Performance Goal may be expressed in terms of overall Company performance or the performance of a business unit, division, Subsidiary, Affiliate or an individual. A Performance Goal may be measured either in absolute terms or relative to the performance of one or more comparable companies or one or more relevant indices. The Administrator may adjust the results under any performance criterion to exclude any of the following events that occurs during a Performance Period: (a) asset write-downs, (b) litigation, claims, judgments or settlements, (c) the effect of changes in tax laws, accounting principles or other laws or provisions affecting reported results, (d) accruals for reorganization and restructuring programs, (e) extraordinary, unusual or non-recurring items, (f) exchange rate effects for non-U.S. dollar denominated net sales and operating earnings, or (g) statutory adjustments to corporate tax rates; provided, however, that if an Award is intended to qualify as "performance-based compensation" within the meaning of Code Section 162(m), such adjustment(s) shall only be made to the extent consistent with Code Section 162(m).
- 14.25 "**Performance Period**" means a period of time selected by the Administrator over which the attainment of one or more Performance Goals will be measured for the purpose of determining a Participant's right to a Performance Cash Award or an Award of Restricted Shares or Stock Units that vests based on the achievement of Performance Goals. Performance Periods may be of varying and overlapping duration, at the discretion of the Administrator.
  - 14.26 "Plan" means this Histogenics Corporation 2013 Equity Incentive Plan, as amended from time to time.
  - 14.27 "Predecessor Plan" means the Company's 2012 Equity Incentive Plan, as amended.
- 14.28 "**Registration Date**" means the effective date of the registration statement filed by the Company with the Securities and Exchange Commission pursuant to Form S-1.
  - 14.29 "Restricted Share" means a Common Share awarded under the Plan.

- 14.30 "**Restricted Stock Agreement**" means the agreement between the Company and the recipient of a Restricted Share that contains the terms, conditions and restrictions pertaining to such Restricted Share.
  - 14.31 "SAR" means a stock appreciation right granted under the Plan.
- 14.32 "SAR Agreement" means the agreement between the Company and an Optionee that contains the terms, conditions and restrictions pertaining to his or her SAR.
  - 14.33 "Service" means service as an Employee, Outside Director or Consultant.
  - 14.34 "Service Provider" means any individual who is an Employee, Outside Director or Consultant.
  - 14.35 "Stock Award" means any award of an Option, a SAR, a Restricted Share or a Stock Unit under the Plan.
- 14.36 "**Stock Option Agreement**" means the agreement between the Company and an Optionee that contains the terms, conditions and restrictions pertaining to his or her Option.
  - 14.37 "Stock Unit" means a bookkeeping entry representing the equivalent of one Common Share, as awarded under the Plan.
- 14.38 "**Stock Unit Agreement**" means the agreement between the Company and the recipient of a Stock Unit that contains the terms, conditions and restrictions pertaining to such Stock Unit.
- 14.39 "**Subsidiary**" means any corporation (other than the Company) in an unbroken chain of corporations beginning with the Company, if each of the corporations other than the last corporation in the unbroken chain owns stock possessing 50% or more of the total combined voting power of all classes of stock in one of the other corporations in such chain. A corporation that attains the status of a Subsidiary on a date after the adoption of the Plan shall be considered a Subsidiary commencing as of such date
- 14.40 "**Substitute Awards**" means Awards or Common Shares issued by the Company in assumption of, or substitution or exchange for, Awards previously granted, or the right or obligation to make future awards, in each case by a corporation acquired by the Company or any Affiliate or with which the Company or any Affiliate combines to the extent permitted by NASDAQ Marketplace Rule 5635 or any successor thereto.

### APPENDIX A

### PERFORMANCE CRITERIA

The Administrator may establish Performance Goals derived from one or more of the following criteria when it makes Awards of Restricted Shares or Stock Units that vest entirely or in part on the basis of performance or when it makes Performance Cash Awards:

- Earnings (before or after taxes)
- · Earnings per share
- Earnings before interest, taxes and depreciation
- Earnings before interest, taxes, depreciation and amortization
- · Total stockholder return
- Return on equity or average stockholders' equity
- · Return on assets, investment or capital employed
- · Operating income
- · Gross margin
- · Operating margin
- · Net operating income
- Net operating income after tax
- Return on operating revenue
- Objective corporate or individual strategic goals

- Sales or revenue (using a measure thereof that complies with Section 162(m))
- · Expense or cost reduction
- · Working capital
- Economic value added (or an equivalent metric)
- · Market share
- Cash measures including cash flow and cash balance
- · Operating cash flow
- · Cash flow per share
- · Share price
- Debt reduction
- Customer satisfaction
- · Stockholders' equity
- · Contract awards or backlog
- Objective individual performance goals
- To the extent that an Award is not intended to comply with Code Section 162(m), other measures of performance selected by the Administrator

## HISTOGENICS CORPORATION

# 2013 EMPLOYEE STOCK PURCHASE PLAN

(AS ADOPTED ON NOVEMBER 13, 2013)

#### HISTOGENICS CORPORATION

## 2013 EMPLOYEE STOCK PURCHASE PLAN

#### SECTION 1. PURPOSE OF THE PLAN.

The Board adopted the Plan effective as of the IPO Date. The purpose of the Plan is to provide Eligible Employees with an opportunity to increase their proprietary interest in the success of the Company by purchasing Stock from the Company on favorable terms and to pay for such purchases through payroll deductions or other approved contributions.

## SECTION 2. ADMINISTRATION OF THE PLAN.

- (a) **Committee Composition**. The Committee shall administer the Plan. The Committee shall consist exclusively of one or more members of the Board, who shall be appointed by the Board.
- (b) **Committee Responsibilities**. The Committee shall interpret the Plan and make all other policy decisions relating to the operation of the Plan. The Committee may adopt such rules, guidelines and forms as it deems appropriate to implement the Plan. The Committee's determinations under the Plan shall be final and binding on all persons.

## SECTION 3. STOCK OFFERED UNDER THE PLAN.

- (a) **Authorized Shares**. The number of shares of Stock available for purchase under the Plan shall be 1,120,000 shares of the Company's Stock (subject to adjustment pursuant to Subsection (c) below), plus the additional shares described in Subsection (b) below. Shares of Stock issued pursuant to the Plan may be authorized but unissued shares or treasury shares.
- (b) **Annual Increase in Shares**. As of the first business day of each fiscal year of the Company during the term of the Plan, commencing on January 1, 2015, the aggregate number of shares of Stock that may be issued under the Plan shall automatically increase by a number equal to the least of (i) 1% of the total number of shares of Stock actually issued and outstanding on the last business day of the prior fiscal year (excluding any rights to purchase shares of common shares that may be outstanding, such as options or warrants), (ii) 560,000 shares of Stock (subject to adjustment pursuant to Subsection (c) below), or (iii) a number of shares of Stock determined by the Board.
- (c) **Anti-Dilution Adjustments**. In the event that any dividend or other distribution (whether in the form of cash, stock or other securities or other property), recapitalization, stock split, reverse stock split, reorganization, merger, consolidation, split-up, spin-off, combination, repurchase, or exchange of Stock or other securities of the Company, or other similar change in the corporate structure of the Company affecting the Stock and effected without receipt or payment of consideration by the Company occurs, then in order to prevent

dilution or enlargement of the benefits or potential benefits intended to be made available under the Plan, there will be a proportionate adjustment of the number and class of Stock that may be delivered under the Plan, the Purchase Price per share and the number of shares of Stock covered by each option under the Plan which has not yet been exercised, and the numerical limits of Sections 3(a), 3(b)(ii) and 9(c).

(d) **Reorganizations**. Any other provision of the Plan notwithstanding, in the event of a Corporate Reorganization, the Plan may be continued or assumed by the surviving corporation or its parent corporation. If such acquirer refuses to continue or assume the Plan, then, immediately prior to the effective time of the Corporate Reorganization, any Offering Period then in progress shall terminate, and, a new Purchase Date for each such Offering Period will be set, immediately prior to the effective time of the Corporate Reorganization. In the event a new Purchase Date is set under this Section 3(d), Participants will be given notice of the new Purchase Date. The Plan shall in no event be construed to restrict in any way the Company's right to undertake a dissolution, liquidation, merger, consolidation or other reorganization.

#### SECTION 4. ENROLLMENT AND PARTICIPATION.

- (a) Offering Periods and Purchase Periods.
- (i) **Base Offering Periods**. The Committee may establish Offering Periods of such frequency and duration as it may from time to time determine as appropriate (the "*Base Offering Periods*"); provided that a Base Offering Period shall in no event be longer than 27 months (or such other period as may be imposed under applicable tax law). The Base Offering Periods are intended to qualify under Code Section 423. Unless changed by the Committee, the Plan shall operate such that two Base Offering Periods, each of six months' duration and each including a single six-month Purchase Period, will commence on May 1 and November 1 of each year, except that the first Base Offering Period will commence on the IPO Date and shall end on October 31, 2014, with the first Purchase Period commencing on the IPO Date and the first Purchase Date occurring on or about October 31, 2014. The Committee may determine that the first Base Offering Period applicable to the Eligible Employees of a new Participating Company shall commence on any later date specified by the Committee.
- (ii) **Additional Offering Periods**. At the discretion of the Committee, additional Offering Periods (the "Additional Offering Periods") may be conducted under the Plan or, if necessary or advisable, in the sole discretion of the Committee, under a separate sub-plan or sub-plans permitting grants to Eligible Employees of certain Participating Companies (each, a "Sub-Plan"). Such Additional Offering Periods may, but need not, qualify under Code Section 423, and may be designed to achieve desired tax or other objectives in particular locations outside the United States of America or to comply with local laws applicable to offerings in such foreign jurisdictions. The Committee shall determine the commencement and duration of each Additional Offering Period, and Additional Offering Periods may be consecutive or overlapping. The other terms and conditions of each Additional Offering Period shall be those set forth in this Plan document or in the applicable Sub-Plan, with such changes or additional features as

the Committee determines necessary to comply with local law. Each Sub-Plan shall be considered a separate plan from the Plan (the "*Statutory Plan*"). The total number of Shares authorized to be issued under the Plan as provided in Section 3 above applies in the aggregate to both the Statutory Plan and any Sub-Plan. Unless otherwise superseded by the terms of such Sub-Plan, the provisions of this Plan document shall govern the operation of such Sub-Plan.

- (iii) Separate Offerings. Each Base Offering Period and Additional Offering Period conducted under the Plan or any Sub-Plan is intended to constitute a separate "offering" for purposes of Code Section 423.
- (iv) Equal Rights and Privileges. To the extent an Offering Period is intended to qualify under Code Section 423, all participants in such Offering Period shall have the same rights and privileges with respect to their participation in such Offering Period in accordance with Code Section 423 and the regulations thereunder except for differences that may be mandated by local law and are consistent with the requirements of Code Section 423(b)(5).
- (b) **Enrollment At IPO**. Each individual who, on the IPO Date, qualifies as an Eligible Employee shall automatically become a Participant on such day, and shall be considered to have been granted an option to participate in the first Offering Period under the Plan at the maximum applicable participation rate. Each Participant who was automatically enrolled on the IPO Date shall file the prescribed enrollment form with the Company. The enrollment form shall be filed at the prescribed location by a date specified by the Company, but in no event later than 30 days after the IPO Date. If a Participant who was automatically enrolled on the IPO Date fails to file such form in a timely manner, then such Participant shall be deemed to have withdrawn from the Plan under Section 6(a). A former Participant who is deemed to have withdrawn from the Plan shall not be a Participant until he or she reenrolls in the Plan under Subsection (c) below. Re-enrollment may be effective only at the commencement of an Offering Period.
- (c) **Enrollment After IPO** Any individual who qualifies as an Eligible Employee on the first day of any Offering Period other than the first Offering Period may elect to become a Participant on such day by filing the prescribed enrollment form with the Company. The enrollment form shall be filed at the prescribed location at least 10 business days (or such other period as the Committee or its designee may designate) prior to such day.
  - (d) **Duration of Participation**. Once enrolled in the Plan, a Participant shall continue to participate in the Plan until he or she:
  - (i) Reaches the end of the Offering Period or Purchase Period, as applicable, in which his or her employee contributions were discontinued under Section 5(c) or 9(b);
    - (ii) Is deemed to withdraw from the Plan under Subsection (b) above;
    - (iii) Withdraws from the Plan under Section 6(a); or

(iv) Ceases to be an Eligible Employee.

A Participant whose employee contributions were discontinued automatically under Section 9(b) shall automatically resume participation at the beginning of the earliest Offering Period ending in a later calendar year, if he or she then is an Eligible Employee. In all other cases, a former Participant may again become a Participant, if he or she then is an Eligible Employee, by following the procedure described in Subsection (b) above.

#### **SECTION 5. EMPLOYEE CONTRIBUTIONS.**

- (a) **Commencement of Payroll Deductions**. A Participant may purchase shares of Stock under the Plan by means of payroll deductions or other approved contributions in form and substance satisfactory to the Committee. Payroll deductions or other approved contributions shall commence as soon as reasonably practicable after the Company has received the prescribed enrollment form. In jurisdictions where payroll deductions are not permitted under local law, Participants may purchase shares of Stock by making contributions in the form that is acceptable and approved by the Committee.
- (b) **Amount of Payroll Deductions**. An Eligible Employee shall designate on the prescribed enrollment form the portion of his or her Compensation that he or she elects to have withheld for the purchase of Stock. Such portion shall be a whole percentage of the Eligible Employee's Compensation, but not less than 1% nor more than 15%.
- (c) **Reducing Withholding Rate or Discontinuing Payroll Deductions**. If a Participant wishes to reduce his or her rate of payroll withholding, such Participant may do so by filing a new enrollment form with the Company at the prescribed location at any time. The new withholding rate shall be effective as soon as reasonably practicable after the Company has received such form. The new withholding rate may be 0% or any whole percentage of the Participant's Compensation, but not more than his or her old withholding rate. No Participant shall make more than two elections under this Subsection (c) during any Purchase Period. (In addition, employee contributions may be discontinued automatically pursuant to Section 9(b).)
- (d) **Increasing Withholding Rate**. If a Participant wishes to increase his or her rate of payroll withholding, such Participant may do so by filing a new enrollment form with the Company at the prescribed location at any time. The new withholding rate may be effective on the first day of the next-upcoming Offering Period in which the Participant participates, provided that the Participant has filed the enrollment form with the Company at the prescribed location at least 10 business days (or such other period as the Committee or its designee may designate) prior to such day. The new withholding rate may be any whole percentage of the Participant's Compensation, but not less than 1% nor more than 15%. An increase in a Participant's rate of payroll withholding may not take effect during an Offering Period.

#### SECTION 6. WITHDRAWAL FROM THE PLAN.

(a) **Withdrawal**. A Participant may elect to withdraw from the Plan (or, if applicable, from an Offering Period) by filing the prescribed form with the Company at the prescribed location at any time before a Purchase Date. As soon as reasonably practicable

thereafter, payroll deductions or other approved contributions shall cease and the entire amount credited to the Participant's Plan Account with respect to such Offering Period shall be refunded to him or her in cash, without interest (except as otherwise required by the laws of the local jurisdiction). No partial withdrawals from an Offering Period shall be permitted.

(b) **Re-Enrollment After Withdrawal**. A former Participant who has withdrawn from the Plan shall not be a Participant until he or she re-enrolls in the Plan under Section 4(b). Re-enrollment may be effective only at the commencement of an Offering Period.

#### **SECTION 7. CHANGE IN EMPLOYMENT STATUS.**

- (a) **Termination of Employment**. Termination of employment as an Eligible Employee for any reason, including death, shall be treated as an automatic withdrawal from the Plan under Section 6(a). (A transfer from one Participating Company to another shall not be treated as a termination of employment provided that each Participating Company is then participating in the same Offering Period.)
- (b) **Leave of Absence**. For purposes of the Plan, employment shall not be deemed to terminate when the Participant goes on a military leave, a sick leave or another bona fide leave of absence, if the leave was approved by the Company in writing. Employment, however, shall be deemed to terminate on the first day following three months after the Participant goes on a leave, unless a contract or statute guarantees his or her right to return to work. Employment shall be deemed to terminate in any event when the approved leave ends, unless the Participant immediately returns to work.
- (c) **Death**. In the event of the Participant's death, the amount credited to his or her Plan Account shall be paid to a beneficiary designated by him or her for this purpose on the prescribed form or, if none, to the Participant's estate. Such form shall be valid only if it was filed with the Company at the prescribed location before the Participant's death.

## SECTION 8. PLAN ACCOUNTS AND PURCHASE OF SHARES.

- (a) **Plan Accounts**. The Company shall maintain a Plan Account on its books in the name of each Participant. Whenever an amount is deducted from the Participant's Compensation under the Plan, such amount shall be credited to the Participant's Plan Account. Amounts credited to Plan Accounts shall not be trust funds and may be commingled with the Company's general assets and applied to general corporate purposes. Unless otherwise required by the laws of the local jurisdiction, no interest shall be credited to Plan Accounts.
  - (b) Purchase Price. The Purchase Price for each share of Stock purchased on a Purchase Date shall be the lower of:
  - (i) 85% of the Fair Market Value of such share on the first day of such Offering Period or, in the case of the first Offering Period under the Plan, 85% of the price at which one share of Stock is offered to the public in the IPO; or
    - (ii) 85% of the Fair Market Value of such share on the Purchase Date.

- (c) **Number of Shares Purchased**. On each Purchase Date, each Participant shall be deemed to have elected to purchase the number of shares of Stock calculated in accordance with this Subsection (c), unless the Participant has previously elected to withdraw from the Offering Period in accordance with Section 6(a). The amount then in the Participant's Plan Account shall be divided by the Purchase Price, and the number of shares that results shall be purchased from the Company with the funds in the Participant's Plan Account. The foregoing number of shares of Stock purchasable by a Participant are subject to the limitations set forth in Section 9. The Committee may determine with respect to all Participants that any fractional share, as calculated under this Subsection (c), shall be (i) rounded down to the next lower whole share or (ii) credited as a fractional share.
- (d) **Available Shares Insufficient**. In the event that the aggregate number of shares that all Participants elect to purchase with respect to a particular Purchase Period exceeds (i) the number of shares of Stock that were available under Section 3 above for sale under the Plan on the first day of the applicable Offering Period, or (ii) the number of shares that were available under Section 3 above for sale under the Plan on the applicable Purchase Date, then the number of shares to which each Participant is entitled shall be determined by multiplying the number of shares available for issuance by a fraction. The numerator of such fraction is the number of shares that such Participant has elected to purchase, and the denominator of such fraction is the number of shares that all Participants have elected to purchase. The Company may make a pro rata allocation of the shares available on the first day of an applicable Offering Period pursuant to the preceding sentence, notwithstanding any authorization of additional shares for issuance under the Plan by the Company's stockholders subsequent to such date. In the event of a pro-rata allocation under this Section (d), the Committee may determine in its discretion to continue all Offering Periods then in effect or terminate all Offering Periods then in effect pursuant to Section 14.
- (e) **Issuance of Stock**. The shares of Stock purchased by a Participant under the Plan may be registered in the name of such Participant, or jointly in the name of such Participant and his or her spouse as joint tenants with the right of survivorship or as community property (with or without the right of survivorship). The Company may permit or require that shares be deposited directly with a broker designated by the Company or to a designated agent of the Company, and the Company may utilize electronic or automated methods of share transfer. The Company may require that shares be retained with such broker or agent for a designated period of time and/or may establish other procedures to permit tracking of disqualifying dispositions of such shares. (The two preceding sentences shall apply whether or not the Participant is required to pay income tax in the United States.)
- (f) **Tax Withholding**. To the extent required by applicable federal, state, local or foreign law, a Participant shall make arrangements satisfactory to the Company for the satisfaction of any withholding tax obligations that arise in connection with the Plan. The Company shall not be required to issue any shares of Stock under the Plan until such obligations, if any, are satisfied.
- (g) **Unused Cash Balances**. Subject to the final sentence of Section 8(c), an amount remaining in the Participant's Plan Account that represents the Purchase Price for any fractional share shall be carried over in the Participant's Plan Account to the next Purchase

Period. Any amount remaining in the Participant's Plan Account that represents the Purchase Price for whole shares that could not be purchased by reason of Subsections (c) or (d) above or Section 9(b) shall be refunded to the Participant in cash, without interest (except as otherwise required by the laws of the local jurisdiction).

(h) **Stockholder Approval**. Any other provision of the Plan notwithstanding, no shares of Stock shall be purchased under the Plan unless and until the Company's stockholders have approved the adoption of the Plan.

#### **SECTION 9. PLAN LIMITATIONS.**

- (a) **Five Percent Limit**. Any other provision of the Plan notwithstanding, no Participant shall be granted a right to purchase Stock under the Plan if such Participant, immediately after his or her election to purchase such Stock, would own stock possessing more than 5% of the total combined voting power or value of all classes of stock of the Company or any parent or Subsidiary of the Company, determined in accordance with applicable tax law.
- (b) **Dollar Limit**. Any other provision of the Plan notwithstanding, no Participant shall purchase Stock with a Fair Market Value in excess of the following limit:
  - (i) In the case of Stock purchased during an Offering Period that commenced in the current calendar year, the limit shall be equal to (A) \$25,000 minus (B) the Fair Market Value of the Stock that the Participant previously purchased under the Plan in the current calendar year.
  - (ii) In the case of Stock purchased during an Offering Period that commenced in the immediately preceding calendar year, the limit shall be equal to (A) \$50,000 minus (B) the Fair Market Value of the Stock that the Participant previously purchased under the Plan in the current calendar year and in the immediately preceding calendar year.
  - (iii) In the case of Stock purchased during an Offering Period that commenced in the second calendar year before the current calendar year, the limit shall be equal to (A) \$75,000 minus (B) the Fair Market Value of the Stock that the Participant previously purchased under the Plan in the current calendar year and in the immediately preceding two calendar years.

For all purposes under this Subsection (b), (A) the Fair Market Value of Stock shall be determined as of the beginning of the Offering Period in which such Stock is purchased; and (B) this Plan shall be aggregated with any other employee stock purchase plans of the Company (or any parent or Subsidiary of the Company) described in Code Section 423. If a Participant is precluded by this Subsection (b) from purchasing additional Stock under the Plan, then his or her employee contributions shall automatically be discontinued and shall automatically resume at the beginning of the next Offering Period with a scheduled Purchase Date in the next calendar year, provided that he or she is an Eligible Employee at the beginning of such Offering Period.

(c) **Purchase Period Share Purchase Limit**. Any other provision of the Plan notwithstanding, no Participant shall purchase more than 3,500 shares of Stock with respect to any Purchase Period; provided that the Committee may, for future Offering Periods, increase or decrease in its absolute discretion, the maximum number of shares of Stock that a Participant may purchase during each Purchase Period.

#### SECTION 10. RIGHTS NOT TRANSFERABLE.

The rights of any Participant under the Plan, or any Participant's interest in any Stock or moneys to which he or she may be entitled under the Plan, shall not be transferable by voluntary or involuntary assignment or by operation of law, or in any other manner other than by beneficiary designation or the laws of descent and distribution. If a Participant in any manner attempts to transfer, assign or otherwise encumber his or her rights or interest under the Plan, other than by beneficiary designation or the laws of descent and distribution, then such act shall be treated as an election by the Participant to withdraw from the Plan under Section 6(a).

#### SECTION 11. NO RIGHTS AS AN EMPLOYEE.

Nothing in the Plan or in any right granted under the Plan shall confer upon the Participant any right to continue in the employ of a Participating Company for any period of specific duration or interfere with or otherwise restrict in any way the rights of the Participating Companies or of the Participant, which rights are hereby expressly reserved by each, to terminate his or her employment at any time and for any reason, with or without cause.

#### SECTION 12. NO RIGHTS AS A STOCKHOLDER.

A Participant shall have no rights as a stockholder with respect to any shares of Stock that he or she may have a right to purchase under the Plan until such shares have been purchased on the applicable Purchase Date.

## SECTION 13. SECURITIES LAW REQUIREMENTS.

Shares of Stock shall not be issued, and the Company shall have no liability for failure to issue shares of Stock, under the Plan unless the issuance and delivery of such shares comply with (or are exempt from) all applicable requirements of law, including (without limitation) the Securities Act of 1933, as amended, the rules and regulations promulgated thereunder, state securities laws and regulations, and the regulations of any stock exchange or other securities market on which the Company's securities may then be traded.

#### SECTION 14. AMENDMENT OR DISCONTINUANCE.

(a) **General Rule**. The Committee, in its sole discretion, may amend, suspend, or terminate the Plan, or any part thereof, at any time and for any reason. If the Plan is terminated, the Committee, in its discretion, may elect to terminate all outstanding Offering Periods either immediately or upon completion of the purchase of shares of Stock on the next Purchase Date, or may elect to permit Offering Periods to expire in accordance with their terms

(and subject to any adjustment pursuant to Section 3(c) or (d)). If the Offering Periods are terminated prior to expiration, all amounts then credited to Participants' accounts which have not been used to purchase shares of Stock will be returned to the Participants (without interest thereon, except as otherwise required by the laws of the local jurisdiction) as soon as administratively practicable.

- (b) **Committee's Discretion**. Without stockholder consent and without limiting Section 14(a), the Committee will be entitled to change the Offering Periods, limit the frequency and/or number of changes in the amount withheld during an Offering Period, establish the exchange ratio applicable to amounts withheld in a currency other than U.S. dollars, permit payroll withholding in excess of the amount designated by a Participant in order to adjust for delays or mistakes in the Company's processing of properly completed withholding elections, establish reasonable waiting and adjustment periods and/or accounting and crediting procedures to ensure that amounts applied toward the purchase of Stock for each Participant properly correspond with amounts withheld from the Participant's Compensation, and establish such other limitations or procedures as it determines in its sole discretion advisable which are consistent with the Plan.
- (c) **Accounting Consideration**. In the event the Committee determines that the ongoing operation of the Plan may result in unfavorable financial accounting consequences, the Committee may, in its discretion and, to the extent necessary or desirable, modify, amend or terminate the Plan to reduce or eliminate such accounting consequence including, but not limited to:
  - (i) Amending the Plan to conform with the safe harbor definition under Financial Accounting Standards Board Accounting Standards Codification Topic 718, including with respect to an Offering Period underway at the time;
    - (ii) Altering the Purchase Price for any Offering Period including an Offering Period underway at the time of the change in Purchase Price;
  - (iii) Shortening any Offering Period by setting a new Purchase Date, including an Offering Period underway at the time of the Committee's action;
    - (iv) Reducing the maximum percentage of Compensation a Participant may elect to set aside as payroll deductions; and
    - (v) Reducing the maximum number of shares of Stock a Participant may purchase during any Purchase Period.

Such modifications or amendments will not require stockholder approval or the consent of any Plan Participants.

(d) **Stockholder Approval**. Except as provided in Section 3, any increase in the aggregate number of shares of Stock that may be issued under the Plan shall be subject to the approval of the Company's stockholders. In addition, any other amendment of the Plan shall be subject to the approval of the Company's stockholders to the extent required under Section 14(e) or by any applicable law or regulation.

(e) **Plan Termination**. The Plan shall terminate automatically 20 years after its adoption by the Board, unless (i) the Plan is extended by the Board and (ii) the extension is approved within 12 months by a vote of the stockholders of the Company.

#### **SECTION 15. DEFINITIONS.**

- (a) "Board" means the Board of Directors of the Company, as constituted from time to time.
- (b) "Code" means the Internal Revenue Code of 1986, as amended.
- (c) "Committee" means a committee of the Board, as described in Section 2.
- (d) "Company" means Histogenics Corporation, a Delaware corporation.
- (e) "Compensation" means (i) the total compensation paid in cash to a Participant by a Participating Company, including salaries, wages, bonuses, incentive compensation, commissions, overtime pay and shift premiums, plus (ii) any pre-tax contributions made by the Participant under Code Sections 401(k) or 125. "Compensation" shall exclude all non-cash items, moving or relocation allowances, cost-of-living equalization payments, car allowances, tuition reimbursements, imputed income attributable to cars or life insurance, severance pay, fringe benefits, contributions or benefits received under employee benefit plans, income attributable to equity compensation awards of the Company, and similar items. The Committee shall determine whether a particular item is included in Compensation.

## (f) "Corporate Reorganization" means:

- (i) The consummation of a merger or consolidation of the Company with or into another entity or any other corporate reorganization; or
- (ii) The sale, transfer or other disposition of all or substantially all of the Company's assets or the complete liquidation or dissolution of the Company.
- (g) "Eligible Employee" means a common law employee of a Participating Company who is customarily employed for more than five months per calendar year and at least 20 hours per week. The foregoing notwithstanding, an individual shall not be considered an Eligible Employee if his or her participation in the Plan is prohibited by the law of any country that has jurisdiction over him or her. In addition, the Committee may determine prior to the commencement of an Offering Period not to exclude part-time employees or exclude employees whose customary employment is for fewer hours per week or fewer months in a calendar year; provided that such terms are applied in an identical manner to all employees of every Participating Company in such Offering Period.
  - (h) "Exchange Act" means the Securities Exchange Act of 1934, as amended.
- (i) "Fair Market Value" means the price at which Stock was last sold in the principal U.S. market for the Stock on the applicable date or, if the applicable date was not a trading day, on the last trading day prior to the applicable date. If Stock is no longer traded on

a public U.S. securities market, the Fair Market Value shall be determined by the Committee in good faith on such basis as it deems appropriate. The Committee's determination shall be conclusive and binding on all persons.

- (j) "IPO" means the Company's initial offering of Stock to the public.
- (k) "**IPO Date**" means the effective date of the registration statement filed by the Company with the Securities and Exchange Commission for its initial offering of Stock to the public.
- (l) "Offering Period" means any period, including as the context requires Base Offering Periods and Additional Offering Periods, with respect to which the right to purchase Stock may be granted under the Plan, as determined pursuant to Section 4(a).
  - (m) "Participant" means an Eligible Employee who participates in the Plan or any Sub-Plan, as provided in Section 4.
- (n) "Participating Company" means (i) the Company and (ii) each present or future Subsidiary designated by the Committee as a Participating Company.
  - (o) "Plan" means this Histogenics Corporation 2013 Employee Stock Purchase Plan, as it may be amended from time to time.
  - (p) "Plan Account" means the account established for each Participant pursuant to Section 8(a).
  - (q) "Purchase Date" means the last trading day of a Purchase Period.
- (r) "**Purchase Period**" means a period within an Offering Period (which for an Offering Period with only a single Purchase Period would be coterminous with the Offering Period) during which contributions may be made toward the purchase of Stock under the Plan, as determined pursuant to Section 4(a).
  - (s) "Purchase Price" means the price at which Participants may purchase Stock under the Plan, as determined pursuant to Section 8(b).
  - (t) "Stock" means the Common Stock of the Company.
- (u) "**Subsidiary**" means any corporation (other than the Company) in an unbroken chain of corporations beginning with the Company, if each of the corporations other than the last corporation in the unbroken chain owns stock possessing 50% or more of the total combined voting power of all classes of stock in one of the other corporations in such chain.

#### LEASE AGREEMENT

THIS LEASE AGREEMENT (this "Lease") is made this 2nd day of June, 2014, between ARE-60 WESTVIEW, LLC, a Delaware limited liability company ("Landlord"), and HISTOGENICS CORPORATION, a Delaware corporation ("Tenant").

**Building:** 60 Westview Street, Lexington, Massachusetts

**Premises:** That portion of the Project, containing approximately 16,601 rentable square feet, as determined by Landlord, as shown on Exhibit A.

The real property on which the Building in which the Premises are located, together with all improvements thereon and appurtenances **Project:** 

thereto as described on Exhibit B.

\$33.00 per rentable square foot of the Premises per annum, subject to adjustment pursuant to Section 4 hereof. **Base Rent:** 

Rentable Area of Premises: 16,601 sq. ft.

Rentable Area of Project: 40,200 sq. ft. **Tenant's Share of Operating Expenses:** 41.30%

**Security Deposit:** \$136,958.25 Target Commencement Date: July 1, 2014

Rent Adjustment Amount': \$0.60 per rentable square foot of the Premises per annum

**Base Term:** Beginning on the Commencement Date and ending 99 months from the first day of the first full month following the Rent

Commencement Date.

**Permitted Use:** Research and development laboratory, commercial manufacturing, related office, accessory storage and other related uses consistent

with the character of the Project and otherwise in compliance with the provisions of <u>Section 7</u> hereof.

**Address for Rent Payment: Landlord's Notice Address:** 

P.O. Box 79840 385 E. Colorado Boulevard, Suite 299

Baltimore. MD 21279-0840 Pasadena, CA 91101

Attention: Corporate Secretary

**Tenant's Notice Address:** 

60 Westview Street, Suite 102 Lexington, MA 02421-3108 Attention: Lease Administrator

The following Exhibits and Addenda are attached hereto and incorporated herein by this reference:

**EXHIBIT A - PREMISES DESCRIPTION** 

**EXHIBIT C - WORK LETTER** 

|X|**EXHIBIT E - RULES AND REGULATIONS** 

- **EXHIBIT B DESCRIPTION OF PROJECT**
- **EXHIBIT D COMMENCEMENT DATE**
- |X|**EXHIBIT F - TENANT'S PERSONAL PROPERTY**

1. Lease of Premises. Upon and subject to all of the terms and conditions hereof, Landlord hereby leases the Premises to Tenant and Tenant hereby leases the Premises from Landlord. The portions of the Project which are for the non-exclusive use of tenants of the Project are collectively referred to herein as the "Common Areas." Landlord reserves the right to modify Common Areas, provided that such modifications do not materially adversely affect Tenant's use of the Premises for the Permitted Use. Tenant may use the loading dock in common with others entitled thereto at no additional charge. The regular hours of operation of the loading dock are 24 hours per day, 7 days per week,



subject to downtime for maintenance and repairs. From and after the Commencement Date through the expiration of the Term, Tenant shall have access to the Building and the Premises 24 hours a day, 7 days a week, except in the case of emergencies, as the result of Legal Requirements, the performance by Landlord of any installation, maintenance or repairs, or any other temporary interruptions, and otherwise subject to the terms of this Lease. Landlord shall, except in the case of emergencies, endeavor to provide Tenant 48 hours advance notice of such installations, maintenance, repairs, or other temporary interruptions.

2. **Delivery; Acceptance of Premises; Commencement Date.** Landlord shall use reasonable efforts to make the Premises available to Tenant, with the Demising Work (as defined below) substantially completed, for the performance by Tenant of the Tenant Improvements under the Work Letter on or before the Target Commencement Date ("**Delivery**" or "**Deliver**"). If Landlord fails to timely Deliver the Premises, Landlord shall not be liable to Tenant for any loss or damage resulting therefrom, and this Lease shall not be void or voidable except as provided herein. If Landlord does not Deliver the Premises within 60 days of the Target Commencement Date for any reason other than Force Majeure delays, this Lease may be terminated by Tenant by written notice to Landlord, and if so terminated by Tenant: (a) the Security Deposit, or any balance thereof (i.e., after deducting therefrom all amounts to which Landlord is entitled under the provisions of this Lease), shall be promptly returned to Tenant, and (b) neither Landlord nor Tenant shall have any further rights, duties or obligations under this Lease, except with respect to provisions which expressly survive termination of this Lease. As used herein, the terms "**Tenant Improvements**" shall have the meaning set forth for such term in the Work Letter. If Tenant does not elect to void this Lease within 10 business days of the lapse of such 60 day period, such right to void this Lease shall be waived and this Lease shall remain in full force and effect. As used herein, "**Demising Work**" shall mean the work remaining as of the date of this Lease required, as reasonably determined by Landlord, to fully demise the Premises from the adjacent premises, which Demising Work shall be performed at Landlord's cost and expense.

The "Commencement Date" shall be the date Landlord Delivers the Premises to Tenant. The "Rent Commencement Date" shall be the date that is 8 months after the Commencement Date. Upon request of Landlord, Tenant shall execute and deliver a written acknowledgment of the Commencement Date, the Rent Commencement Date and the expiration date of the Term when such are established in the form of the "Acknowledgment of Commencement Date" attached to this Lease as Exhibit D; provided, however, Tenant's failure to execute and deliver such acknowledgment shall not affect Landlord's rights hereunder. The "Term" of this Lease shall be the Base Term, as defined above on the first page of this Lease and the Extension Term which Tenant may elect pursuant to Section 39 hereof.

Except as set forth in the Work Letter: (i) Tenant shall accept the Premises in their condition as of the Commencement Date, subject to all applicable Legal Requirements (as defined in Section 7 hereof); (ii) Landlord shall have no obligation for any defects in the Premises; and (iii) Tenant's taking possession of the Premises shall be conclusive evidence that Tenant accepts the Premises and that the Premises were in good condition at the time possession was taken.

Tenant agrees and acknowledges that neither Landlord nor any agent of Landlord has made any representation or warranty with respect to the condition of all or any portion of the Premises or the Project, and/or the suitability of the Premises or the Project for the conduct of Tenant's business, and Tenant waives any implied warranty that the Premises or the Project are suitable for the Permitted Use. This Lease constitutes the complete agreement of Landlord and Tenant with respect to the subject matter hereof and supersedes any and all prior representations, inducements, promises, agreements, understandings and negotiations which are not contained herein. Landlord in executing this Lease does so in reliance upon Tenant's representations, warranties, acknowledgments and agreements contained herein.



- 3. Rent.
- (a) Base Rent. The Security Deposit shall be due and payable on delivery of an executed copy of this Lease to Landlord. Base Rent for the month in which the Rent Commencement Date occurs shall be due and payable on the Rent Commencement Date. Tenant shall pay to Landlord in advance, without demand, abatement, deduction or set-off, equal monthly installments of Base Rent on or before the first day of each calendar month during the Term hereof after the Rent Commencement Date, in lawful money of the United States of America, at the office of Landlord for payment of Rent set forth above, or to such other person or at such other place as Landlord may from time to time designate in writing. Payments of Base Rent for any fractional calendar month shall be prorated. The obligation of Tenant to pay Base Rent and other sums to Landlord and the obligations of Landlord under this Lease are independent obligations. Tenant shall have no right at any time to abate, reduce, or set-off any Rent (as defined in Section 5) due hereunder except for any abatement as may be expressly provided in this Lease.
- (b) Additional Rent. In addition to Base Rent, Tenant agrees to pay to Landlord as additional rent ("Additional Rent"): (i) commencing on the date that is 4 months after the Commencement Date, Tenant's Share of "Operating Expenses" (as defined in Section 5), and (ii) any and all other amounts Tenant assumes or agrees to pay under the provisions of this Lease, including, without limitation, any and all other sums that may become due by reason of any default of Tenant or failure to comply with the agreements, terms, covenants and conditions of this Lease to be performed by Tenant, after any applicable notice and cure period.
- 4. Base Rent Adjustments. Base Rent shall be increased on each annual anniversary of the first day of the first full month after the Rent Commencement Date (each an "Adjustment Date") by adding the Rent Adjustment Amount to the per square foot Base Rent payable for the Premises per annum immediately before such Adjustment Date. Base Rent, as so adjusted, shall thereafter be due as provided herein. Base Rent adjustments for any fractional calendar month shall be prorated.
- 5. Operating Expense Payments. Landlord shall deliver to Tenant a written estimate of Operating Expenses for each calendar year during the Term (the "Annual Estimate"), which may be revised by Landlord from time to time during such calendar year. Commencing on the date that is 4 months after the Commencement Date, and continuing thereafter on the first day of each month during the Term, Tenant shall pay Landlord an amount equal to 1/12th of Tenant's Share of the Annual Estimate. Payments for any fractional calendar month shall be prorated.

The term "Operating Expenses" means all costs and expenses of any kind or description whatsoever incurred or accrued each calendar year by Landlord with respect to the Project (including, without duplication, Taxes (as defined in Section 9), capital repairs and improvements amortized over the useful life of such capital items (as reasonably determined by Landlord taking into account all relevant factors), and the costs of Landlord's third party property manager (not to exceed 3% of Base Rent), if there is no third party property manager, administration rent in the amount of 3% of Base Rent (or, prior to the Rent Commencement Date, 3% of the Base Rent that would have been payable during such period if Tenant had been required to pay Base Rent, which amount shall be equal to the Base Rent payable for the 8th month of the Base Term)), excluding only:

- (a) the original construction costs of the Project and renovation prior to the date of the Lease and costs of correcting defects in such original construction or renovation;
  - (b) capital expenditures for expansion of the Project;
- (c) interest, principal payments of Mortgage (as defined in Section 27) debts of Landlord, financing costs and amortization of funds borrowed by Landlord, whether secured or unsecured;



- (d) depreciation of the Project (except for capital improvements, the cost of which are includable in Operating Expenses);
- (e) advertising, legal and space planning expenses and leasing commissions and other costs and expenses incurred in procuring and leasing space to tenants for the Project, including any leasing office maintained in the Project, free rent and construction allowances for tenants;
  - (f) legal and other expenses incurred in the negotiation or enforcement of leases;
- (g) completing, fixturing, improving, renovating, painting, redecorating or other work, which Landlord pays for or performs for other tenants within their premises, and costs of correcting defects in such work;
- (h) costs to be reimbursed by other tenants of the Project or Taxes to be paid directly by Tenant or other tenants of the Project, whether or not actually paid;
- (i) salaries, wages, benefits and other compensation paid to officers and employees of Landlord who are not assigned in whole or in part to the operation, management, maintenance or repair of the Project;
- (j) general organizational, administrative and overhead costs relating to maintaining Landlord's existence, either as a corporation, partnership, or other entity, including general corporate, legal and accounting expenses;
- (k) costs (including attorneys' fees and costs of settlement, judgments and payments in lieu thereof) incurred in connection with disputes with tenants, other occupants, or prospective tenants, and costs and expenses, including legal fees, incurred in connection with negotiations or disputes with employees, consultants, management agents, leasing agents, purchasers or mortgagees of the Building;
- (l) costs incurred by Landlord due to the violation by Landlord, its employees, agents or contractors or any tenant of the terms and conditions of any lease of space in the Project or any Legal Requirement (as defined in <u>Section 7</u>);
- (m) penalties, fines or interest incurred as a result of Landlord's inability or failure to make payment of Taxes and/or to file any tax or informational returns when due, or from Landlord's failure to make any payment of Taxes required to be made by Landlord hereunder before delinquency;
- (n) overhead and profit increment paid to Landlord or to subsidiaries or affiliates of Landlord for goods and/or services in or to the Project to the extent the same exceeds the costs of such goods and/or services rendered by unaffiliated third parties on a competitive basis;
  - (o) costs of Landlord's charitable or political contributions, or of fine art maintained at the Project;
- (p) costs in connection with services (including electricity), items or other benefits of a type which are not standard for the Project and which are not available to Tenant without specific charges therefor, but which are provided to another tenant or occupant of the Project, whether or not such other tenant or occupant is specifically charged therefor by Landlord;
  - (q) costs incurred in the sale or refinancing of the Project;
- (r) net income taxes of Landlord or the owner of any interest in the Project, franchise, capital stock, gift, estate or inheritance taxes or any federal, state or local documentary taxes imposed against the Project or any portion thereof or interest therein;



- (s) any expenses otherwise includable within Operating Expenses to the extent actually reimbursed by persons other than tenants of the Project under leases for space in the Project;
  - (t) the preparation of audited financial statements for Landlord if they are required by an agreement between Landlord and any other party;
  - (u) any insurance costs of Landlord that are not related to the Project or Landlord's interest or activities with respect to the Project; and
  - (v) costs related to tenant appreciation events including, without limitation, parties, holiday gifts and welcoming gifts.

Within 90 days after the end of each calendar year (or such longer period as may be reasonably required, not to exceed 120 days after the end of such calendar year), Landlord shall furnish to Tenant a statement (an "Annual Statement") showing in reasonable detail: (a) the total and Tenant's Share of actual Operating Expenses for the previous calendar year, and (b) the total of Tenant's payments in respect of Operating Expenses for such year. If Tenant's Share of actual Operating Expenses for such year exceeds Tenant's payments of Operating Expenses for such year, the excess shall be due and payable by Tenant as Rent within 30 days after delivery of such Annual Statement to Tenant. If Tenant's payments of Operating Expenses for such year exceed Tenant's Share of actual Operating Expenses for such year Landlord shall pay the excess to Tenant within 30 days after delivery of such Annual Statement, except that after the expiration, or earlier termination of the Term or if Tenant is delinquent in its obligation to pay Rent, Landlord shall pay the excess to Tenant after deducting all other amounts due Landlord.

The Annual Statement shall be final and binding upon Tenant unless Tenant, within 30 days after Tenant's receipt thereof, shall contest any item therein by giving written notice to Landlord, specifying each item contested and the reason therefor. If, during such 30 day period, Tenant reasonably and in good faith questions or contests the accuracy of Landlord's statement of Tenant's Share of Operating Expenses, Landlord will provide Tenant with access to Landlord's books and records relating to the operation of the Project and such information as Landlord reasonably determines to be responsive to Tenant's questions (the "Expense Information"). If after Tenant's review of such Expense Information, Landlord and Tenant cannot agree upon the amount of Tenant's Share of Operating Expenses, then Tenant shall have the right to have a regionally recognized independent public accounting firm selected by Tenant, working pursuant to a fee arrangement other than a contingent fee (at Tenant's sole cost and expense except as otherwise expressly provided below) and approved by Landlord (which approval shall not be unreasonably withheld or delayed), audit and/or review the Expense Information for the year in question (the "Independent Review"). The results of any such Independent Review shall be binding on Landlord and Tenant. If the Independent Review shows that the payments actually made by Tenant with respect to Operating Expenses for the calendar year in question exceeded Tenant's Share of Operating Expenses for such calendar year, Landlord shall at Landlord's option either (i) credit the excess amount to the next succeeding installments of estimated Operating Expenses or (ii) pay the excess to Tenant within 30 days after delivery of such statement, except that after the expiration or earlier termination of this Lease or if Tenant is delinquent in its obligation to pay Rent, Landlord shall pay the excess to Tenant after deducting all other amounts due Landlord. If the Independent Review shows that Tenant's payments with respect to Operating Expenses for such calendar year were less than Tenant's Share of Operating Expenses for the calendar year, Tenant shall pay the deficiency to Landlord within 30 days after delivery of such statement. If the Independent Review shows that Tenant has overpaid with respect to Operating Expenses by more than 5% then Landlord shall reimburse Tenant for all costs incurred by Tenant for the Independent Review. Operating Expenses for the calendar years in which Tenant's obligation to share therein begins and ends shall be prorated. Notwithstanding anything set forth herein to the contrary, if the Project is not at least 95% occupied on average during any year of the Term, Tenant's Share of Operating Expenses for such year with respect to Variable Operating Expenses shall be computed as though the Project had been 95% occupied on average during such year. "Variable



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Operating Expenses" shall mean those Operating Expenses which vary by occupancy including, without limitation, electricity, trash removal and other Utilities (as defined in Section 11).

"Tenant's Share" shall be the percentage set forth on the first page of this Lease as Tenant's Share as reasonably adjusted by Landlord for changes in the physical size of the Premises or the Project occurring thereafter. The rentable square footage of the Building is 40,200 rentable square feet and shall not be subject to re-measurement. Landlord shall, within a reasonable period following the substantial completion of the Demising Work, re-measure the rentable square footage of the Premises using an architect or engineer reasonably acceptable to Landlord and Tenant. Any such re-measurement shall be performed in accordance with the BOMA 2010 Standard Methods of Measurement for multi-tenant buildings. If such re-measurement determines that the actual rentable square footage of the Premises' set forth on page 1 of this Lease, then, upon Landlord's or Tenant's request, Landlord and Tenant shall amend this Lease so as to reflect the actual square footage thereof in the definitions of "Premises," "Rentable Area of Premises" and "Tenant's Share of Operating Expenses." Landlord may equitably increase Tenant's Share for any item of expense or cost reimbursable by Tenant as an Operating Expense pursuant to this Section 5 that relates to a repair, replacement, or service that benefits only the Premises or only a portion of the Project that includes the Premises or that varies with occupancy or use. Base Rent, Tenant's Share of Operating Expenses and all other amounts payable by Tenant to Landlord hereunder are collectively referred to herein as "Rent."

6. **Security Deposit**. Tenant shall deposit with Landlord, upon delivery of an executed copy of this Lease to Landlord, a security deposit (the "Security Deposit") for the performance of all of Tenant's obligations hereunder in the amount set forth on page 1 of this Lease, which Security Deposit shall be in the form of an unconditional and irrevocable letter of credit (the "Letter of Credit"): (i) in form and substance reasonably satisfactory to Landlord, (ii) naming Landlord as beneficiary, (iii) expressly allowing Landlord to draw upon it at any time from time to time by delivering to the issuer notice that Landlord is entitled to draw thereunder, (iv) issued by an FDIC-insured financial institution satisfactory to Landlord, and (v) redeemable by presentation of a sight draft in the state of Landlord's choice. If Tenant does not provide Landlord with a substitute Letter of Credit complying with all of the requirements hereof at least 5 days before the stated expiration date of any then current Letter of Credit, Landlord shall have the right to draw the full amount of the current Letter of Credit and hold the funds drawn in cash without obligation for interest thereon as the Security Deposit. The Security Deposit shall be held by Landlord as security for the performance of Tenant's obligations under this Lease. The Security Deposit is not an advance rental deposit or a measure of Landlord's damages in case of Tenant's default. Upon each occurrence of a Default (as defined in Section 20), Landlord may use all or any part of the Security Deposit to pay delinquent payments due under this Lease, future rent damages, and the cost of any damage, injury, expense or liability caused by such Default, without prejudice to any other remedy provided herein or provided by law. Landlord's right to use the Security Deposit under this Section 6 includes the right to use the Security Deposit to pay future rent damages following the termination of this Lease pursuant to Section 21(c) below. Upon any use of all or any portion of the Security Deposit, Tenant shall pay Landlord within 5 days after Tenant's receipt of a demand therefor the amount that will restore the Security Deposit to the amount set forth on Page 1 of this Lease. Tenant hereby waives the provisions of any law, now or hereafter in force which provide that Landlord may claim from a security deposit only those sums reasonably necessary to remedy defaults in the payment of Rent, to repair damage caused by Tenant or to clean the Premises, it being agreed that Landlord may, in addition, claim those sums reasonably necessary to compensate Landlord for any other loss or damage, foreseeable or unforeseeable, caused by the act or omission of Tenant or any officer, employee, agent or invitee of Tenant. Upon bankruptcy or other debtorcreditor proceedings against Tenant, the Security Deposit shall be deemed to be applied first to the payment of Rent and other charges due Landlord for periods prior to the filing of such proceedings. Upon any such use of all or any portion of the Security Deposit, Tenant shall, within 10 days after demand from Landlord, restore the Security Deposit to its original amount. If Tenant shall fully perform every provision of this Lease to be performed by Tenant, the Security Deposit, or any balance thereof (i.e., after deducting therefrom all amounts to which Landlord is entitled under the provisions of this Lease), shall be returned to Tenant (or, at Landlord's option, to the last assignee of Tenant's interest hereunder) within 60 days after the expiration or earlier termination of this Lease.



If Landlord transfers its interest in the Project or this Lease, Landlord shall either (a) transfer any Security Deposit then held by Landlord to a person or entity assuming Landlord's obligations under this Section 6 and shall provide written notice to Tenant of such transfer, including the name and address of such person or entity, or (b) return to Tenant any Security Deposit then held by Landlord and remaining after the deductions permitted herein. Upon such transfer to such transferee or the return of the Security Deposit to Tenant, Landlord shall have no further obligation with respect to the Security Deposit, and Tenant's right to the return of the Security Deposit shall apply solely against Landlord's transferee. The Security Deposit is not an advance rental deposit or a measure of Landlord's damages in case of Tenant's default. Landlord's obligation respecting the Security Deposit is that of a debtor, not a trustee, and no interest shall accrue thereon.

7. **Use**. The Premises shall be used solely for the Permitted Use set forth in the basic lease provisions on page 1 of this Lease, and in compliance with all laws, orders, judgments, ordinances, regulations, codes, directives, permits, licenses, covenants and restrictions now or hereafter applicable to the Premises, and to the use and occupancy thereof, including, without limitation, the Americans With Disabilities Act, 42 U.S.C. § 12101, et seq. (together with the regulations promulgated pursuant thereto, "ADA") (collectively, "Legal Requirements" and each, a "Legal Requirement"). Tenant shall, upon 5 days' written notice from Landlord, discontinue any use of the Premises which is declared by any Governmental Authority (as defined in Section 9) having jurisdiction to be a violation of a Legal Requirement. Tenant will not use or permit the Premises to be used for any purpose or in any manner that would void Tenant's or Landlord's insurance, increase the insurance risk, or cause the disallowance of any sprinkler or other credits. Tenant shall not permit any part of the Premises to be used as a "place of public accommodation", as defined in the ADA or any similar legal requirement. Tenant shall reimburse Landlord promptly upon demand for any additional premium charged for any such insurance policy by reason of Tenant's failure to comply with the provisions of this Section or otherwise caused by Tenant's use and/or occupancy of the Premises. Tenant will use the Premises in a careful, safe and proper manner and will not commit or permit waste, overload the floor or structure of the Premises, subject the Premises to use that would damage the Premises or obstruct or interfere with the rights of Landlord or other tenants or occupants of the Project, including conducting or giving notice of any auction, liquidation, or going out of business sale on the Premises, or using or allowing the Premises to be used for any unlawful purpose. Tenant shall cause any equipment or machinery to be installed in the Premises so as to reasonably prevent sounds or vibrations from the Premises that would have an adverse effect on any other tenant or occupant of the Project from extending into Common Areas, or other space in the Project. Tenant shall not place any machinery or equipment weighing 500 pounds or more in or upon the Premises or transport or move such items through the Common Areas of the Project or in the Project elevators without the prior written consent of Landlord, which consent shall not be unreasonably withheld, conditioned or delayed. Except as may be provided under the Work Letter, Tenant shall not, without the prior written consent of Landlord, which consent shall not be unreasonably withheld, conditioned or delayed, use the Premises in any manner which will require ventilation, air exchange, heating, gas, steam, electricity or water beyond the existing capacity of the Project as proportionately allocated to the Premises based upon Tenant's Share as usually furnished for the Permitted Use.

Landlord shall, at Landlord's cost and expense, and in a manner reasonably acceptable to Landlord, install a ramp providing ADA compliant access to the main entrance of the Premises. Landlord shall use reasonable efforts to complete such ramp on or before the date that is 3 months after the Commencement Date. Except as provided in the two immediately preceding sentences, Tenant, at its sole expense, shall make any alterations or modifications to the interior or the exterior of the Premises or the Project that are required by Legal Requirements (including, without limitation, compliance of the Premises with the ADA) related to Tenant's use or occupancy of the Premises. Notwithstanding any other provision herein to the contrary, Tenant shall be responsible for any and all demands, claims, liabilities, losses, costs, expenses, actions, causes of action, damages or judgments, and all reasonable expenses incurred in investigating or resisting the same (including, without limitation, reasonable attorneys' fees, charges and disbursements and costs of suit) (collectively, "Claims") arising out of or in connection with Legal Requirements, and Tenant shall indemnify, defend, hold and save Landlord harmless from and against any and all Claims arising out of or in connection with any failure of the Premises to comply with any Legal Requirement.



- 8. Holding Over. If, with Landlord's express written consent, Tenant retains possession of the Premises after the termination of the Term, (i) unless otherwise agreed in such written consent, such possession shall be subject to immediate termination by Landlord at any time upon 10 days' written notice to Tenant, (ii) all of the other terms and provisions of this Lease (including, without limitation, the adjustment of Base Rent pursuant to Section 4 hereof) shall remain in full force and effect (excluding any expansion or renewal option or other similar right or option) during such holdover period, (iii) Tenant shall continue to pay Base Rent in the amount payable upon the date of the expiration or earlier termination of this Lease or such other amount as Landlord may indicate, in Landlord's sole and absolute discretion, in such written consent, and (iv) all other payments shall continue under the terms of this Lease. If Tenant remains in possession of the Premises after the expiration or earlier termination of the Term without the express written consent of Landlord, (A) Tenant shall become a tenant at sufferance upon the terms of this Lease except that the monthly rental shall be equal to 150% of Rent in effect during the last 30 days of the Term, and (B) Tenant shall be responsible for all damages suffered by Landlord resulting from or occasioned by Tenant's holding over, including consequential damages. No holding over by Tenant, whether with or without consent of Landlord, shall operate to extend this Lease except as otherwise expressly provided, and this Section 8 shall not be construed as consent for Tenant to retain possession of the Premises. Acceptance by Landlord of Rent after the expiration of the Term or earlier termination of this Lease shall not result in a renewal or reinstatement of this Lease.
- 9. Taxes. Landlord shall pay, as part of Operating Expenses, all taxes, levies, fees, assessments and governmental charges of any kind, existing as of the Commencement Date or thereafter enacted (collectively referred to as "Taxes"), imposed by any federal, state, regional, municipal, local or other governmental authority or agency, including, without limitation, quasi-public agencies (collectively, "Governmental Authority") during the Term, including, without limitation, all Taxes: (i) imposed on or measured by or based, in whole or in part, on rent payable to (or gross receipts received by) Landlord under this Lease and/or from the rental by Landlord of the Project or any portion thereof, or (ii) based on the square footage, assessed value or other measure or evaluation of any kind of the Premises or the Project, or (iii) assessed or imposed by or on the operation or maintenance of any portion of the Premises or the Project, including parking, or (iv) assessed or imposed by, or at the direction of, or resulting from Legal Requirements, or interpretations thereof, promulgated by any Governmental Authority, or (v) imposed as a license or other fee, charge, tax, or assessment on Landlord's business or occupation of leasing space in the Project. Landlord may contest by appropriate legal proceedings the amount, validity, or application of any Taxes or liens securing Taxes. Taxes shall not include any net income taxes imposed on Landlord except to the extent such net income taxes are in substitution for any Taxes payable hereunder. If any such Tax is levied or assessed directly against Tenant, then Tenant shall be responsible for and shall pay the same at such times and in such manner as the taxing authority shall require. Tenant shall pay, prior to delinquency, any and all Taxes levied or assessed against any personal property or trade fixtures placed by Tenant in the Premises, whether levied or assessed against Landlord or Tenant. If any Taxes on Tenant's personal property or trade fixtures are levied against Landlord or Landlord's property, or if the assessed valuation of the Project is increased by a value attributable to improvements in or alterations to the Premises, whether owned by Landlord or Tenant and whether or not affixed to the real property so as to become a part thereof, higher than the base valuation on which Landlord from time-to-time allocates Taxes to all tenants in the Project, Landlord shall have the right, but not the obligation, to pay such Taxes. Landlord's determination of any excess assessed valuation shall be binding and conclusive, absent manifest error. The amount of any such payment by Landlord shall constitute Additional Rent due from Tenant to Landlord immediately upon demand.
- 10. Parking. Subject to all matters of record, Force Majeure, a Taking (as defined in Section 19 below) and the exercise by Landlord of its rights hereunder, Tenant shall have the right, in common with other tenants of the Project pro rata in accordance with the rentable area of the Premises and the rentable areas of the Project occupied by such other tenants, to park in those surface parking areas designated for non-reserved parking, subject in each case to Landlord's rules and regulations, at no additional cost to Tenant. As of the date of this Lease, Tenant's pro rata share of parking is equal to 2.5 parking spaces per 1,000 rentable square feet of the Premises. Landlord may allocate parking spaces among Tenant and other tenants in the Project pro rata as described above if Landlord determines that



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such parking facilities are becoming crowded. Landlord shall not be responsible for enforcing Tenant's parking rights against any third parties, including other tenants of the Project.

## 11. Utilities, Services.

- (a) Landlord shall provide, subject to the terms of this Section 11, water, electricity, heat, light, HVAC, power, sewer, and other utilities (including gas and fire sprinklers to the extent the Project is plumbed for such services), and with respect to the Common Areas, refuse and trash collection and janitorial services (collectively, "Utilities"). Landlord shall pay, as Operating Expenses or subject to Tenant's reimbursement obligation, for all Utilities used on the Premises, all maintenance charges for Utilities, and any storm sewer charges or other similar charges for Utilities imposed by any Governmental Authority or Utility provider, and any taxes, penalties, surcharges or similar charges thereon. Electricity to the Premises is separately metered. Landlord may cause, at Tenant's expense, any other Utilities to be separately metered or charged directly to Tenant by the provider. Tenant shall pay directly to the Utility provider, prior to delinquency, any separately metered Utilities and services which may be furnished to Tenant or the Premises during the Term. Tenant shall pay, as part of Operating Expenses, its share of all charges for jointly metered Utilities based upon consumption, as reasonably determined by Landlord. No interruption or failure of Utilities, from any cause whatsoever other than Landlord's gross negligence or willful misconduct, shall result in eviction or constructive eviction of Tenant, termination of this Lease or the abatement of Rent. Tenant agrees to limit use of water and sewer with respect to Common Areas to normal restroom use. Tenant shall be responsible for obtaining and paying for its own janitorial services for the Premises.
- (b) Landlord's sole obligation for either providing emergency generators or providing emergency back-up power to Tenant shall be: (i) to provide emergency generators with not less than the capacity of the emergency generators located in the Building as of the Commencement Date, and (ii) to contract with a third party to maintain the emergency generators as per the manufacturer's standard maintenance guidelines. Landlord shall have no obligation to provide Tenant with operational emergency generators or back-up power or to supervise, oversee or confirm that the third party maintaining the emergency generators is maintaining the generators as per the manufacturer's standard guidelines or otherwise. During any period of replacement, repair or maintenance of the emergency generators when the emergency generators are not operational, including any delays thereto due to the inability to obtain parts or replacement equipment, Landlord shall have no obligation to provide Tenant with an alternative back-up generator or generators or alternative sources of back-up power. Tenant expressly acknowledges and agrees that Landlord does not guaranty that such emergency generators will be operational at all times or that emergency power will be available to the Premises when needed.
- (c) Landlord shall provide Tenant with access to the acid neutralization system existing as of the date of this Lease ("Acid Neutralization System") pursuant to the terms and conditions of this Lease. Tenant acknowledges and agrees that the Acid Neutralization System shall be shared with other tenants of the Project. Tenant's obligation to pay its share of ongoing operation costs shall be allocated among Tenant and other user tenants on a pro rata basis, with Tenant's share based on the ratio of the rentable square footage of the Premises to the sum of the rentable square footages of the Premises and the premises of all other user tenants. Landlord's sole obligations for providing the Acid Neutralization System, or any acid neutralization system facilities, to Tenant shall be (the "Acid Neutralization Obligations") to (i) use reasonable efforts to obtain and maintain the permit required from the Massachusetts Water Resources Authority for discharge through the Acid Neutralization System (the "Discharge Permit"), provided that Tenant cooperates with Landlord and provides all information and documents necessary in connection with the Discharge Permit, and (ii) contract with a third party to maintain the Acid Neutralization System as operating as per the manufacturer's standard maintenance guidelines. Notwithstanding anything herein to the contrary, if the Acid Neutralization System must be replaced and the cost thereof is not included in such third party maintenance contract, then, Landlord shall replace the Acid Neutralization System, it being acknowledged, however, that Tenant shall be responsible for its share of all costs incurred in connection as an Operating Expense.



Tenant shall be solely responsible for the use of the Acid Neutralization System by Tenant, its employees, any sublessees, invitees or any party other than Landlord or Landlord's contractors, and Tenant shall be jointly and severally responsible for the use of the Acid Neutralization System with the other user tenants. Tenant shall use, and cause other parties under its control or for which it is responsible to use, the Acid Neutralization System in accordance with this Lease and in accordance with all applicable Legal Requirements, the Discharge Permit and any permits and approvals from Governmental Authorities for or applicable to Tenant's use of the Acid Neutralization System. Tenant shall not take any action or make any omission that would result in a violation of the Discharge Permit or any other permit or Legal Requirements applicable to the Acid Neutralization System. The scope of the Surrender Plan (as defined in Section 28 of this Lease) shall include all actions for the proper cleaning, decommissioning and cessation of Tenant's use of the Acid Neutralization System, and all requirements under this Lease for the surrender of the Premises shall also apply to Tenant's cessation of use of the Acid Neutralization System, in each case whether at Lease expiration, termination or prior thereto (but Tenant shall not be required to complete the decommissioning of the Acid Neutralization System if other tenants or occupants will continue to use the same after the expiration or earlier termination of the Lease, nor shall Tenant be responsible for or bear any costs of decommissioning arising from the use of the Acid Neutralization System by any party other than Tenant; it being agreed that if multiple tenants use the Acid Neutralization System, then Landlord shall be responsible for completing the decommissioning thereof, and Tenant shall pay to Landlord within thirty (30) days after invoice therefor Tenant's share of the reasonable, actual costs of decommissioning based on the ratio of the rentable square footage of the Premises to the rentable square footage of the Premises and the premises of all other user tenants). The obligations of Tenant under this Lease with respect to the Acid Neutralization System shall be joint and several with such other tenants as aforesaid, except in the event that Tenant can prove to Landlord's reasonable satisfaction that neither Tenant nor any Tenant Party caused, contributed to or exacerbated the matter for which Tenant would otherwise be responsible but for this exception. Without in any way limiting the Acid Neutralization Obligations, Landlord shall have no obligation to provide Tenant with operational emergency or back-up acid neutralization facilities or to supervise, oversee or confirm that the third party maintaining the Acid Neutralization System is maintaining such system as per the manufacturer's standard guidelines or otherwise. During any period of replacement, repair or maintenance of the Acid Neutralization System when such system is not operational, including any delays thereto due to the inability to obtain parts or replacement equipment, Landlord shall have no obligation to provide Tenant with an alternative back-up system or facilities. Tenant expressly acknowledges and agrees that Landlord does not guaranty that such Acid Neutralization System will be operational at all times or that such system will be available to the Premises when needed. Without in any way limiting the Acid Neutralization Obligations, in no event shall Landlord be liable to Tenant or any other party for any damages of any type, whether actual or consequential, suffered by Tenant or any such other person in the event that the Acid Neutralization System or back-up system, if any, or any replacement thereof fails or does not operate in a manner that meets Tenant's requirements.

12. Alterations and Tenant's Property. Any alterations, additions, or improvements made to the Premises by or on behalf of Tenant, including additional locks or bolts of any kind or nature upon any doors or windows in the Premises, but excluding installation, removal or realignment of furniture systems (other than removal of furniture systems owned or paid for by Landlord) not involving any modifications to the structure or connections (other than by ordinary plugs or jacks) to Building Systems (as defined in Section 13) ("Alterations") shall be subject to Landlord's prior written consent, which may be given or withheld in Landlord's sole discretion if any such Alteration affects the structure or Building Systems and shall not be otherwise unreasonably withheld, conditioned or delayed. If Landlord approves any Alterations, Landlord may impose such reasonable conditions on Tenant in connection with the commencement, performance and completion of such Alterations as Landlord may deem appropriate in Landlord's reasonable discretion. Any request for approval shall be in writing, delivered not less than 15 business days in advance of any proposed construction, and accompanied by plans, specifications, bid proposals, work contracts and such other information concerning the nature and cost of the alterations as may be reasonably requested by Landlord, including the identities and mailing addresses of all persons performing work or supplying materials. Landlord's right to review plans and specifications and to monitor construction shall be solely for its own benefit, and Landlord shall have no duty to ensure that such plans



and specifications or construction comply with applicable Legal Requirements. Tenant shall cause, at its sole cost and expense, all Alterations to comply with insurance requirements and with Legal Requirements and shall implement at its sole cost and expense any alteration or modification required by Legal Requirements as a result of any Alterations. Tenant shall pay to Landlord, as Additional Rent, on demand an amount equal to 3% of all charges incurred by Tenant or its contractors or agents in connection with any Alteration to cover Landlord's overhead and expenses for plan review, coordination, scheduling and supervision. Before Tenant begins any Alteration, Landlord may post on and about the Premises notices of non-responsibility pursuant to applicable law. Tenant shall reimburse Landlord for, and indemnify and hold Landlord harmless from, any expense incurred by Landlord by reason of faulty work done by Tenant or its contractors, delays caused by such work, or inadequate cleanup.

Tenant shall furnish security or make other arrangements satisfactory to Landlord to assure payment for the completion of all Alterations work free and clear of liens, and shall provide (and cause each contractor or subcontractor to provide) certificates of insurance for workers' compensation and other coverage in amounts and from an insurance company satisfactory to Landlord protecting Landlord against liability for personal injury or property damage during construction. Upon completion of any Alterations, Tenant shall deliver to Landlord: (i) sworn statements setting forth the names of all contractors and subcontractors who did the work and final lien waivers from all such contractors and subcontractors; and (ii) "as built" plans for any such Alteration.

Except for Removable Installations (as hereinafter defined), all Installations (as hereinafter defined) shall be and shall remain the property of Landlord during the Term and following the expiration or earlier termination of the Term, shall not be removed by Tenant at any time during the Term, and shall remain upon and be surrendered with the Premises as a part thereof. Notwithstanding the foregoing, Landlord may, at the time its approval of any such Installation is requested, notify Tenant that Landlord requires that Tenant remove such Installation upon the expiration or earlier termination of the Term, in which event Tenant shall remove such Installation in accordance with the immediately succeeding sentence. Upon the expiration or earlier termination of the Term unless otherwise required by Landlord, Tenant shall remove (i) all wires, cables or similar equipment which Tenant has installed in the Premises or in the risers or plenums of the Building, (ii) any Installations for which Landlord has given Tenant notice of removal in accordance with the immediately preceding sentence, and (iii) all of Tenant's Property (as hereinafter defined), and Tenant shall restore and repair any damage caused by or occasioned as a result of such removal, including, without limitation, capping off all such connections behind the walls of the Premises and repairing any holes. During any restoration period beyond the expiration or earlier termination of the Term, Tenant shall pay Rent to Landlord as provided herein as if said space were otherwise occupied by Tenant. If Landlord is requested by Tenant or any lender, lessor or other person or entity claiming an interest in any of Tenant's Property to waive any lien Landlord may have against any of Tenant's Property, and Landlord consents to such waiver, then Landlord shall be entitled to be paid as administrative rent a fee of \$1,000 per occurrence for its time and effort in preparing and negotiating such a waiver of lien.

For purposes of this Lease, (x) "Removable Installations" means any items listed on Exhibit F attached hereto and any items agreed by Landlord in writing to be included on Exhibit F in the future, (y) "Tenant's Property" means Removable Installations and, other than Installations, any personal property or equipment of Tenant that may be removed without material damage to the Premises, and (z) "Installations" means all property of any kind paid for with the TI Fund, all Alterations, all fixtures, and all partitions, hardware, built-in machinery, built-in casework and cabinets and other similar additions, equipment, property and improvements built into the Premises so as to become an integral part of the Premises, including, without limitation, fume hoods which penetrate the roof or plenum area, built-in cold rooms, built-in warm rooms, walk-in cold rooms, walk-in warm rooms, deionized water systems, builtin plumbing, electrical and mechanical equipment and systems, and any power generator and transfer switch.

13. Landlord's Repairs. Landlord, as an Operating Expense, shall maintain all of the structural, exterior, parking and other Common Areas of the Project, including HVAC, plumbing, fire sprinklers, elevators and all other building systems serving the Premises and other portions of the Project



("Building Systems"), in good repair, reasonable wear and tear and uninsured losses and damages caused by Tenant, or by any of Tenant's agents, servants, employees, invitees and contractors (collectively, "Tenant Parties") excluded. Losses and damages caused by Tenant or any Tenant Party shall be repaired by Landlord, to the extent not covered by insurance, at Tenant's sole cost and expense. Landlord reserves the right to stop Building Systems services when reasonably necessary (i) by reason of accident or emergency, or (ii) for planned repairs, alterations or improvements, which are, in the judgment of Landlord, desirable or necessary to be made, until said repairs, alterations or improvements shall have been completed. Landlord shall have no responsibility or liability for failure to supply Building Systems services during any such period of interruption; provided, however, that Landlord shall, except in case of emergency, make a commercially reasonable effort to give Tenant 48 hours advance notice of any planned stoppage of Building Systems services for routine maintenance, repairs, alterations or improvements. Tenant shall promptly give Landlord written notice of any repair required by Landlord pursuant to this Section 13 after which Landlord shall make a commercially reasonable effort to effect such repair. Subject to the terms of Section 31 hereof, Landlord shall not be liable for any failure to make any repairs or to perform any maintenance unless such failure shall persist for an unreasonable time after Tenant's written notice of the need for such repairs or maintenance. Tenant waives its rights under any state or local law to terminate this Lease or to make such repairs at Landlord's expense and agrees that the parties' respective rights with respect to such matters shall be solely as set forth herein. Repairs required as the result of fire, earthquake, flood, vandalism, war, or similar cause of damage or destruction shall be controlled by Section 18.

- 14. **Tenant's Repairs**. Subject to Section 13 hereof, Tenant, at its expense, shall repair, replace and maintain in good condition all portions of the Premises, including, without limitation, entries, doors, ceilings, interior windows, interior walls, and the interior side of demising walls. Such repair and replacement may include capital expenditures and repairs whose benefit may extend beyond the Term. Should Tenant fail to make any such repair or replacement or fail to maintain the Premises, Landlord shall give Tenant notice of such failure. If Tenant fails to commence cure of such failure within 15 days of Landlord's notice, and thereafter diligently prosecute such cure to completion, Landlord may perform such work and shall be reimbursed by Tenant within 30 days after demand therefor; provided, however, that if such failure by Tenant creates or could create an emergency, Landlord may immediately commence cure of such failure and shall thereafter be entitled to recover the costs of such cure from Tenant. Subject to Sections 17 and 18, Tenant shall bear the full uninsured cost of any repair or replacement to any part of the Project that results from damage caused by Tenant or any Tenant Party and any repair that benefits only the Premises.
- 15. Mechanic's Liens. Tenant shall discharge, by bond or otherwise, any mechanic's lien filed against the Premises or against the Project for work claimed to have been done for, or materials claimed to have been furnished to, Tenant within 10 days after the filing thereof, at Tenant's sole cost and shall otherwise keep the Premises and the Project free from any liens arising out of work performed, materials furnished or obligations incurred by Tenant. Should Tenant fail to discharge any lien described herein, Landlord shall have the right, but not the obligation, to pay such claim or post a bond or otherwise provide security to eliminate the lien as a claim against title to the Project and the cost thereof shall be immediately due from Tenant as Additional Rent. If Tenant shall lease or finance the acquisition of office equipment, furnishings, or other personal property of a removable nature utilized by Tenant in the operation of Tenant's business, Tenant warrants that any Uniform Commercial Code Financing Statement filed as a matter of public record by any lessor or creditor of Tenant will upon its face or by exhibit thereto indicate that such Financing Statement is applicable only to removable personal property of Tenant located within the Premises. In no event shall the address of the Project be furnished on the statement without qualifying language as to applicability of the lien only to removable personal property, located in an identified suite held by Tenant.
- 16. Indemnification. Tenant hereby indemnifies and agrees to defend, save and hold Landlord harmless from and against any and all Claims for injury or death to persons or damage to property occurring within or about the Premises, arising directly or indirectly out of use or occupancy of the Premises or a breach or default by Tenant in the performance of any of its obligations hereunder, unless caused solely by the willful misconduct or negligence of Landlord or any employees or agents of



Landlord. Landlord shall not be liable to Tenant for, and Tenant assumes all risk of damage to, personal property (including, without limitation, loss of records kept within the Premises). Tenant further waives any and all Claims for injury to Tenant's business or loss of income relating to any such damage or destruction of personal property (including, without limitation, any loss of records). Landlord shall not be liable for any damages arising from any act, omission or neglect of any tenant in the Project or of any other third party.

17. Insurance. Landlord shall maintain all risk property and, if applicable, sprinkler damage insurance covering the full replacement cost of the Project or such lesser coverage amount as Landlord may elect provided such coverage amount is not less than 90% of such full replacement cost. Landlord shall further procure and maintain commercial general liability insurance with a single loss limit of not less than \$2,000,000 for bodily injury and property damage with respect to the Project. Landlord may, but is not obligated to, maintain such other insurance and additional coverages as it may deem reasonably necessary, including, but not limited to, flood, environmental hazard and earthquake, loss or failure of building equipment, errors and omissions, rental loss during the period of repair or rebuilding, workers' compensation insurance and fidelity bonds for employees employed to perform services and insurance for any improvements installed by Tenant or which are in addition to the standard improvements customarily furnished by Landlord without regard to whether or not such are made a part of the Project. All such insurance shall be included as part of the Operating Expenses. The Project may be included in a blanket policy (in which case the cost of such insurance allocable to the Project will be determined by Landlord based upon the insurer's cost calculations). Tenant shall also reimburse Landlord for any increased premiums or additional insurance which Landlord reasonably deems necessary as a result of Tenant's use of the Premises.

Tenant, at its sole cost and expense, shall maintain during the Term: all risk property insurance with business interruption and extra expense coverage, covering the full replacement cost of all property and improvements installed or placed in the Premises by Tenant at Tenant's expense; workers' compensation insurance with no less than the minimum limits required by law; employer's liability insurance with such limits as required by law; and commercial general liability insurance, with a minimum limit of not less than \$2,000,000 per occurrence for bodily injury and property damage with respect to the Premises. The commercial general liability insurance policy shall name Alexandria Real Estate Equities, Inc., and Landlord, its officers, directors, employees, managers, agents, invitees and contractors (collectively, "Landlord Parties"), as additional insureds; insure on an occurrence and not a claims-made basis; be issued by insurance companies which have a rating of not less than policyholder rating of A and financial category rating of at least Class X in "Best's Insurance Guide"; shall not be cancelable for nonpayment of premium unless 15 days prior written notice shall have been given to Landlord from the insurer; contain a hostile fire endorsement and a contractual liability endorsement; and provide primary coverage to Landlord (any policy issued to Landlord providing duplicate or similar coverage shall be deemed excess over Tenant's policies). Copies of such policies (if requested by Landlord), or certificates of insurance showing the limits of coverage required hereunder and showing Landlord as an additional insured, along with reasonable evidence of the payment of premiums for the applicable period, shall be delivered to Landlord by Tenant upon commencement of the Term and upon each renewal of said insurance. Tenant's policy may be a "blanket policy" with an aggregate per location endorsement which specifically provides that the amount of insurance shall not be prejudiced by other losses covered by the policy. Tenant shall, at least 5 days prior to the expiration of such policies, furnish Landlord with renewal certificates.

In each instance where insurance is to name Landlord as an additional insured, Tenant shall upon written request of Landlord also designate and furnish certificates so evidencing Landlord as additional insured to: (i) any lender of Landlord holding a security interest in the Project or any portion thereof, (ii) the landlord under any lease wherein Landlord is tenant of the real property on which the Project is located, if the interest of Landlord is or shall become that of a tenant under a ground or other underlying lease rather than that of a fee owner, and/or (iii) any management company retained by Landlord to manage the Project.



The property insurance obtained by Landlord and Tenant shall include a waiver of subrogation by the insurers and all rights based upon an assignment from its insured, against Landlord or Tenant, and their respective officers, directors, employees, managers, agents, invitees and contractors ("Related Parties"), in connection with any loss or damage thereby insured against. Neither party nor its respective Related Parties shall be liable to the other for loss or damage caused by any risk insured against under property insurance required to be maintained hereunder, and each party waives any claims against the other party, and its respective Related Parties, for such loss or damage. The failure of a party to insure its property shall not void this waiver. Landlord and its respective Related Parties shall not be liable for, and Tenant hereby waives all claims against such parties for, business interruption and losses occasioned thereby sustained by Tenant or any person claiming through Tenant resulting from any accident or occurrence in or upon the Premises or the Project from any cause whatsoever. If the foregoing waivers shall contravene any law with respect to exculpatory agreements, the liability of Landlord or Tenant shall be deemed not released but shall be secondary to the other's insurer.

Landlord may require insurance policy limits to be raised to conform with requirements of Landlord's lender and/or to bring coverage limits to levels then being generally required of new tenants within the Project.

18. Restoration. If, at any time during the Term, the Project or the Premises are damaged or destroyed by a fire or other insured casualty, Landlord shall notify Tenant within 45 days after discovery of such damage as to the amount of time Landlord reasonably estimates it will take to restore the Project or the Premises, as applicable (the "Restoration Period"). If the Restoration Period is estimated to exceed 9 months (the "Maximum Restoration Period"), Landlord may, in such notice, elect to terminate this Lease as of the date that is 75 days after the date of discovery of such damage or destruction; provided, however, that notwithstanding Landlord's election to restore, Tenant may elect to terminate this Lease by written notice to Landlord delivered within 10 business days of receipt of a notice from Landlord estimating a Restoration Period for the Premises longer than the Maximum Restoration Period. Unless Landlord or Tenant so elect to terminate this Lease, Landlord shall, subject to receipt of sufficient insurance proceeds (with any deductible to be treated as a current Operating Expense), promptly restore the Premises (excluding the improvements installed by Tenant or by Landlord and paid for by Tenant), subject to delays arising from the collection of insurance proceeds, from Force Majeure events or as needed to obtain any license, clearance or other authorization of any kind required to enter into and restore the Premises issued by any Governmental Authority having jurisdiction over the use, storage, handling, treatment, generation, release, disposal, removal or remediation of Hazardous Materials (as defined in Section 30) in, on or about the Premises (collectively referred to herein as "Hazardous Materials Clearances"); provided, however, that if repair or restoration of the Premises is not substantially complete as of the end of the Maximum Restoration Period or, if longer, the Restoration Period, Landlord may, in its sole and absolute discretion, elect not to proceed with such repair and restoration, in which event Landlord shall be relieved of its obligation to make such repairs or restoration and this Lease shall terminate as of the date that is 75 days after the later of: (i) discovery of such damage or destruction, or (ii) the date all required Hazardous Materials Clearances are obtained, but Landlord shall retain any Rent paid and the right to any Rent payable by Tenant prior to such election by Landlord or Tenant.

Tenant, at its expense, shall promptly perform, subject to delays arising from the collection of insurance proceeds, from Force Majeure (as defined in Section 34) events or to obtain Hazardous Material Clearances, all repairs or restoration not required to be done by Landlord. Notwithstanding the foregoing, either Landlord or Tenant may terminate this Lease upon written notice to the other if the Premises are damaged during the last year of the Term and Landlord reasonably estimates that it will take more than 2 months to repair such damage; provided, however, that such notice is delivered within 10 business days after the date that Landlord provides Tenant with written notice of the estimated Restoration Period. Landlord shall also have the right to terminate this Lease if insurance proceeds are not available for such restoration. Rent shall be abated from the date all required Hazardous Material Clearances are obtained until the Premises are repaired and restored, in the proportion which the area of the Premises, if any, which is not usable by Tenant bears to the total area of the Premises, unless Landlord provides Tenant with other space reasonably acceptable to Tenant during the period of repair



that is suitable for the temporary conduct of Tenant's business. Such abatement shall be the sole remedy of Tenant, and except as provided in this Section 18, Tenant waives any right to terminate the Lease by reason of damage or casualty loss.

The provisions of this Lease, including this Section 18, constitute an express agreement between Landlord and Tenant with respect to any and all damage to, or destruction of, all or any part of the Premises, or any other portion of the Project, and any statute or regulation which is now or may hereafter be in effect shall have no application to this Lease or any damage or destruction to all or any part of the Premises or any other portion of the Project, the parties hereto expressly agreeing that this Section 18 sets forth their entire understanding and agreement with respect to such matters.

- 19. **Condemnation**. If the whole or any material part of the Premises or the Project is taken for any public or quasi-public use under governmental law, ordinance, or regulation, or by right of eminent domain, or by private purchase in lieu thereof (a "Taking" or "Taken"), and the Taking would in Landlord's reasonable judgment, either prevent or materially interfere with Tenant's use of the Premises or materially interfere with or impair Landlord's ownership or operation of the Project, then upon written notice by Landlord this Lease shall terminate and Rent shall be apportioned as of said date. If part of the Premises shall be Taken, and this Lease is not terminated as provided above, Landlord shall promptly restore the Premises and the Project as nearly as is commercially reasonable under the circumstances to their condition prior to such partial Taking and the rentable square footage of the Building, the rentable square footage of the Premises, Tenant's Share of Operating Expenses and the Rent payable hereunder during the unexpired Term shall be reduced to such extent as may be fair and reasonable under the circumstances. Upon any such Taking, Landlord shall be entitled to receive the entire price or award from any such Taking without any payment to Tenant, and Tenant hereby assigns to Landlord Tenant's interest, if any, in such award. Tenant shall have the right, to the extent that same shall not diminish Landlord's award, to make a separate claim against the condemning authority (but not Landlord) for such compensation as may be separately awarded or recoverable by Tenant for moving expenses and damage to Tenant's trade fixtures, if a separate award for such items is made to Tenant. Tenant hereby waives any and all rights it might otherwise have pursuant to any provision of state law to terminate this Lease upon a partial Taking of the Premises or the Project.
  - 20. Events of Default. Each of the following events shall be a default ("Default") by Tenant under this Lease:
- (a) Payment Defaults. Tenant shall fail to pay any installment of Rent or any other payment hereunder when due; provided, however, that Landlord will give Tenant notice and an opportunity to cure any failure to pay Rent within 3 business days of any such notice not more than once in any 12 month period and Tenant agrees that such notice shall be in lieu of and not in addition to, or shall be deemed to be, any notice required by law.
- (b) Insurance. Any insurance required to be maintained by Tenant pursuant to this Lease shall be canceled or terminated or shall expire or shall be reduced or materially changed, or Landlord shall receive a notice of nonrenewal of any such insurance and Tenant shall fail to obtain replacement insurance at least 20 days before the expiration of the current coverage.
  - (c) **Abandonment**. Tenant shall abandon the Premises.
- (d) Improper Transfer. Tenant shall assign, sublease or otherwise transfer or attempt to transfer all or any portion of Tenant's interest in this Lease or the Premises except as expressly permitted herein, or Tenant's interest in this Lease shall be attached, executed upon, or otherwise judicially seized and such action is not released within 90 days of the action.
- (e) Liens. Tenant shall fail to discharge or otherwise obtain the release of any lien placed upon the Premises in violation of this Lease within 10 days after any such lien is filed against the Premises.



- (f) Insolvency Events. Tenant or any guarantor or surety of Tenant's obligations hereunder shall: (A) make a general assignment for the benefit of creditors; (B) commence any case, proceeding or other action seeking to have an order for relief entered on its behalf as a debtor or to adjudicate it a bankrupt or insolvent, or seeking reorganization, arrangement, adjustment, liquidation, dissolution or composition of it or its debts or seeking appointment of a receiver, trustee, custodian or other similar official for it or for all or of any substantial part of its property (collectively a "Proceeding for Relief"); (C) become the subject of any Proceeding for Relief which is not dismissed within 90 days of its filing or entry; or (D) die or suffer a legal disability (if Tenant, guarantor, or surety is an individual) or be dissolved or otherwise fail to maintain its legal existence (if Tenant, guarantor or surety is a corporation, partnership or other
- (g) Estoppel Certificate or Subordination Agreement. Tenant fails to execute any document required from Tenant under Sections 23 or 27 within 5 days after a second notice requesting such document.
- (h) Other Defaults. Tenant shall fail to comply with any provision of this Lease other than those specifically referred to in this Section 20, and, except as otherwise expressly provided herein, such failure shall continue for a period of 10 business days after written notice thereof from Landlord to Tenant.

Any notice given under Section 20(h) hereof shall: (i) specify the alleged default, (ii) demand that Tenant cure such default, (iii) be in lieu of, and not in addition to, or shall be deemed to be, any notice required under any provision of applicable law, and (iv) not be deemed a forfeiture or a termination of this Lease unless Landlord elects otherwise in such notice; provided that if the nature of Tenant's default pursuant to Section 20(h) is such that it cannot be cured by the payment of money and reasonably requires more than 10 business days to cure, then Tenant shall not be deemed to be in default if Tenant commences such cure within said 10 business day period and thereafter diligently prosecutes the same to completion; provided, however, that such cure shall be completed no later than 45 days from the date of Landlord's notice.

#### 21. Landlord's Remedies.

- (a) Payment By Landlord; Interest. Upon a Default by Tenant hereunder, Landlord may, without waiving or releasing any obligation of Tenant hereunder, make such payment or perform such act. All sums so paid or incurred by Landlord, together with interest thereon, from the date such sums were paid or incurred, at the annual rate equal to 12% per annum or the highest rate permitted by law (the "Default Rate"), whichever is less, shall be payable to Landlord on demand as Additional Rent. Nothing herein shall be construed to create or impose a duty on Landlord to mitigate any damages resulting from Tenant's Default hereunder.
- (b) Late Payment Rent. Late payment by Tenant to Landlord of Rent and other sums due will cause Landlord to incur costs not contemplated by this Lease, the exact amount of which will be extremely difficult and impracticable to ascertain. Such costs include, but are not limited to, processing and accounting charges and late charges which may be imposed on Landlord under any Mortgage covering the Premises. Therefore, if any installment of Rent due from Tenant is not received by Landlord within 7 days after the date such payment is due, Tenant shall pay to Landlord an additional sum of 6% of the overdue Rent as a late charge. Notwithstanding the foregoing, before assessing a late charge the first time in any calendar year, Landlord shall provide Tenant written notice of the delinquency and will waive the right if Tenant pays such delinquency within 7 days thereafter. The parties agree that this late charge represents a fair and reasonable estimate of the costs Landlord will incur by reason of late payment by Tenant. In addition to the late charge, Rent not paid when due shall bear interest at the Default Rate from the 7th day after the date due until paid.
- (c) Remedies. Upon the occurrence of a Default, Landlord, at its option, without further notice or demand to Tenant, shall have in addition to all other rights and remedies provided in this Lease, at law or in equity, the option to pursue any one or more of the following remedies, each and all of which



shall be cumulative and nonexclusive, without any notice or demand whatsoever. No cure in whole or in part of such Default by Tenant after Landlord has taken any action beyond giving Tenant notice of such Default to pursue any remedy provided for herein (including retaining counsel to file an action or otherwise pursue any remedies) shall in any way affect Landlord's right to pursue such remedy or any other remedy provided Landlord herein or under law or in equity, unless Landlord, in its sole discretion, elects to waive such Default.

- (i) This Lease and the Term and estate hereby granted are subject to the limitation that whenever a Default shall have happened and be continuing, Landlord shall have the right, at its election, then or thereafter while any such Default shall continue and notwithstanding the fact that Landlord may have some other remedy hereunder or at law or in equity, to give Tenant written notice of Landlord's intention to terminate this Lease on a date specified in such notice, which date shall be not less than 5 days after the giving of such notice, and upon the date so specified, this Lease and the estate hereby granted shall expire and terminate with the same force and effect as if the date specified in such notice were the date hereinbefore fixed for the expiration of this Lease, and all right of Tenant hereunder shall expire and terminate, and Tenant shall be liable as hereinafter in this Section 21(c) provided. If any such notice is given, Landlord shall have, on such date so specified, the right of re-entry and possession of the Premises and the right to remove all persons and property therefrom and to store such property in a warehouse or elsewhere at the risk and expense, and for the account, of Tenant. Should Landlord elect to re-enter as herein provided or should Landlord take possession pursuant to legal proceedings or pursuant to any notice provided for by law, Landlord may from time to time re-let the Premises or any part thereof for such term or terms and at such rental or rentals and upon such terms and conditions as Landlord may deem advisable, with the right to make commercially reasonable alterations in and repairs to the Premises.
- (ii) In the event of any termination of this Lease as in this Section 21 provided or as required or permitted by law or in equity, Tenant shall forthwith quit and surrender the Premises to Landlord, and Landlord may, without further notice, enter upon, re-enter, possess and repossess the same by summary proceedings, ejectment or otherwise, and again have, repossess and enjoy the same as if this Lease had not been made, and in any such event Tenant and no person claiming through or under Tenant by virtue of any law or an order of any court shall be entitled to possession or to remain in possession of the Premises. Landlord, at its option, notwithstanding any other provision of this Lease, shall be entitled to recover from Tenant, as and for liquidated damages, the sum of:
  - (A) all Base Rent, Additional Rent and other amounts payable by Tenant hereunder then due or accrued and unpaid: and
  - (B) the amount equal to the aggregate of all unpaid Base Rent and Additional Rent which would have been payable if this Lease had not been terminated prior to the end of the Term then in effect, discounted to its then present value in accordance with accepted financial practice using a rate of 5% per annum, for loss of the bargain; and
  - (C) all other damages and expenses (including attorneys' fees and expenses), if any, which Landlord shall have sustained by reason of the breach of any provision of this Lease; less
  - (D) the net proceeds of any re-letting actually received by Landlord and the amount of damages which Tenant proves could have been avoided had Landlord taken reasonable steps to mitigate its damages.
- (iii) Nothing herein contained shall limit or prejudice the right of Landlord, in any bankruptcy or insolvency proceeding, to prove for and obtain as liquidated damages by reason of

such termination an amount equal to the maximum allowed by any bankruptcy or insolvency proceedings, or to prove for and obtain as liquidated damages by reason of such termination, an amount equal to the maximum allowed by any statute or rule of law, but in each case not more than the amount to which Landlord would otherwise be entitled under this Section 21.

- (iv) Nothing in this Section 21 shall be deemed to affect the right of either party to indemnifications pursuant to this Lease.
- (v) If Landlord terminates this Lease upon the occurrence of a Default, Tenant will quit and surrender the Premises to Landlord or its agents, and Landlord may, without further notice, enter upon, re-enter and repossess the Premises by summary proceedings, ejectment or otherwise. The words "enter", "re-enter", and "re-entry" are not restricted to their technical legal meanings.
- (vi) If either party shall be in default in the observance or performance of any provision of this Lease, and an action shall be brought for the enforcement thereof, the non-prevailing party shall pay to the prevailing party all fees, costs and other expenses which may become payable as a result thereof or in connection therewith, including attorneys' fees and expenses.
- (vii) If Tenant shall default in the keeping, observance or performance of any covenant, agreement, term, provision or condition herein contained, Landlord, without thereby waiving such default, may perform the same for the account and at the expense of Tenant (a) immediately or at any time thereafter and without notice in the case of emergency or in case such default will result in a violation of any legal or insurance requirements, or in the imposition of any lien against all or any portion of the Premises (but only after Tenant has failed to respond to such lien as permitted by Section 15 within the time period provided in Section 15), and (b) in any other case if such default continues after any applicable notice and cure period provided in Section 21. All reasonable costs and expenses incurred by Landlord in connection with any such performance by it for the account of Tenant and also all reasonable costs and expenses, including attorneys' fees and disbursements incurred by Landlord in any action or proceeding (including any summary dispossess proceeding) brought by Landlord to enforce any obligation of Tenant under this Lease and/or right of Landlord in or to the Premises, shall be paid by Tenant to Landlord within 10 days after demand.
- (viii) Independent of the exercise of any other remedy of Landlord hereunder or under applicable law, Landlord may conduct an environmental test of the Premises as generally described in <u>Section 30(d)</u>, at Tenant's reasonable expense, to the extent provided in <u>Section 30(d)</u>.
- (ix) In the event that Tenant is in breach or Default under this Lease, whether or not Landlord exercises its right to terminate or any other remedy, Tenant shall reimburse Landlord upon demand for any reasonable costs and expenses that Landlord may incur in connection with any such breach or Default, as provided in this Section 21(c). Such costs shall include reasonable legal fees and costs incurred for the negotiation of a settlement, enforcement of rights or otherwise. Tenant shall also indemnify Landlord against and hold Landlord harmless from all reasonable costs, expenses, demands and liability, including without limitation, legal fees and costs Landlord shall incur if Landlord shall become or be made a party to any claim or action instituted by Tenant against any third party, or by any third party against Tenant, or by or against any person holding any interest under or using the Premises by license of or agreement with Tenant.

Except as otherwise provided in this <u>Section 21</u>, no right or remedy herein conferred upon or reserved to Landlord is intended to be exclusive of any other right or remedy, and every right and remedy shall be cumulative and in addition to any other legal or equitable right or remedy given



hereunder, or now or hereafter existing. No waiver of any provision of this Lease shall be deemed to have been made unless expressly so made in writing. Landlord shall be entitled, to the extent permitted by law, to seek injunctive relief in case of the violation, or attempted or threatened violation, of any provision of this Lease, or to seek a decree compelling observance or performance of any provision of this Lease, or to seek any other legal or equitable remedy.

## 22. Assignment and Subletting.

- (a) General Prohibition. Without Landlord's prior written consent subject to and on the conditions described in this Section 22, Tenant shall not, directly or indirectly, voluntarily or by operation of law, assign this Lease or sublease the Premises or any part thereof or mortgage, pledge, or hypothecate its leasehold interest or grant any concession or license within the Premises, and any attempt to do any of the foregoing shall be void and of no effect. If Tenant is a corporation, partnership or limited liability company, the shares or other ownership interests thereof which are not actively traded upon a stock exchange or in the over-the-counter market, a transfer or series of transfers whereby 50% or more of the issued and outstanding shares or other ownership interests of such corporation are, or voting control is, transferred (but excepting transfers upon deaths of individual owners) from a person or persons or entity or entities which were owners thereof at time of execution of this Lease to persons or entities who were not owners of shares or other ownership interests of the corporation, partnership or limited liability company at time of execution of this Lease, shall be deemed an assignment of this Lease requiring the consent of Landlord as provided in this Section 22. Notwithstanding the foregoing, any public offering of shares or other ownership interest in Tenant shall not be deemed an assignment under the terms of this Lease.
- (b) Permitted Transfers. If Tenant desires to assign, sublease, hypothecate or otherwise transfer this Lease or sublet the Premises other than pursuant to a Permitted Assignment (as defined below), then at least 15 business days, but not more than 45 business days, before the date Tenant desires the assignment or sublease to be effective (the "Assignment Date"), Tenant shall give Landlord a written notice (the "Assignment Notice") containing such information about the proposed assignee or sublessee, including the proposed use of the Premises and any Hazardous Materials proposed to be used, stored handled, treated, generated in or released or disposed of from the Premises, the Assignment Date, any relationship between Tenant and the proposed assignee or sublessee, and all material terms and conditions of the proposed assignment or sublease, including a copy of any proposed assignment or sublease in substantially its final form, and such other information as Landlord may deem reasonably necessary or appropriate to its consideration whether to grant its consent. Landlord may, by giving written notice to Tenant within 15 business days after receipt of the Assignment Notice: (i) grant such consent, or (ii) refuse such consent, in its reasonable discretion. Among other reasons, it shall be reasonable for Landlord to withhold its consent in any of these instances: (1) the proposed assignee or subtenant is a governmental agency; (2) in Landlord's reasonable judgment, the use of the Premises by the proposed assignee or subtenant would entail any alterations that would lessen the value of the leasehold improvements in the Premises, or would require increased services by Landlord; (3) in Landlord's reasonable judgment, the proposed assignee or subtenant is engaged in areas of scientific research or other business concerns that are controversial; (4) in Landlord's reasonable judgment, the proposed assignee or subtenant lacks the creditworthiness to support the financial obligations it will incur under the proposed assignment or sublease; (5) in Landlord's reasonable judgment, the character, reputation, or business of the proposed assignee or subtenant is inconsistent with the desired tenant-mix or the quality of other tenancies in the Project or is inconsistent with the type and quality of the nature of the Building; (6) Landlord has received from any prior landlord to the proposed assignee or subtenant a negative report concerning such prior landlord's experience with the proposed assignee or subtenant; (7) Landlord has experienced previous defaults by or is in litigation with the proposed assignee or subtenant; (8) the use of the Premises by the proposed assignee or subtenant will violate any applicable Legal Requirement; (9) the proposed assignee or subtenant, or any entity that, directly or indirectly, controls, is controlled by, or is under common control with the proposed assignee or subtenant, is then an occupant of the Project; (10) the proposed assignee or subtenant is an entity with whom Landlord is negotiating to lease space in the Project; or (11) the assignment or sublease is prohibited by Landlord's lender. No failure of Landlord to deliver a timely notice in response to the Assignment Notice, shall be deemed to be



Landlord's consent to the proposed assignment, sublease or other transfer. Tenant shall pay to Landlord a fee equal to One Thousand Five Hundred Dollars (\$1,500) in connection with its consideration of any Assignment Notice and/or its preparation or review of any consent documents. Notwithstanding the foregoing, Landlord's consent to an assignment of this Lease or a subletting of any portion of the Premises to any entity controlling, controlled by or under common control with Tenant (a "Control Permitted Assignment") shall not be required, provided that Landlord shall have the right to approve the form of any such sublease or assignment. In addition, Tenant shall have the right to assign this Lease, upon 10 days prior written notice to Landlord but without obtaining Landlord's prior written consent, to a corporation or other entity which is a successor-in-interest to Tenant, by way of merger, consolidation or corporate reorganization, or by the purchase of all or substantially all of the assets or the ownership interests of Tenant provided that (i) such merger or consolidation, or such acquisition or assumption, as the case may be, is for a good business purpose and not principally for the purpose of transferring the Lease, and (ii) the net worth (as determined in accordance with generally accepted accounting principles ("GAAP")) of the assignee is not less than the greater of the net worth (as determined in accordance with GAAP) of Tenant as of (A) the Commencement Date, or (B) as of the date of Tenant's most current quarterly or annual financial statements, and (iii) such assignee shall agree in writing to assume all of the terms, covenants and conditions of this Lease arising after the effective date of the assignment (a "Corporate Permitted Assignment"). Control Permitted Assignments and Corporate Permitted Assignments are hereinafter referred to as "Permitted Assignments."

- (c) **Additional Conditions**. As a condition to any such assignment or subletting, whether or not Landlord's consent is required, Landlord may require:
- (i) that any assignee or subtenant agree, in writing at the time of such assignment or subletting, that if Landlord gives such party notice that Tenant is in default under this Lease, such party shall thereafter make all payments otherwise due Tenant directly to Landlord, which payments will be received by Landlord without any liability except to credit such payment against those due under the Lease, and any such third party shall agree to attorn to Landlord or its successors and assigns should this Lease be terminated for any reason; provided, however, in no event shall Landlord or its successors or assigns be obligated to accept such attornment; and
- (ii) A list of Hazardous Materials, certified by the proposed assignee or sublessee to be true and correct, which the proposed assignee or sublessee intends to use, store, handle, treat, generate in or release or dispose of from the Premises, together with copies of all documents relating to such use, storage, handling, treatment, generation, release or disposal of Hazardous Materials by the proposed assignee or subtenant in the Premises or on the Project, prior to the proposed assignment or subletting, including, without limitation: permits; approvals; reports and correspondence; storage and management plans; plans relating to the installation of any storage tanks to be installed in or under the Project (provided, said installation of tanks shall only be permitted after Landlord has given its written consent to do so, which consent may be withheld in Landlord's sole and absolute discretion); and all closure plans or any other documents required by any and all federal, state and local Governmental Authorities for any storage tanks installed in, on or under the Project for the closure of any such tanks. Neither Tenant nor any such proposed assignee or subtenant is required, however, to provide Landlord with any portion(s) of the such documents containing information of a proprietary nature which, in and of themselves, do not contain a reference to any Hazardous Materials or hazardous activities.
- (d) No Release of Tenant, Sharing of Excess Rents. Notwithstanding any assignment or subletting, Tenant and any guarantor or surety of Tenant's obligations under this Lease shall at all times remain fully and primarily responsible and liable for the payment of Rent and for compliance with all of Tenant's other obligations under this Lease. If the Rent due and payable by a sublessee or assignee (or a combination of the rental payable under such sublease or assignment plus any bonus or other consideration therefor or incident thereto in any form) exceeds the sum of the rental payable under this Lease, (excluding however, any Rent payable under this Section) and actual and reasonable brokerage fees, legal costs and any design or construction fees directly related to and required pursuant to the terms of any such sublease) ("Excess Rent"), then Tenant shall be bound and obligated to pay Landlord as



Additional Rent hereunder 50% of such Excess Rent within 10 days following receipt thereof by Tenant. If Tenant shall sublet the Premises or any part thereof, Tenant hereby immediately and irrevocably assigns to Landlord, as security for Tenant's obligations under this Lease, all rent from any such subletting, and Landlord as assignee and as attorney-in-fact for Tenant, or a receiver for Tenant appointed on Landlord's application, may collect such rent and apply it toward Tenant's obligations under this Lease; except that, until the occurrence of a Default, Tenant shall have the right to collect such rent.

- (e) No Waiver. The consent by Landlord to an assignment or subletting shall not relieve Tenant or any assignees of this Lease or any sublessees of the Premises from obtaining the consent of Landlord to any further assignment or subletting nor shall it release Tenant or any assignee or sublessee of Tenant from full and primary liability under the Lease. The acceptance of Rent hereunder, or the acceptance of performance of any other term, covenant, or condition thereof, from any other person or entity shall not be deemed to be a waiver of any of the provisions of this Lease or a consent to any subletting, assignment or other transfer of the Premises.
- (f) Prior Conduct of Proposed Transferee. Notwithstanding any other provision of this Section 22, if (i) the proposed assignee or sublessee of Tenant has been required by any prior landlord, lender or Governmental Authority to take remedial action in connection with Hazardous Materials contaminating a property, where the contamination resulted from such party's action or use of the property in question, (ii) the proposed assignee or sublessee is subject to an enforcement order issued by any Governmental Authority in connection with the use, storage, handling, treatment, generation, release or disposal of Hazardous Materials (including, without limitation, any order related to the failure to make a required reporting to any Governmental Authority), or (iii) because of the existence of a pre-existing environmental condition in the vicinity of or underlying the Project, the risk that Landlord would be targeted as a responsible party in connection with the remediation of such pre-existing environmental condition would be materially increased or exacerbated by the proposed use of Hazardous Materials by such proposed assignee or sublessee, Landlord shall have the absolute right to refuse to consent to any assignment or subletting to any such party.
- 23. **Estoppel Certificate**. Tenant shall, within 10 business days of written notice from Landlord, execute, acknowledge and deliver a statement in writing in any form reasonably requested by a proposed lender or purchaser, (i) certifying that this Lease is unmodified and in full force and effect (or, if modified, stating the nature of such modification and certifying that this Lease as so modified is in full force and effect) and the dates to which the rental and other charges are paid in advance, if any, (ii) acknowledging that there are not any uncured defaults on the part of Landlord hereunder, or specifying such defaults if any are claimed, and (iii) setting forth such further information with respect to the status of this Lease or the Premises as may be requested thereon. Any such statement may be relied upon by any prospective purchaser or encumbrancer of all or any portion of the real property of which the Premises are a part. Tenant's failure to deliver such statement within such time shall, at the option of Landlord, constitute a Default under this Lease, and, in any event, shall be conclusive upon Tenant that the Lease is in full force and effect and without modification except as may be represented by Landlord in any certificate prepared by Landlord and delivered to Tenant for execution.
- 24. Quiet Enjoyment. So long as Tenant is not in Default under this Lease, Tenant shall, subject to the terms of this Lease, at all times during the Term, have peaceful and quiet enjoyment of the Premises against any person claiming by, through or under Landlord.
  - 25. **Prorations**. All prorations required or permitted to be made hereunder shall be made on the basis of a 360 day year and 30 day months.
- 26. Rules and Regulations. Tenant shall, at all times during the Term and any extension thereof, comply with all reasonable rules and regulations at any time or from time to time established by Landlord covering use of the Premises and the Project. The current rules and regulations are attached hereto as **Exhibit E.** If there is any conflict between said rules and regulations and other provisions of this Lease, the terms and provisions of this Lease shall control. Landlord shall not have any liability or



obligation for the breach of any rules or regulations by other tenants in the Project and shall not enforce such rules and regulations in a discriminatory manner.

27. **Subordination**. This Lease and Tenant's interest and rights hereunder are hereby made and shall be subject and subordinate at all times to the lien of any Mortgage now existing or hereafter created on or against the Project or the Premises, and all amendments, restatements, renewals, modifications, consolidations, refinancing, assignments and extensions thereof, without the necessity of any further instrument or act on the part of Tenant; provided, however that so long as there is no Default hereunder, Tenant's right to possession of the Premises shall not be disturbed by the Holder of any such Mortgage. Tenant agrees, at the election of the Holder of any such Mortgage, to attorn to any such Holder. Tenant agrees upon demand to execute, acknowledge and deliver such instruments, confirming such subordination, and such instruments of attornment as shall be requested by any such Holder, provided any such instruments contain appropriate non-disturbance provisions assuring Tenant's quiet enjoyment of the Premises as set forth in Section 24 hereof. Tenant hereby appoints Landlord attorney-in-fact for Tenant irrevocably (such power of attorney being coupled with an interest) to execute, acknowledge and deliver any such instrument and instruments for and in the name of Tenant and to cause any such instrument to be recorded. Notwithstanding the foregoing, any such Holder may at any time subordinate its Mortgage to this Lease, without Tenant's consent, by notice in writing to Tenant, and thereupon this Lease shall be deemed prior to such Mortgage without regard to their respective dates of execution, delivery or recording and in that event such Holder shall have the same rights with respect to this Lease as though this Lease had been executed prior to the execution, delivery and recording of such Mortgage and had been assigned to such Holder. The term "Mortgage" whenever used in this Lease shall be deemed to include deeds of trust, security assignments and any other encumbrances, and any reference to the "Holder" of

28. Surrender. Upon the expiration of the Term or earlier termination of Tenant's right of possession, Tenant shall surrender the Premises to Landlord in the same condition as received, subject to any Tenant Improvements, Alterations or Installations permitted by Landlord to remain in the Premises, free of Hazardous Materials brought upon, kept, used, stored, handled, treated, generated in, or released or disposed of from, the Premises by any person other than a Landlord Party (collectively, "Tenant HazMat Operations") and released of all Hazardous Materials Clearances, broom clean, ordinary wear and tear and casualty loss and condemnation covered by Sections 18 and 19 excepted. At least 3 months prior to the surrender of the Premises, Tenant shall deliver to Landlord a narrative description of the actions proposed (or required by any Governmental Authority) to be taken by Tenant in order to surrender the Premises (including any Installations permitted by Landlord to remain in the Premises) at the expiration or earlier termination of the Term, free from any residual impact from the Tenant HazMat Operations and otherwise released for unrestricted use and occupancy (the "Surrender Plan"). Such Surrender Plan shall be accompanied by a current listing of (i) all Hazardous Materials licenses and permits held by or on behalf of any Tenant Party with respect to the Premises, and (ii) all Hazardous Materials used, stored, handled, treated, generated, released or disposed of from the Premises, and shall be subject to the review and approval of Landlord's environmental consultant. In connection with the review and approval of the Surrender Plan, upon the request of Landlord, Tenant shall deliver to Landlord or its consultant such additional non-proprietary information concerning Tenant HazMat Operations as Landlord shall request. On or before such surrender, Tenant shall deliver to Landlord evidence that the approved Surrender Plan shall have been satisfactorily completed and Landlord shall have the right, subject to reimbursement at Tenant's expense as set forth below, to cause Landlord's environmental consultant to inspect the Premises and perform such additional procedures as may be deemed reasonably necessary to confirm that the Premises are, as of the effective date of such surrender or early termination of the Lease, free from any residual impact from Tenant HazMat Operations. Tenant shall reimburse Landlord, as Additional Rent, for the reasonable actual out-of pocket expense incurred by Landlord for Landlord's environmental consultant to review and approve the Surrender Plan and to visit the Premises and verify satisfactory completion of the same, which cost shall not exceed \$5,000. Landlord shall have the unrestricted right to deliver such Surrender Plan and any report by Landlord's environmental consultant with respect to the surrender of the Premises to third parties.



If Tenant shall fail to prepare or submit a Surrender Plan approved by Landlord, or if Tenant shall fail to complete the approved Surrender Plan, or if such Surrender Plan, whether or not approved by Landlord, shall fail to adequately address any residual effect of Tenant HazMat Operations in, on or about the Premises, Landlord shall have the right to take such actions as Landlord may deem reasonable or appropriate to assure that the Premises and the Project are surrendered free from any residual impact from Tenant HazMat Operations, the reasonable cost of which actions shall be reimbursed by Tenant as Additional Rent, without regard to the limitation set forth in the first paragraph of this Section 28.

Tenant shall immediately return to Landlord all keys and/or access cards to parking, the Project, restrooms or all or any portion of the Premises furnished to or otherwise procured by Tenant. If any such access card or key is lost, Tenant shall pay to Landlord, at Landlord's election, either the cost of replacing such lost access card or key or the cost of reprogramming the access security system in which such access card was used or changing the lock or locks opened by such lost key. Any Tenant's Property, Alterations and property not so removed by Tenant as permitted or required herein shall be deemed abandoned and may be stored, removed, and disposed of by Landlord at Tenant's expense, and Tenant waives all claims against Landlord for any damages resulting from Landlord's retention and/or disposition of such property. All obligations of Tenant hereunder not fully performed as of the termination of the Term, including the obligations of Tenant under Section 30 hereof, shall survive the expiration or earlier termination of the Term, including, without limitation, indemnity obligations, payment obligations with respect to Rent and obligations concerning the condition and repair of the Premises.

29. Waiver of Jury Trial. TO THE EXTENT PERMITTED BY LAW, TENANT AND LANDLORD WAIVE ANY RIGHT TO TRIAL BY JURY OR TO HAVE A JURY PARTICIPATE IN RESOLVING ANY DISPUTE, WHETHER SOUNDING IN CONTRACT, TORT, OR OTHERWISE, BETWEEN LANDLORD AND TENANT ARISING OUT OF THIS LEASE OR ANY OTHER INSTRUMENT, DOCUMENT, OR AGREEMENT EXECUTED OR DELIVERED IN CONNECTION HEREWITH OR THE TRANSACTIONS RELATED HERETO.

### 30. Environmental Requirements.

(a) **Prohibition/Compliance/Indemnity**. Tenant shall not cause or permit any Hazardous Materials (as hereinafter defined) to be brought upon, kept, used, stored, handled, treated, generated in or about, or released or disposed of from, the Premises or the Project in violation of applicable Environmental Requirements (as hereinafter defined) by Tenant or any Tenant Party. If Tenant breaches the obligation stated in the preceding sentence, or if the presence of Hazardous Materials in the Premises during the Term or any holding over results in contamination of the Premises, the Project or any adjacent property or if contamination of the Premises, the Project or any adjacent property by Hazardous Materials brought into, kept, used, stored, handled, treated, generated in or about, or released or disposed of from, the Premises by anyone other than Landlord and Landlord's employees, agents and contractors otherwise occurs during the Term or any holding over, Tenant hereby indemnifies and shall defend and hold Landlord, its officers, directors, employees, agents and contractors harmless from any and all actions (including, without limitation, remedial or enforcement actions of any kind, administrative or judicial proceedings, and orders or judgments arising out of or resulting therefrom), costs, claims, damages (including, without limitation, punitive damages and damages based upon diminution in value of the Premises or the Project, or the loss of, or restriction on, use of the Premises or any portion of the Project), expenses (including, without limitation, attorneys', consultants' and experts' fees, court costs and amounts paid in settlement of any claims or actions), fines, forfeitures or other civil, administrative or criminal penalties, injunctive or other relief (whether or not based upon personal injury, property damage, or contamination of, or adverse effects upon, the environment, water tables or natural resources), liabilities or losses (collectively, "Environmental Claims") which arise during or after the Term as a result of such contamination. This indemnification of Landlord by Tenant includes, without limitation, costs incurred in connection with any investigation of site conditions or any cleanup, treatment, remedial, removal, or restoration work required by any federal, state or local Governmental Authority because of Hazardous Materials present in the air, soil or ground water above, on, or under the Premises. Without limiting the foregoing, if the presence of any Hazardous Materials on the Premises, the Project or any adjacent property caused or permitted by Tenant or any Tenant Party results in any contamination of the



Premises, the Project or any adjacent property, Tenant shall promptly take all actions at its sole expense and in accordance with applicable Environmental Requirements as are necessary to return the Premises, the Project or any adjacent property to the condition existing prior to the time of such contamination, provided that Landlord's approval of such action shall first be obtained, which approval shall not unreasonably be withheld, conditioned or delayed so long as such actions would not potentially have any material adverse long-term or short-term effect on the Premises or the Project.

- (b) **Business**. Landlord acknowledges that it is not the intent of this Section 30 to prohibit Tenant from using the Premises for the Permitted Use. Tenant may operate its business according to prudent industry practices so long as the use or presence of Hazardous Materials is strictly and properly monitored according to all then applicable Environmental Requirements. As a material inducement to Landlord to allow Tenant to use Hazardous Materials in connection with its business, Tenant agrees to deliver to Landlord prior to the Commencement Date a list identifying each type of Hazardous Materials to be brought upon, kept, used, stored, handled, treated, generated on, or released or disposed of from, the Premises and setting forth any and all governmental approvals or permits required in connection with the presence, use, storage, handling, treatment, generation, release or disposal of such Hazardous Materials on or from the Premises ("Hazardous Materials List"). Tenant shall deliver to Landlord an updated Hazardous Materials List at least once a year upon written request from Landlord, and, if Tenant is required to disclose the use of any new Hazardous Materials at the Premises to any Governmental Authority, Tenant shall also deliver to Landlord an updated list before any new Hazardous Material is brought onto, kept, used, stored, handled, treated, generated on, or released or disposed of from, the Premises. Tenant shall deliver to Landlord true and correct copies of the following documents (the "Haz Mat Documents") relating to the use, storage, handling, treatment, generation, release or disposal of Hazardous Materials prior to the Commencement Date, or if unavailable at that time, concurrent with the receipt from or submission to a Governmental Authority: permits; approvals; reports and correspondence; storage and management plans, notice of violations of any Legal Requirements; plans relating to the installation of any storage tanks to be installed in or under the Project (provided, said installation of tanks shall only be permitted after Landlord has given Tenant its written consent to do so, which consent may be withheld in Landlord's sole and absolute discretion); all closure plans or any other documents required by any and all federal, state and local Governmental Authorities for any storage tanks installed in, on or under the Project for the closure of any such tanks; and a Surrender Plan (to the extent surrender in accordance with Section 28 cannot be accomplished in 3 months). Tenant is not required, however, to provide Landlord with any portion(s) of the Haz Mat Documents containing information of a proprietary nature which, in and of themselves, do not contain a reference to any Hazardous Materials or hazardous activities. It is not the intent of this Section to provide Landlord with information which could be detrimental to Tenant's business should such information become possessed by Tenant's competitors.
- (c) Tenant Representation and Warranty. Tenant hereby represents and warrants to Landlord that (i) neither Tenant nor any of its legal predecessors has been required by any prior landlord, lender or Governmental Authority at any time to take remedial action in connection with Hazardous Materials contaminating a property which contamination was permitted by Tenant of such predecessor or resulted from Tenant's or such predecessor's action or use of the property in question, and (ii) Tenant is not subject to any enforcement order issued by any Governmental Authority in connection with the use, storage, handling, treatment, generation, release or disposal of Hazardous Materials (including, without limitation, any order related to the failure to make a required reporting to any Governmental Authority). If Landlord determines that this representation and warranty was not true as of the date of this lease, Landlord shall have the right to terminate this Lease in Landlord's sole and absolute discretion.
- (d) Testing. Landlord shall have the right to conduct annual tests of the Premises to determine whether any contamination of the Premises or the Project has occurred as a result of Tenant's use. Tenant shall be required to pay the reasonable cost of such annual test of the Premises; provided, however, that if Tenant conducts its own tests of the Premises using third party contractors and test procedures acceptable to Landlord which tests are certified to Landlord, Landlord shall accept such tests in lieu of the annual tests to be paid for by Tenant. In addition, at any time, and from time to time, prior to the expiration or earlier termination of the Term, Landlord shall have the right to conduct appropriate tests of the Premises and the Project to determine if contamination has occurred as a result of Tenant's use of



the Premises. In connection with such testing, upon the request of Landlord, Tenant shall deliver to Landlord or its consultant such non-proprietary information concerning the use of Hazardous Materials in or about the Premises by Tenant or any Tenant Party. If contamination has occurred for which Tenant is liable under this Section 30, Tenant shall pay all reasonable costs to conduct such tests. If no such contamination is found, Landlord shall pay the costs of such tests (which shall not constitute an Operating Expense). Landlord shall provide Tenant with a copy of all third party, non-confidential reports and tests of the Premises made by or on behalf of Landlord during the Term without representation or warranty and subject to a confidentiality agreement. Tenant shall, at its sole cost and expense, promptly and satisfactorily remediate any environmental conditions identified by such testing in accordance with all Environmental Requirements. Landlord's receipt of or satisfaction with any environmental assessment in no way waives any rights which Landlord may have against Tenant.

- (e) Control Areas. Tenant shall be allowed to utilize up to its pro rata share of the Hazardous Materials inventory within any control area or zone (located within the Premises), as designated by the applicable building code, for chemical use or storage. As used in the preceding sentence, Tenant's pro rata share of any control areas or zones located within the Premises shall be determined based on the rentable square footage that Tenant leases within the applicable control area or zone. For purposes of example only, if a control area or zone contains 10,000 rentable square feet and 2,000 rentable square feet of a tenant's premises are located within such control area or zone (while such premises as a whole contains 5,000 rentable square feet), the applicable tenant's pro rata share of such control area would be 20%.
- (f) Underground Tanks. If underground or other storage tanks storing Hazardous Materials located on the Premises or the Project are used by Tenant or are hereafter placed on the Premises or the Project by Tenant, Tenant shall install, use, monitor, operate, maintain, upgrade and manage such storage tanks, maintain appropriate records, obtain and maintain appropriate insurance, implement reporting procedures, properly close any underground storage tanks, and take or cause to be taken all other actions necessary or required under applicable state and federal Legal Requirements, as such now exists or may hereafter be adopted or amended in connection with the installation, use, maintenance, management, operation, upgrading and closure of such storage tanks.
- (g) **Tenant's Obligations**. Tenant's obligations under this <u>Section 30</u> shall survive the expiration or earlier termination of the Lease. During any period of time after the expiration or earlier termination of this Lease required by Tenant or Landlord to complete the removal from the Premises of any Hazardous Materials (including, without limitation, the release and termination of any licenses or permits restricting the use of the Premises and the completion of the approved Surrender Plan), Tenant shall continue to pay the full Rent in accordance with this Lease for any portion of the Premises not relet by Landlord in Landlord's sole discretion, which Rent shall be prorated daily.
- (h) **Definitions**. As used herein, the term "Environmental Requirements" means all applicable present and future statutes, regulations, ordinances, rules, codes, judgments, orders or other similar enactments of any Governmental Authority regulating or relating to health, safety, or environmental conditions on, under, or about the Premises or the Project, or the environment, including without limitation, the following: the Comprehensive Environmental Response, Compensation and Liability Act; the Resource Conservation and Recovery Act; and all state and local counterparts thereto, and any regulations or policies promulgated or issued thereunder. As used herein, the term "Hazardous Materials" means and includes any substance, material, waste, pollutant, or contaminant listed or defined as hazardous or toxic, or regulated by reason of its impact or potential impact on humans, animals and/or the environment under any Environmental Requirements, asbestos and petroleum, including crude oil or any fraction thereof, natural gas liquids, liquefied natural gas, or synthetic gas usable for fuel (or mixtures of natural gas and such synthetic gas). As defined in Environmental Requirements, Tenant is and shall be deemed to be the "operator" of Tenant's "facility" and the "owner" of all Hazardous Materials brought on the Premises by Tenant or any Tenant Party, and the wastes, byproducts, or residues generated, resulting, or produced therefrom.



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31. Tenant's Remedies/Limitation of Liability. Landlord shall not be in default hereunder unless Landlord fails to perform any of its obligations hereunder within 30 days after written notice from Tenant specifying such failure (unless such performance will, due to the nature of the obligation, require a period of time in excess of 30 days, then after such period of time as is reasonably necessary). Upon any default by Landlord, Tenant shall give notice by registered or certified mail to any Holder of a Mortgage covering the Premises and to any landlord of any lease of property in or on which the Premises are located and Tenant shall offer such Holder and/or landlord a reasonable opportunity to cure the default, including time to obtain possession of the Project by power of sale or a judicial action if such should prove necessary to effect a cure; provided Landlord shall have furnished to Tenant in writing the names and addresses of all such persons who are to receive such notices. All obligations of Landlord hereunder shall be construed as covenants, not conditions; and, except as may be otherwise expressly provided in this Lease, Tenant may not terminate this Lease for breach of Landlord's obligations hereunder.

All obligations of Landlord under this Lease will be binding upon Landlord only with respect to the period of its ownership of the Premises. The term "Landlord" in this Lease shall mean only the owner for the time being of the Premises. Upon the transfer by such owner of its interest in the Premises, such owner shall thereupon be released and discharged from all obligations of Landlord thereafter accruing, but such obligations shall be binding during the Term upon each new owner for the duration of such owner's ownership.

- 32. **Inspection and Access**. Landlord and its agents, representatives, and contractors may enter the Premises at any reasonable time to inspect the Premises and to make such repairs as may be required or permitted pursuant to this Lease and for any other business purpose. Landlord and Landlord's representatives may enter the Premises during business hours on not less than 48 hours advance written notice (except in the case of emergencies in which case no such notice shall be required and such entry may be at any time) for the purpose of effecting any such repairs, inspecting the Premises, showing the Premises to prospective purchasers and, during the last year of the Term, to prospective tenants or for any other business purpose. Landlord may erect a suitable sign on the Premises stating the Premises are available to let during the last year of the Term or that the Project is available for sale. Landlord may grant easements, make public dedications, designate Common Areas and create restrictions on or about the Premises, provided that no such easement, dedication, designation or restriction materially, adversely affects Tenant's use or occupancy of the Premises for the Permitted Use. At Landlord's request, Tenant shall execute such instruments as may be necessary for such easements, dedications or restrictions. Tenant shall at all times, except in the case of emergencies, have the right to escort Landlord or its agents, representatives, contractors or guests while the same are in the Premises, provided such escort does not materially and adversely affect Landlord's access rights hereunder.
- 33. **Security**. Landlord shall issue to Tenant cards for the use by Tenant of the card access system existing in the Building as of the date of this Lease. Tenant shall be permitted as of the Commencement Date to use any security system existing in the Premises as of the Commencement Date or to activate such security system at Tenant's discretion and at Tenant's cost and expense, and Landlord agrees, following receipt of a written request from Tenant, to provide Tenant with any documentation in Landlord's possession regarding the maintenance and use of the security system. Tenant acknowledges and agrees that security devices and services, if any, while intended to deter crime may not in given instances prevent theft or other criminal acts and that Landlord is not providing any security services with respect to the Premises. Tenant agrees that Landlord shall not be liable to Tenant for, and Tenant waives any claim against Landlord with respect to, any loss by theft or any other damage suffered or incurred by Tenant in connection with any unauthorized entry into the Premises or any other breach of security with respect to the Premises. Tenant shall be solely responsible for the personal safety of Tenant's officers, employees, agents, contractors, guests and invitees while any such person is in, on or about the Premises and/or the Project. Tenant shall at Tenant's cost obtain insurance coverage to the extent Tenant desires protection against such criminal acts.
- 34. **Force Majeure**. Landlord shall not be responsible or liable for delays in the performance of its obligations hereunder when caused by, related to, or arising out of acts of God, sinkholes or



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subsidence, strikes, lockouts, or other labor disputes, embargoes, quarantines, weather, national, regional, or local disasters, calamities, or catastrophes, inability to obtain labor or materials (or reasonable substitutes therefor) at reasonable costs or failure of, or inability to obtain, utilities necessary for performance, governmental restrictions, orders, limitations, regulations, or controls, national emergencies, delay in issuance or revocation of permits, enemy or hostile governmental action, terrorism, insurrection, riots, civil disturbance or commotion, fire or other casualty, and other causes or events beyond the reasonable control of Landlord ("Force Majeure").

- 35. **Brokers**. Landlord and Tenant each represents and warrants that it has not dealt with any broker, agent or other person (collectively, "**Broker**") in connection with this transaction and that no Broker brought about this transaction, other than Jones Lang LaSalle, Inc. and Avison Young, New England. Landlord and Tenant each hereby agree to indemnify and hold the other harmless from and against any claims by any Broker, other than the broker, if any named in this Section 35, claiming a commission or other form of compensation by virtue of having dealt with Tenant or Landlord, as applicable, with regard to this leasing transaction.
- 36. Limitation on Landlord's Liability. NOTWITHSTANDING ANYTHING SET FORTH HEREIN OR IN ANY OTHER AGREEMENT BETWEEN LANDLORD AND TENANT TO THE CONTRARY: (A) LANDLORD SHALL NOT BE LIABLE TO TENANT OR ANY OTHER PERSON FOR (AND TENANT AND EACH SUCH OTHER PERSON ASSUME ALL RISK OF) LOSS, DAMAGE OR INJURY, WHETHER ACTUAL OR CONSEQUENTIAL TO: TENANT'S PERSONAL PROPERTY OF EVERY KIND AND DESCRIPTION, INCLUDING, WITHOUT LIMITATION TRADE FIXTURES, EQUIPMENT, INVENTORY, SCIENTIFIC RESEARCH, SCIENTIFIC EXPERIMENTS, LABORATORY ANIMALS, PRODUCT, SPECIMENS, SAMPLES, AND/OR SCIENTIFIC, BUSINESS, ACCOUNTING AND OTHER RECORDS OF EVERY KIND AND DESCRIPTION KEPT AT THE PREMISES AND ANY AND ALL INCOME DERIVED OR DERIVABLE THEREFROM; (B) THERE SHALL BE NO PERSONAL RECOURSE TO LANDLORD FOR ANY ACT OR OCCURRENCE IN, ON OR ABOUT THE PREMISES OR ARISING IN ANY WAY UNDER THIS LEASE OR ANY OTHER AGREEMENT BETWEEN LANDLORD AND TENANT WITH RESPECT TO THE SUBJECT MATTER HEREOF AND ANY LIABILITY OF LANDLORD HEREUNDER SHALL BE STRICTLY LIMITED SOLELY TO LANDLORD'S INTEREST IN THE PROJECT OR ANY PROCEEDS FROM SALE OR CONDEMNATION THEREOF AND ANY INSURANCE PROCEEDS PAYABLE IN RESPECT OF LANDLORD'S INTEREST IN THE PROJECT OR IN CONNECTION WITH ANY SUCH LOSS; AND (C) IN NO EVENT SHALL ANY PERSONAL LIABILITY BE ASSERTED AGAINST LANDLORD IN CONNECTION WITH THIS LEASE NOR SHALL ANY RECOURSE BE HAD TO ANY OTHER PROPERTY OR ASSETS OF LANDLORD OR ANY OF LANDLORD'S OFFICERS, DIRECTORS, EMPLOYEES, AGENTS OR CONTRACTORS. UNDER NO CIRCUMSTANCES SHALL LANDLORD OR ANY OF LANDLORD'S OFFICERS, DIRECTORS, EMPLOYEES, AGENTS OR CONTRACTORS BE LIABLE FOR INJURY TO TENANT'S BUSINESS OR FOR ANY LOSS OF INCOME OR PROFIT THEREFROM.
- 37. Severability. If any clause or provision of this Lease is illegal, invalid or unenforceable under present or future laws, then and in that event, it is the intention of the parties hereto that the remainder of this Lease shall not be affected thereby. It is also the intention of the parties to this Lease that in lieu of each clause or provision of this Lease that is illegal, invalid or unenforceable, there be added, as a part of this Lease, a clause or provision as similar in effect to such illegal, invalid or unenforceable clause or provision as shall be legal, valid and enforceable.
- 38. Signs; Exterior Appearance. Tenant shall not, without the prior written consent of Landlord, which may be granted or withheld in Landlord's sole discretion: (i) attach any awnings, exterior lights, decorations, balloons, flags, pennants, banners, painting or other projection to any outside wall of the Project, (ii) use any curtains, blinds, shades or screens other than Landlord's standard window coverings, (iii) coat or otherwise sunscreen the interior or exterior of any windows, (iv) place any bottles, parcels, or other articles on the window sills, (v) place any equipment, furniture or other items of personal property on any exterior balcony, or (vi) paint, affix or exhibit on any part of the Premises or the Project any signs, notices, window or door lettering, placards, decorations, or advertising media of any type which can be viewed from the exterior of the Premises. Interior signs on doors and the directory tablet shall be



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inscribed, painted or affixed for Tenant by Landlord at the sole cost and expense of Tenant, and shall be of a size, color and type acceptable to Landlord. Nothing may be placed on the exterior of corridor walls or corridor doors other than Landlord's standard lettering. The directory tablet shall be provided exclusively for the display of the name and location of tenants.

Tenant shall, at Tenant's sole cost and expense, have the right to display 1 sign bearing Tenant's name and logo on the Building near the main entry to the Premises in a location reasonably acceptable to Landlord and Tenant ("Entry Sign"). Tenant acknowledges and agrees that the Entry Sign including, without limitation, the size, color, type, and location shall be subject to Landlord's prior written approval, which shall not be unreasonably withheld and shall be consistent with Landlord's signage program at the Project and applicable Legal Requirements. Tenant shall be responsible, at Tenant's sole cost and expense, for the maintenance of the Entry Sign, for the removal of the Entry Sign at the expiration or earlier termination of this Lease and for the repair of all damage resulting from such removal.

- 39. **Right to Extend Term**. Tenant shall have the right to extend the Term of the Lease upon the following terms and conditions:
- (a) Extension Rights. Tenant shall have 1 right (the "Extension Right") to extend the term of this Lease for 5 years (the "Extension Term") on the same terms and conditions as this Lease (other than with respect to Base Rent and the Work Letter) by giving Landlord written notice of its election to exercise each Extension Right at least 9 months prior, to the expiration of the Base Term of the Lease.

Base Rent payable for the first year of the Extension Term shall be equal to \$37.80 per rentable square foot of the Premises per annum. Base Rent shall thereafter increase on each annual anniversary of the commencement of the Extension Term by adding the Rent Adjustment Amount to the per square foot Base Rent payable for the Premises per annum immediately before such adjustment. In addition, Landlord may impose a market rent for the parking rights provided hereunder.

- (b) Rights Personal. The Extension Right is personal to Tenant and is not assignable without Landlord's consent, which may be granted or withheld in Landlord's sole discretion separate and apart from any consent by Landlord to an assignment of Tenant's interest in the Lease, except that it may be assigned in connection with any Permitted Assignment of this Lease.
- (c) Exceptions. Notwithstanding anything set forth above to the contrary, the Extension Right shall, at Landlord's option, not be in effect and Tenant may not exercise the Extension Right:
  - (i) during any period of time that Tenant is in Default under any provision of this Lease; or
  - (ii) if Tenant has been in Default under any provision of this Lease 3 or more times, whether or not the Defaults are cured, during the 12 month period immediately prior to the date that Tenant intends to exercise the Extension Right, whether or not the Defaults are cured.
- (d) No Extensions. The period of time within which the Extension Right may be exercised shall not be extended or enlarged by reason of Tenant's inability to exercise the Extension Right.
- (e) **Termination**. The Extension Right shall, at Landlord's option, terminate and be of no further force or effect even after Tenant's due and timely exercise of the Extension Right, if, after such exercise, but prior to the commencement date of the Extension Term, (i) Tenant fails to timely cure any default by Tenant under this Lease; or (ii) Tenant has Defaulted 3 or more times during the period from the date of the exercise of the Extension Right to the date of the commencement of the Extension Term, whether or not such Defaults are cured.



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- 40. Right to Expand.
- (a) Expansion in the Building. In the event that any Available Space (as defined below) shall become available in the Building, Landlord shall have the right to offer such Available Space to any tenant leasing in excess of 16,601 rentable square feet at any project located adjacent to the Project and owned by Landlord or an affiliate of Landlord (each, a "Qualifying Adjacent Tenant"). If no Qualifying Adjacent Tenant elects to lease the Available Space, then Tenant shall, during the Base Term, have the one-time right, but not the obligation, to expand the Premises (the "Expansion Right") to include any Available Space in the Building upon the terms and conditions set forth in this Section. For purposes of this Section 40(a), "Available Space" shall mean the balance of the rentable space in the Building, to the extent such space is not occupied by a tenant or which is occupied by an existing tenant whose lease is expiring within 6 months or less and such tenant does not wish to renew (whether or not such tenant has a right to renew) its occupancy of such space. If there is any Available Space in the Building, Landlord shall, at such time as Landlord shall elect so long as Tenant's rights hereunder are preserved, deliver to Tenant written notice (the "Expansion Notice") of such Available Space, together with the terms and conditions on which Landlord is prepared to lease Tenant such Available Space. Tenant shall be entitled to exercise its right under this <u>Section 40(a)</u> only with respect to the entire Available Space described in such Expansion Notice ("Identified Available Space"). Tenant shall have 5 days following delivery of the Expansion Notice to deliver to Landlord written notification of Tenant's exercise of the Expansion Right with respect to the Identified Available Space ("Exercise Notice"). Tenant shall be entitled to lease such Identified Available Space upon the terms and conditions set forth in the Expansion Notice. Tenant acknowledges and agrees that, if Tenant has delivered an Exercise Notice pursuant to this Section 40(a), Tenant shall have no right thereafter to rescind or elect not to lease the Available Space. Tenant acknowledges that the Term of this Lease with respect to the Identified Available Space may not be coterminous with the Term of this Lease with respect to the original Premises. If Tenant fails to deliver an Exercise Notice to Landlord for the Identified Available Space within the required 5 day period, Tenant shall be deemed to have forever waived its rights under this Section 40(a) to lease the Identified Available Space, and Landlord shall have the right to lease the Identified Available Space to any third party on any terms and conditions acceptable to Landlord; provided, however, that Tenant's Expansion Notice shall be restored if, within 6 months after Tenant's election (or deemed election) not to lease the Identified Available Space, Landlord proposes to lease the Identified Available Space to a third party on economic terms that are more than 10% lower than the economic terms set forth in the Expansion Notice.
- (b) Amended Lease. If: (i) Tenant fails to timely deliver an Exercise Notice, or (ii) after the expiration of a period of 10 days from the date Tenant gives notice accepting Landlord's offer to lease such Identified Available Space, no lease amendment or lease agreement for the Identified Available Space has been executed, and Landlord tenders to Tenant an amendment to this Lease setting forth the terms for the rental of the Identified Available Space consistent with those set forth in the Expansion Notice and otherwise consistent with the terms of this Lease and Tenant fails to execute such Lease amendment within 10 business days following such tender, Tenant shall be deemed to have forever waived its right to lease such Identified Available Space.
  - (c) Exceptions. Notwithstanding the above, the Expansion Right shall, at Landlord's option, not be in effect and may not be exercised by Tenant:
    - (i) during any period of time that Tenant is in Default under any provision of this Lease; or
  - (ii) if Tenant has been in Default under any provision of this Lease 3 or more times, whether or not the Defaults are cured, during the 12 month period prior to the date on which Tenant seeks to exercise the Expansion Right.
- (d) **Termination**. The Expansion Right shall, at Landlord's option, terminate and be of no further force or effect even after Tenant's due and timely exercise of the Expansion Right, if, after such exercise, but prior to the commencement date of the lease of such Identified Available Space, (i) Tenant



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fails to timely cure any Default by Tenant under this Lease; or (ii) Tenant has Defaulted 3 or more times during the period from the date of the exercise of the Expansion Right to the date of the commencement of the lease of the Identified Available Space, whether or not such Defaults are cured.

- (e) Subordinate. Tenant's rights in connection with the Expansion Right are and shall be subject to and subordinate any and all Qualifying Adjacent Tenants.
- (f) Rights Personal. The Expansion Right is personal to Tenant and are not assignable without Landlord's consent, which may be granted or withheld in Landlord's sole discretion separate and apart from any consent by Landlord to an assignment of Tenant's interest in this Lease, except that they may be assigned in connection with any Permitted Assignment of this Lease.
- (g) No Extensions. The period of time within which the Expansion Right may be exercised shall not be extended or enlarged by reason of Tenant's inability to exercise the Expansion Right.

#### 41. Miscellaneous.

- (a) Notices. All notices or other communications between the parties shall be in writing and shall be deemed duly given upon delivery or refusal to accept delivery by the addressee thereof if delivered in person, or upon actual receipt if delivered by reputable overnight guaranty courier, addressed and sent to the parties at their addresses set forth above on page 1 of this Lease. Landlord and Tenant may from time to time by written notice to the other designate another address for receipt of future notices.
- (b) **Joint and Several Liability**. If and when included within the term "**Tenant**," as used in this instrument, there is more than one person or entity, each shall be jointly and severally liable for the obligations of Tenant.
- (c) Financial Information. Tenant shall furnish Landlord with true and complete copies of (i) Tenant's most recent audited annual financial statements within 120 days of the end of each of Tenant's fiscal years during the Term, (ii) Tenant's most recent unaudited quarterly financial statements within 45 days of the end of each of Tenant's first three fiscal quarters of each of Tenant's fiscal years during the Term, (iii) at Landlord's request from time to time, updated business plans, including cash flow projections and/or pro forma balance sheets and income statements, all of which shall be treated by Landlord as confidential information belonging to Tenant, (iv) corporate brochures and/or profiles prepared by Tenant for prospective investors, and (v) any other financial information or summaries that Tenant typically provides to its lenders or shareholders. In the event that Tenant is a "public company" and its financial information is publicly available, then the foregoing delivery requirements of this Section 41(c) shall not apply.
- (d) **Recordation**. Neither this Lease nor a memorandum of lease shall be filed by or on behalf of Tenant in any public record. Landlord may prepare and file, and upon request by Landlord Tenant will execute, a memorandum of lease. The foregoing is not intended to prohibit Tenant from filing this Lease to the extent that Tenant is required to do so pursuant to applicable SEC requirements. Landlord agrees to promptly review any items requested by Tenant and cooperate with Tenant so that Tenant may timely comply with its SEC filing obligations. Further, other than in connection with SEC requirements, the foregoing is not intended to prohibit Tenant from filing this Lease to the extent required pursuant to applicable Legal Requirements; provided, however, that (i) Tenant has provided Landlord with prior written notice thereof, and (ii) Tenant shall seek confidential treatment from any applicable Governmental Authorities with respect to certain information contained in this Lease, as requested by Landlord following receipt of Tenant's notice.
- (e) **Interpretation**. The normal rule of construction to the effect that any ambiguities are to be resolved against the drafting party shall not be employed in the interpretation of this Lease or any exhibits or amendments hereto. Words of any gender used in this Lease shall be held and construed to



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include any other gender, and words in the singular number shall be held to include the plural, unless the context otherwise requires. The captions inserted in this Lease are for convenience only and in no way define, limit or otherwise describe the scope or intent of this Lease, or any provision hereof, or in any way affect the interpretation of this Lease.

- (f) **Not Binding Until Executed**. The submission by Landlord to Tenant of this Lease shall have no binding force or effect, shall not constitute an option for the leasing of the Premises, nor confer any right or impose any obligations upon either party until execution of this Lease by both parties.
- (g) **Limitations on Interest**. It is expressly the intent of Landlord and Tenant at all times to comply with applicable law governing the maximum rate or amount of any interest payable on or in connection with this Lease. If applicable law is ever judicially interpreted so as to render usurious any interest called for under this Lease, or contracted for, charged, taken, reserved, or received with respect to this Lease, then it is Landlord's and Tenant's express intent that all excess amounts theretofore collected by Landlord be credited on the applicable obligation (or, if the obligation has been or would thereby be paid in full, refunded to Tenant), and the provisions of this Lease immediately shall be deemed reformed and the amounts thereafter collectible hereunder reduced, without the necessity of the execution of any new document, so as to comply with the applicable law, but so as to permit the recovery of the fullest amount otherwise called for hereunder.
- (h) **Choice of Law**. Construction and interpretation of this Lease shall be governed by the internal laws of the state in which the Premises are located, excluding any principles of conflicts of laws.
  - (i) **Time**. Time is of the essence as to the performance of Tenant's and Landlord's obligations under this Lease.
- (j) **OFAC**. Tenant, and all beneficial owners of Tenant, are currently (a) in compliance with and shall at all times during the Term of this Lease remain in compliance with the regulations of the Office of Foreign Assets Control ("**OFAC**") of the U.S. Department of Treasury and any statute, executive order, or regulation relating thereto (collectively, the "**OFAC Rules**"), (b) not listed on, and shall not during the term of this Lease be listed on, the Specially Designated Nationals and Blocked Persons List maintained by OFAC and/or on any other similar list maintained by OFAC or other governmental authority pursuant to any authorizing statute, executive order, or regulation, and (c) not a person or entity with whom a U.S. person is prohibited from conducting business under the OFAC Rules.
- (k) **Incorporation by Reference**. All exhibits and addenda attached hereto are hereby incorporated into this Lease and made a part hereof. If there is any conflict between such exhibits or addenda and the terms of this Lease, such exhibits or addenda shall control.
- (l) **Entire Agreement**. This Lease, including the exhibits attached hereto, constitutes the entire agreement between Landlord and Tenant pertaining to the subject matter hereof and supersedes all prior and contemporaneous agreements, understandings, letters of intent, negotiations and discussions, whether oral or written, of the parties, and there are no warranties, representations or other agreements, express or implied, made to either party by the other party in connection with the subject matter hereof except as specifically set forth herein.
- (m) **No Accord and Satisfaction**. No payment by Tenant or receipt by Landlord of a lesser amount than the monthly installment of Base Rent or any Additional Rent will be other than on account of the earliest stipulated Base Rent and Additional Rent, nor will any endorsement or statement on any check or letter accompanying a check for payment of any Base Rent or Additional Rent be an accord and satisfaction. Landlord may accept such check or payment without prejudice to Landlord's right to recover the balance of such Rent or to pursue any other remedy provided in this Lease.
- (n) **Hazardous Activities**. Notwithstanding any other provision of this Lease, Landlord, for itself and its employees, agents and contractors, reserves the right to refuse to perform any repairs or



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services in any portion of the Premises which, pursuant to Tenant's routine safety guidelines, practices or custom or prudent industry practices, require any form of protective clothing or equipment other than safety glasses. In any such case, Tenant shall contract with parties who are reasonably acceptable to Landlord, in Landlord's reasonable discretion, for all such repairs and services, and Landlord shall, to the extent required, equitably adjust Tenant's Share of Operating Expenses in respect of such repairs or services to reflect that Landlord is not providing such repairs or services to Tenant.

#### [ Signatures on next page ]



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IN WITNESS WHEREOF, Landlord and Tenant have executed this Lease as of the day and year first above written.

#### TENANT:

#### HISTOGENICS CORPORATION,

a Delaware corporation

By: /s/ Kevin McArdle

Its: Chief Financial Officer

#### LANDLORD:

#### ARE-60 WESTVIEW, LLC,

a Delaware limited liability company

By: AREE-HOLDINGS, L.P.,

a Delaware limited partnership, managing member

By: ARE-GP HOLDINGS QRS CORP., a Delaware corporation, general partner

By: /s/ Eric S. Johnson

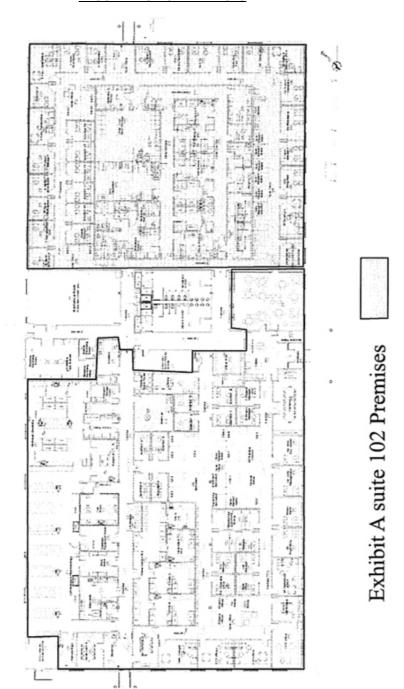
Its: Vice President, Real Estate Legal Affairs

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### EXHIBIT A TO LEASE

#### **DESCRIPTION OF PREMISES**



60 Westview Street First Floor



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#### **EXHIBIT B TO LEASE**

#### **DESCRIPTION OF PROJECT**

A certain parcel of registered and unregistered land situated on Westview Street, Lexington, Middlesex County, Massachusetts, the same being shown as Lot 5 on a plan entitled "Plan of Land in Lexington, Mass." dated December 18, 1972, by Albert A. Miller and Wilbur C. Nylander, Civil Engineers and Surveyors, recorded with said Deeds in Book 12398, Page 433, being more particularly bounded and described according to said plan as follows:

NORTHEASTERLY by land now or formerly of The 115 Kendall Corp. 270.76 feet;

SOUTHEASTERLY in part by land now or formerly of Majilite Corporation and in part by Lot 6 as shown on said plan, 543.88 feet;

SOUTHWESTERLY by Lot 6 as shown on said plan, 309.13 feet; and

NORTHWESTERLY by Westview Street, by three lines respectively measuring 92.25 feet, 271.31 feet, and 185.92 feet.

The following described portion of the above land shown as lot 3 on Land Court Plan 28759B in Registration Book 821, Page 143 is registered land;

NORTHEASTERLY by land now or formerly of Ernest Reiss et al, 307.96 feet;
SOUTHEASTERLY by Lot 1 and Lot 2 as shown on said Land Court Plan 120.03 feet;
SOUTHWESTERLY by land now or formerly of Charles A. Linehan, 345.92 feet; and

NORTHWESTERLY by Westview Street, 400 feet.

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#### **EXHIBIT C TO LEASE**

#### **WORK LETTER**

THIS WORK LETTER (this "Work Letter") is incorporated into that certain Lease Agreement (the "Lease") dated as of June 2, 2014 by and between ARE-60 WESTVIEW, LLC, a Delaware limited liability company ("Landlord"), and HISTOGENICS CORPORATION, a Delaware corporation ("Tenant"). Any initially capitalized terms used but not defined herein shall have the meanings given them in the Lease.

#### 1. General Requirements.

- (a) Tenant's Authorized Representative. Tenant designates Adam Gridley, Kevin McArdle and Stephen Kennedy (and any such individual acting alone, "Tenant's Representative") as the only persons authorized to act for Tenant pursuant to this Work Letter. Landlord shall not be obligated to respond to or act upon any request, approval, inquiry or other communication ("Communication") from or on behalf of Tenant in connection with this Work Letter unless such Communication is in writing from Tenant's Representative. Tenant may change any Tenant's Representative at any time upon not less than 5 business days advance written notice to Landlord.
- (b) Landlord's Authorized Representative. Landlord designates Timothy White and Dawn Leaman (either such individual acting alone, "Landlord's Representative") as the only persons authorized to act for Landlord pursuant to this Work Letter. Tenant shall not be obligated to respond to or act upon any request, approval, inquiry or other Communication from or on behalf of Landlord in connection with this Work Letter unless such Communication is in writing from Landlord's Representative. Landlord may change either Landlord's Representative at any time upon not less than 5 business days advance written notice to Tenant.
- (c) Architects, Consultants and Contractors. Landlord and Tenant hereby acknowledge and agree that the architect (the "TI Architect") for the Tenant Improvements (as defined in Section 2(a) below), the general contractor and any subcontractors for the Tenant Improvements shall be selected by Tenant, subject to Landlord's approval, which approval shall not be unreasonably withheld, conditioned or delayed. Landlord shall be named a third party beneficiary of any contract entered into by Tenant with the TI Architect, any consultant, any contractor or any subcontractor, and of any warranty made by any contractor or any subcontractor.

#### 2. Tenant Improvements.

- (a) Tenant Improvements Defined. As used herein, "Tenant Improvements" shall mean all improvements to the Premises desired by Tenant of a fixed and permanent nature. Other than funding the TI Allowance (as defined below) as provided herein, Landlord shall not have any obligation whatsoever with respect to the finishing of the Premises for Tenant's use and occupancy.
- (b) Tenant's Space Plans. Tenant shall deliver to Landlord schematic drawings and outline specifications (the "TI Design Drawings") detailing Tenant's requirements for the Tenant Improvements within 60 days of the date hereof. Not more than 10 days thereafter, Landlord shall deliver to Tenant the written objections, questions or comments of Landlord and the TI Architect with regard to the TI Design Drawings. Tenant shall cause the TI Design Drawings to be revised to address such written comments and shall resubmit said drawings to Landlord for approval within 30 days thereafter. Such process shall continue until Landlord has reasonably approved the TI Design Drawings.
- (c) Working Drawings. Not later than 30 days following the approval of the TI Design Drawings by Landlord, Tenant shall cause the TI Architect to prepare and deliver to Landlord for review and comment construction plans, specifications and drawings for the Tenant Improvements ("TI Construction Drawings"), which TI Construction Drawings shall be prepared substantially in accordance



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with the TI Design Drawings. Tenant shall be solely responsible for ensuring that the TI Construction Drawings reflect Tenant's requirements for the Tenant Improvements. Landlord shall deliver its written comments on the TI Construction Drawings to Tenant not later than 10 business days after Landlord's receipt of the same; provided, however, that Landlord may not disapprove any matter that is consistent with the TI Design Drawings. Tenant and the TI Architect shall consider all such comments in good faith and shall, within 10 business days after receipt, notify Landlord how Tenant proposes to respond to such comments. Any disputes in connection with such comments shall be resolved in accordance with Section 2(d) hereof. Provided that the design reflected in the TI Construction Drawings is consistent with the TI Design Drawings, Landlord shall approve the TI Construction Drawings submitted by Tenant. Once approved by Landlord, subject to the provisions of Section 4 below, Tenant shall not materially modify the TI Construction Drawings except as may be reasonably required in connection with the issuance of the TI Permit (as defined in Section 3(a) below).

(d) Approval and Completion. If any dispute regarding the design of the Tenant Improvements is not settled within 10 business days after notice of such dispute is delivered by one party to the other, Tenant may make the final decision regarding the design of the Tenant Improvements, provided (i) Tenant acts reasonably and such final decision is either consistent with or a compromise between Landlord's and Tenant's positions with respect to such dispute, (ii) that all costs and expenses resulting from any such decision by Tenant shall be payable out of the TI Fund (as defined in Section 5(d) below), and (iii) Tenant's decision will not affect the base Building, structural components of the Building or any Building systems (in which case Landlord shall make the final decision). Any changes to the TI Construction Drawings following Landlord's and Tenant's approval of same requested by Tenant shall be processed as provided in Section 4 hereof.

#### 3. Performance of the Tenant Improvements.

- (a) Commencement and Permitting of the Tenant Improvements. Tenant shall commence construction of the Tenant Improvements upon obtaining and delivering to Landlord a building permit (the "TI Permit") authorizing the construction of the Tenant Improvements consistent with the TI Construction Drawings approved by Landlord. The cost of obtaining the TI Permit shall be payable from the TI Fund. Landlord shall assist Tenant in obtaining the TI Permit. Prior to the commencement of the Tenant Improvements, Tenant shall deliver to Landlord a copy of any contract with Tenant's contractors (including the TI Architect), and certificates of insurance from any contractor performing any part of the Tenant Improvement evidencing industry standard commercial general liability, automotive liability, "builder's risk", and workers' compensation insurance. Tenant shall cause the general contractor to provide a certificate of insurance naming Landlord, Alexandria Real Estate Equities, Inc., and Landlord's lender (if any) as additional insureds for the general contractor's liability coverages required above.
- (b) Selection of Materials, Etc. Where more than one type of material or structure is indicated on the TI Construction Drawings approved by Tenant and Landlord, the option will be within Tenant's reasonable discretion if the matter concerns the Tenant Improvements, and within Landlord's sole and absolute subjective discretion if the matter concerns the structural components of the Building or any Building system.
  - (c) Tenant Liability. Tenant shall be responsible for correcting any deficiencies or defects in the Tenant Improvements.
- (d) Substantial Completion. Tenant shall substantially complete or cause to be substantially completed the Tenant Improvements in a good and workmanlike manner, in accordance with the TI Permit subject, in each case, to Minor Variations and normal "punch list" items of a non-material nature which do not interfere with the use of the Premises ("Substantial Completion" or "Substantially Complete"). Upon Substantial Completion of the Tenant Improvements, Tenant shall require the TI Architect and the general contractor to execute and deliver, for the benefit of Tenant and Landlord, a Certificate of Substantial Completion in the form of the American Institute of Architects ("AIA") document G704. For purposes of this Work Letter, "Minor Variations" shall mean any modifications reasonably



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required: (i) to comply with all applicable Legal Requirements and/or to obtain or to comply with any required permit (including the TI Permit); (ii) to comport with good design, engineering, and construction practices which are not material; or (iii) to make reasonable adjustments for field deviations or conditions encountered during the construction of the Tenant Improvements.

- 4. Changes. Any changes requested by Tenant to the Tenant Improvements after the delivery and approval by Landlord of the TI Design Drawings, shall be requested and instituted in accordance with the provisions of this Section 4 and shall be subject to the written approval of Landlord, which approval shall not be unreasonably withheld, conditioned or delayed.
- (a) Tenant's Right to Request Changes. If Tenant shall request changes ("Changes"), Tenant shall request such Changes by notifying Landlord in writing in substantially the same form as the AIA standard change order form (a "Change Request"), which Change Request shall detail the nature and extent of any such Change. Such Change Request must be signed by Tenant's Representative. Landlord shall review and approve or disapprove such Change Request within 10 business days thereafter, provided that Landlord's approval shall not be unreasonably withheld, conditioned or delayed.
- (b) Implementation of Changes. If Landlord approves such Change, Tenant may cause the approved Change to be instituted. If any TI Permit modification or change is required as a result of such Change, Tenant shall promptly provide Landlord with a copy of such TI Permit modification or change.
  - 5. Costs.
- (a) Budget For Tenant Improvements. Before the commencement of construction of the Tenant Improvements, Tenant shall obtain a reasonably detailed breakdown, by trade, of the costs incurred or that will be incurred, in connection with the design and construction of the Tenant Improvements (the "Budget"), and deliver a copy of the Budget to Landlord for Landlord's approval, which shall not be unreasonably withheld, conditioned or delayed. The Budget shall be based upon the TI Construction Drawings approved by Landlord.
- (b) TI Allowance. Landlord shall provide to Tenant a tenant improvement allowance ("TI Allowance") of \$60.00 per rentable square foot of the Premises, or \$996,060 in the aggregate. Within 10 business days after receipt of notice of Landlord's approval of the Budget, Tenant shall notify Landlord how much of the TI Allowance Tenant has elected to receive from Landlord. Such election shall be final and binding on Tenant, and may not thereafter be modified without Landlord's consent, which may be granted or withheld in Landlord's sole and absolute subjective discretion. The TI Allowance shall be disbursed in accordance with this Work Letter.

Tenant shall have no right to the use or benefit (including any reduction to Base Rent) of any portion of the TI Allowance not required for the construction of (i) the Tenant Improvements described in the TI Construction Drawings approved pursuant to Section 2(d) or (ii) any Changes pursuant to Section 4. Tenant shall have no right to any portion of the TI Allowance that is not disbursed before the last day of the month that is 18 months after the Commencement Date.

(c) Costs Includable in TI Fund. The TI Fund shall be used solely for the payment of design, permits and construction costs in connection with the construction of the Tenant Improvements, including, without limitation, the cost of electrical power and other utilities used in connection with the construction of the Tenant Improvements, the cost of preparing the TI Design Drawings and the TI Construction Drawings, all costs set forth in the Budget, and the cost of Changes (collectively, "TI Costs"). Notwithstanding anything to the contrary contained herein, in no event shall Landlord be required to pay for any furniture, personal property or other non-Building system materials or equipment, including, but not limited to, Tenant's voice or data cabling, non-ducted biological safety cabinets and other scientific equipment not incorporated into the Tenant Improvements. Notwithstanding anything to the contrary contained in the Lease or in this Work Letter, any and all fixed casework installed in the



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Premises shall be the property of Landlord and may not be removed by Tenant at any time during the Term or upon the expiration or earlier termination of the Term.

- (d) Excess TI Costs. Landlord shall have no obligation to bear any portion of the cost of any of the Tenant Improvements except to the extent of the TI Allowance. If at any time and from time-to-time, the remaining TI Costs under the Budget exceed the remaining unexpended TI Allowance ("Excess TI Costs"), Tenant shall be responsible for the payment of such Excess TI Costs in accordance with this Section 5(d). Subject to the terms of Section 5(e) below, during the course of the design and construction of the Tenant Improvements, Landlord shall reimburse Tenant on a pro rata basis, a percentage of the TI Costs actually incurred and paid for by Tenant for the Tenant Improvements equal to the percentage that the TI Allowance bears to the Budget (up to the amount of the TI Allowance). For example, if the total Budget for the Tenant Improvements equals \$1,025,000 and Tenant pays Tenant's contractor \$100,000 for costs incurred, then Landlord shall reimburse Tenant \$97,176.59 (\$996,060 ÷ \$1,025,000 x \$100,000). If Tenant fails to pay any portion of the Excess TI Costs, Landlord shall have all of the rights and remedies set forth in the Lease for nonpayment of Rent (including, but not limited to, the right to interest at the Default Rate and the right to assess a late charge). For purposes of any litigation instituted with regard to such amounts, those amounts will be deemed Rent under the Lease. The TI Allowance and Excess TI Costs is herein referred to as the "TI Fund." Notwithstanding anything to the contrary set forth in this Section 5(d), Tenant shall be fully and solely liable for TI Costs and the cost of Minor Variations in excess of the TI Allowance.
- (e) **Payment for TI Costs**. During the course of design and construction of the Tenant Improvements, Landlord shall reimburse Tenant for TI Costs once a month against a draw request in Landlord's standard form, containing reasonable evidence of payment of such TI Costs by Tenant and such certifications, lien waivers (including a conditional lien release for each progress payment and unconditional lien releases for the prior month's progress payments), inspection reports and other matters as Landlord customarily obtains, to the extent of Landlord's approval thereof for payment, no later than 30 days following receipt of such draw request. Upon completion of the Tenant Improvements (and prior to any final disbursement of the TI Fund), Tenant shall deliver to Landlord: (i) sworn statements setting forth the names of all contractors and first tier subcontractors who did the work and final, unconditional lien waivers from all such contractors and first tier subcontractors; (ii) as-built plans (one copy in print format and two copies in electronic CAD format) for such Tenant Improvements; (iii) a certification of substantial completion in Form AIA G704, (iv) a certificate of occupancy for the Premises; and (v) copies of all operation and maintenance manuals and warranties affecting the Premises.

#### 6. Miscellaneous.

- (a) **Consents**. Whenever consent or approval of either party is required under this Work Letter, that party shall not unreasonably withhold, condition or delay such consent or approval, except as may be expressly set forth herein to the contrary.
- (b) **Modification**. No modification, waiver or amendment of this Work Letter or of any of its conditions or provisions shall be binding upon Landlord or Tenant unless in writing signed by Landlord and Tenant.



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### EXHIBIT D TO LEASE

ACKNOWLEDGMENT OF COMM	ENCEMENT DATE
This <b>ACKNOWLEDGMENT OF COMMENCEMENT DATE</b> is made this Delaware limited liability company (" <b>Landlord</b> "), and <b>HISTOGENICS CORPORAT</b> a part of the Lease dated , (the " <b>Lease</b> "), by and between Landlord and Tenanave the meanings given them in the Lease.	ION, a Delaware corporation ("Tenant"), and is attached to and mad
Landlord and Tenant hereby acknowledge and agree, for all purposes of the Lease , , the Rent Commencement Date is , and the termination date case of a conflict between the terms of the Lease and the terms of this Acknowledgment Date shall control for all purposes.	of the Base Term of the Lease shall be midnight on , . In
IN WITNESS WHEREOF, Landlord and Tenant have executed this ACKNOWLE date first above written.	EDGMENT OF COMMENCEMENT DATE to be effective on the
	TENANT:
	HISTOGENICS CORPORATION, a Delaware corporation
	Ву:
	Its:
	LANDLORD:
	ARE-60 WESTVIEW, LLC,
	a Delaware limited liability company
	By: AREE-HOLDINGS, L.P.,
	a Delaware limited partnership, managing member
	By: ARE-GP HOLDINGS QRS CORP., a Delaware corporation, general partner
	By:
	Its:

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#### **EXHIBIT E TO LEASE**

#### **Rules and Regulations**

- 1. The sidewalk, entries, and driveways of the Project shall not be obstructed by Tenant, or any Tenant Party, or used by them for any purpose other than ingress and egress to and from the Premises.
- 2. Tenant shall not place any objects, including antennas, outdoor furniture, etc., in the parking areas, landscaped areas or other areas outside of its Premises, or on the roof of the Project.
  - 3. Except for animals assisting the disabled, no animals shall be allowed in the offices, halls, or corridors in the Project.
- 4. Tenant shall not disturb the occupants of the Project or adjoining buildings by the use of any radio or musical instrument or by the making of loud or improper noises.
- 5. If Tenant desires telegraphic, telephonic or other electric connections in the Premises, Landlord or its agent will direct the electrician as to where and how the wires may be introduced; and, without such direction, no boring or cutting of wires will be permitted. Any such installation or connection shall be made at Tenant's expense.
- 6. Tenant shall not install or operate any steam or gas engine or boiler, or other mechanical apparatus in the Premises, except as specifically approved in the Lease. The use of oil, gas or inflammable liquids for heating, lighting or any other purpose is expressly prohibited. Explosives or other articles deemed extra hazardous shall not be brought into the Project.
- 7. Parking any type of recreational vehicles is specifically prohibited on or about the Project. Except for the overnight parking of operative vehicles, no vehicle of any type shall be stored in the parking areas at any time. In the event that a vehicle is disabled, it shall be removed within 48 hours. There shall be no "For Sale" or other advertising signs on or about any parked vehicle. All vehicles shall be parked in the designated parking areas in conformity with all signs and other markings. All parking will be open parking, and no reserved parking, numbering or lettering of individual spaces will be permitted except as specified by Landlord.
  - 8. Tenant shall maintain the Premises free from rodents, insects and other pests.
- 9. Landlord reserves the right to exclude or expel from the Project any person who, in the judgment of Landlord, is intoxicated or under the influence of liquor or drugs or who shall in any manner do any act in violation of the Rules and Regulations of the Project.
- 10. Tenant shall not cause any unnecessary labor by reason of Tenant's carelessness or indifference in the preservation of good order and cleanliness. Landlord shall not be responsible to Tenant for any loss of property on the Premises, however occurring, or for any damage done to the effects of Tenant by the janitors or any other employee or person.
- 11. Tenant shall give Landlord prompt notice of any defects in the water, lawn sprinkler, sewage, gas pipes, electrical lights and fixtures, heating apparatus, or any other service equipment affecting the Premises.
- 12. Tenant shall not permit storage outside the Premises, including without limitation, outside storage of trucks and other vehicles, or dumping of waste or refuse or permit any harmful materials to be placed in any drainage system or sanitary system in or about the Premises.



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- 13. All moveable trash receptacles provided by the trash disposal firm for the Premises must be kept in the trash enclosure areas, if any, provided for that purpose.
  - 14. No auction, public or private, will be permitted on the Premises or the Project.
  - 15. No awnings shall be placed over the windows in the Premises except with the prior written consent of Landlord.
- 16. The Premises shall not be used for lodging, sleeping or cooking or for any immoral or illegal purposes or for any purpose other than that specified in the Lease. No gaming devices shall be operated in the Premises.
- 17. Tenant shall ascertain from Landlord the maximum amount of electrical current which can safely be used in the Premises, taking into account the capacity of the electrical wiring in the Project and the Premises and the needs of other tenants, and shall not use more than such safe capacity. Landlord's consent to the installation of electric equipment shall not relieve Tenant from the obligation not to use more electricity than such safe capacity.
  - 18. Tenant assumes full responsibility for protecting the Premises from theft, robbery and pilferage.
- 19. Tenant shall not install or operate on the Premises any machinery or mechanical devices of a nature not directly related to Tenant's ordinary use of the Premises and shall keep all such machinery free of vibration, noise and air waves which may be transmitted beyond the Premises.



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#### EXHIBIT F TO LEASE

#### TENANT'S PERSONAL PROPERTY

None.



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**DATE: JULY 9, 2014** 



#### LOAN AND SECURITY AGREEMENT

BORROWER: HISTOGENICS CORPORATION

This **LOAN AND SECURITY AGREEMENT** (this "**Agreement**") is entered into as of the date set forth above (the "**Effective Date**") by and between SILICON VALLEY BANK ("**Bank**"), and the borrower named above ("**Borrower**"). Capitalized terms used but not otherwise defined herein shall have the meanings given them on <u>Schedule C</u>. The parties agree as follows:

- 1. Loans. Bank will make extensions of credit or other financial accommodations for Borrower's benefit (each, a "Loan" and collectively, "Loans"), and Borrower promises to pay Bank the amount of all Loans and other debts, principal, interest, Bank Expenses (as defined in Section 8.2), the Prepayment Premium, the Final Payment, and other amounts Borrower owes Bank now or later and interest accruing after insolvency proceedings begin and debts, liabilities, or obligations of Borrower assigned to Bank (collectively, "Obligations") pursuant to the terms and conditions of this Agreement or the other Loan Documents, and as set forth on Schedule A. Bank's obligation to make any Loan is subject to its receipt of the agreements, documents and fees it reasonably requires.
- **2.** *Security Interest.* As security for all present and future Obligations and for Borrower's performance for each of its duties hereunder, Borrower grants Bank a continuing security interest in all of Borrower's interest in the Collateral (as defined in <u>Schedule B</u>).
- **3.** Representations, Warranties and Covenants of Borrower. Except as set forth under Item 12 of Schedule D attached hereto, Borrower represents, warrants and covenants to Bank as follows, as of the Effective Date and with respect to covenants, for so long as this Agreement is in effect or any Obligations remain outstanding:
- 3.1 Corporate Existence; Authority. Each of Borrower and its Subsidiaries is and will continue to be, duly existing and in good standing in its state of formation and qualified and licensed to do business in, and in good standing in, any state where such qualification is necessary, except for jurisdictions in which failure to do so would not have a material adverse effect on Borrower. The execution, delivery and performance by Borrower of this Agreement and all other related documents have been duly and validly authorized, do not conflict with Borrower's formation documents, and do not constitute an event of default under any material agreement by which Borrower is bound. "Subsidiaries" means any entity of which more than 50% of the voting stock or other equity interests is owned or controlled, directly or indirectly, by Borrower.
- 63.2 *Collateral.* Bank has and will at all times continue to have a first-priority perfected security interest in all of the Collateral. Borrower has, and will continue to have, good title to the Collateral, free of any liens except Permitted Liens. Borrower will immediately advise Bank in writing of any material loss or damage to the Collateral.

- **3.3 Financial Matters.** All financial statements (including notes and schedules) now or in the future delivered to Bank, (i) have presented, and will present, fairly in all material respects Borrower's financial condition and its results of operations, and (ii) have been, and will be, prepared in conformity with generally accepted accounting principles ("GAAP"), except for the absence of footnotes and subject to year-end adjustments. Since the last date covered by any such statement, there has been no material impairment in the financial condition or business of Borrower. Borrower will provide Bank with all financial reports as set forth on Schedule A attached hereto, as well as any other financial information reasonably requested by Bank from time to time, including budgets, projections and plans.
- **3.4 Taxes; Legal Compliance.** Borrower has filed, and will file, when due (including under any permitted extensions under applicable law), all tax returns and reports required by applicable law. Borrower has paid, and will pay when due, all taxes, assessments, deposits and contributions now or in the future owed (except for taxes and assessments being contested in good faith with adequate reserves under GAAP). Borrower has complied, and will comply, in all material respects, with all applicable laws, rules and regulations.
- *3.5 Insurance.* Borrower shall at all times insure all of the tangible personal property Collateral and carry such other business insurance as is customary for companies similarly situated to Borrower. All property policies will have a lender's loss payable endorsement showing Bank as a lender loss payee and provide that the insurer must give Bank at least twenty (20) days' notice before canceling its policy.
- 3.6 Access. Upon one (1) Business Day's prior notice, Bank or its agents shall have the right to inspect the Collateral and to audit and copy Borrower's books and records during Borrower's regular business hours. A "Business Day" is any day that is not a Saturday, Sunday or a day on which the Bank is closed. Notwithstanding the foregoing, if an Event of Default has occurred and is continuing, Bank shall not be required to provide written notice to Borrower of any inspection or audit.
- *3.7 Banking Matters.* Borrower shall at all times maintain its banking relationship with Bank in a manner as set forth on <u>Schedule A</u>.
- **3.8 Statement of Borrower's Information.** All of Borrower's information set forth on <u>Schedule D</u> is true and correct as of the Effective Date, and Borrower shall provide written notice to Bank of any material changes within the prescribed periods of time set forth therein.

**3.9** *Insolvency.* Borrower is able, and will continue to be able, to pay its debts (including trade debts) as they mature.

**3.10** Additional Agreements. Borrower will not, and will not permit any of its Subsidiaries to, without Bank's prior written consent (which shall be a matter of Bank's good faith business judgment), do any of the following: (i) convey, sell, lease, transfer or otherwise dispose of ("Transfer") any property other than Permitted Transfers; (ii) engage in any business other than the business currently engaged in by Borrower or reasonably related thereto; (iii) permit or suffer to exist a change in its ownership existing as of the Effective Date in excess of the Ownership Threshold, except for the sale of capital stock to venture or strategic investors, provided that Bank receives at least five (5) Business Days' prior written notice of such sale and such sale does not otherwise result in an Event of Default (as defined in Section 5); (iv) merge or consolidate with any party, or acquire all or substantially all of the capital stock or assets of another party; (v) incur or become liable for any indebtedness other than Permitted Indebtedness; (vi) assign or convey any rights to income or incur or allow any lien, security interest or other encumbrance on any of its property other than Permitted Liens, or enter into any agreement, document, instrument or other arrangement (except with or in favor of Bank) with any Person which directly or indirectly prohibits or has the effect of prohibiting Borrower or any Subsidiary from assigning, mortgaging, pledging, granting a security interest in or upon, or encumbering any of Borrower's or any Subsidiary's Intellectual Property; (vii) make any investments except for Permitted Investments; (viii) pay or declare any dividends on Borrower's stock; (ix) redeem, retire, purchase or otherwise acquire, directly or indirectly, any of Borrower's stock other than stock repurchased in connection with the termination of employment or service as a consultant or director; (x) directly or indirectly enter into any material transaction with any affiliate except in the ordinary course of business upon reasonable terms no less favorable than those in an arm's-length transaction with a non-affiliate (provided that the foregoing restriction shall not apply to reasonable and customary compensation arrangements with, and the award of equity for compensatory purposes to officers, employees and directors of Borrower in the ordinary course of business); or (xi) make any payment on, or materially change any term relating to, any indebtedness which is subordinated to any indebtedness owed to Bank by Borrower. Borrower shall not, without at least thirty (30) days' prior written notice to Bank, relocate its principal offices from Borrower's address set forth on the signature page hereof or change its state of formation. Borrower shall take or authorize any further actions (including Bank's filing of financing statements to perfect Bank's security interest in the Collateral) and execute any further instruments as Bank reasonably requests to perfect or continue Bank's security interests or to effect the purposes of this Agreement.

**3.11** *Full Disclosure.* No written representation, warranty or other statement of Borrower in any certificate or written statement given to Bank, in the aggregate, contains any untrue statement of a material fact or omits to state a material fact necessary to make the statement contained in such certificates or statements not misleading.

- **4. Term.** This Agreement shall continue in effect until the maturity date set forth on Schedule A (the "Maturity Date"). On the Maturity Date or on any earlier effective date of termination of this Agreement, Borrower shall pay in cash all Obligations in full, whether or not such Obligations are otherwise then due and payable. No termination shall in any way affect or impair any security interest or other right or remedy of Bank, nor shall any such termination relieve Borrower of any obligation to Bank, until all of the Obligations have been paid and performed in full.
- **5.** *Events of Default.* The occurrence of any of the following events shall constitute an "Event of Default" hereunder: (i) Borrower fails to deliver the financial statements and other information pursuant to Section 3.3 above within the prescribed period of time; (ii) Borrower fails to pay when due any Loan or other monetary Obligation within three (3) Business Days after the due date (during which time no additional Loans shall be made by Bank); (iii) Borrower fails to perform any obligation (other than payment of any Loan or other Obligations or those pursuant to Section 3.3 above) or covenant hereunder, which, if such default can be reasonably cured, is not cured within ten (10) days after the date due (or a later date, as approved in writing by Bank); (iv) a Material Adverse Change; (v) any representation, or written statement given to Bank by or on behalf of Borrower, now or in the future, is untrue or misleading in a material respect; (vi) a default in any agreement between Borrower and a third party that gives the third party the right to accelerate any indebtedness exceeding the Contract Threshold Amount or that could reasonably be expected to cause any material impairment in the Borrower's business, operations or financial or other condition of the Borrower; (vii) the attachment, seizure, levy or possession by a trustee or receiver of any material portion of Borrower's assets which is not removed within ten (10) days from its occurrence; (viii) the enjoinment, restraint or prevention by court order from conducting a material part of Borrower's business, which is not terminated within ten (10) days of its occurrence; (ix) the dissolution, winding up, or insolvency of Borrower; or (x) the appointment of a receiver, trustee or custodian, for all or part of the property of, assignment for the benefit of creditors by, or commencement of any proceeding by or against, Borrower under any reorganization, bankruptcy, insolvency, arrangement, readjustment of debt, dissolution or liquidation law or statute of any jurisdiction, now or in the future in effect.
- 6. Rights and Remedies. If an Event of Default occurs and continues, Bank may, without notice or demand do any or all of the following: (i) accelerate and declare all of the Loans and other Obligations to be immediately due and payable (but if an Event of Default described in Sections 5(ix) or 5(x) occurs, all Obligations are immediately due and payable without any action by Bank); (ii) stop advancing money or extending credit for Borrower's benefit under this Agreement or any other agreement between Borrower and Bank; (iii) make any payments and do any acts it considers necessary or reasonable to protect its security interest in the Collateral (and Borrower will reasonably cooperate with Bank accordingly); (iv) apply to the Obligations any balances and deposits of Borrower that Bank holds or any amount held by Bank owing to or for the credit or the account of Borrower; (v) increase the then-existing

interest rate by an additional five percent (5.0%) per annum; (vi) ship, reclaim, recover, store, finish, maintain, repair, prepare for sale, advertise for sale and sell or otherwise dispose of the Collateral; and/or (vii) exercise any other rights and remedies permitted by applicable law. Effective only when an Event of Default occurs and continues, Borrower irrevocably appoints Bank as its lawful attorney to: (a) make, settle, and adjust all claims under Borrower's insurance policies; and (b) transfer the Collateral into the name of Bank or a third party as the Massachusetts Uniform Commercial Code permits. Bank may exercise the power of attorney to sign Borrower's name on any documents necessary to perfect or continue the perfection of any security interest regardless of whether an Event of Default has occurred. Bank's appointment as Borrower's attorney in fact, and all of Bank's rights and powers, coupled with an interest, are irrevocable until all Obligations have been fully repaid and performed. All of Bank's rights and remedies under this Agreement or any other agreement between Bank and Borrower are cumulative. Borrower waives demand, notice of default or dishonor, notice of payment and nonpayment, notice of any default, nonpayment at maturity, release, compromise, settlement, extension, or renewal of accounts, documents, instruments, chattel paper, and guarantees held by Bank on which Borrower is liable.

**7. Indemnification.** Borrower will indemnify, defend and hold harmless Bank and its affiliates, and each of their officers, directors, employees, attorneys, accountants and agents against: (i) all obligations, demands, claims, and liabilities asserted by any other party in connection with the transactions contemplated hereunder; and (ii) all losses and expenses incurred, or paid by Bank arising from transactions between Bank and Borrower contemplated by the Loan Documents (including reasonable attorneys' fees and expenses), except, as to both "(i)" and "(ii)" in this Section 7, for losses caused by Bank's gross negligence or willful misconduct. This Section 7 shall survive termination of this Agreement.

#### 8. General.

**8.1** No Waivers; Amendments. The failure of Bank at any time to require Borrower to comply strictly with any of the provisions of this Agreement shall not waive Bank's right to later demand and receive strict compliance. Any waiver of a default shall not waive any other default. None of the provisions of this Agreement may be waived except by a specific written waiver signed by Bank and delivered to Borrower. The provisions of this Agreement may not be amended except in a writing signed by Borrower and Bank.

8.2 Bank Expenses; Attorneys' Fees. Borrower shall reimburse Bank for all audit fees and expenses and reasonable costs and expenses (including reasonable attorneys' fees and expenses) for preparing, negotiating, administering, defending and enforcing this Agreement and the other Loan Documents with Bank (including appeals or insolvency proceedings) (collectively, "Bank Expenses"). If, subject to the foregoing, Bank or Borrower files any lawsuit against the other predicated on a breach of this Agreement, the prevailing party shall be entitled to recover its costs and reasonable attorneys' fees from the non-prevailing party.

**8.3** Binding Effect; Assignment. This Agreement is binding upon and for the benefit of the successors and permitted assignees of each party. Borrower may not assign any rights under this Agreement without Bank's prior written consent. Bank has the right, without the consent of or notice to Borrower, to sell transfer, assign, negotiate, or grant participation in all or any part of, or any interest in, Bank's obligations, rights, and benefits under this Agreement and the other Loan Documents.

**8.4 Notices.** All notices by any party required or permitted under this Agreement or any other related agreement must be in writing and be personally delivered or sent by overnight delivery, certified mail (postage prepaid and return receipt requested), or facsimile to the addresses and numbers below.

**8.5** Governing Law; Jurisdiction. This Agreement shall be governed by the laws of the Commonwealth of Massachusetts without regard to principles of conflicts of law. Borrower and Bank each submit to the exclusive jurisdiction of the federal and state courts in Boston, Massachusetts; provided that if for any reason Bank cannot avail itself of such courts in the Commonwealth of Massachusetts, Borrower accepts jurisdiction of the courts and venue in Santa Clara County, California.

8.6 Other. If any provision hereof is unenforceable, the remainder of this Agreement shall continue in full force and effect. This Agreement (including schedules hereto) and any other written agreements and, documents executed in connection herewith are the complete agreement between Borrower and Bank and supersede all prior and contemporaneous negotiations and oral representations and agreements, all of which are merged and integrated herein. This Agreement may be executed in one or more counterparts, all of which when taken together will constitute one agreement.

9. Confidentiality. In handling any confidential information, Bank will exercise the same degree of care that it exercises for its own proprietary information, but disclosure of information may be made: (i) to Bank's Subsidiaries or affiliates (provided that such Subsidiaries and affiliates are bound by the terms of this provision); (ii) to prospective transferees or purchasers of any interest in the Loans (provided that Bank shall use commercially reasonable efforts in obtaining such transferee's or purchaser's agreement to the terms of this provision); (iii) as required by law, regulation, subpoena, or other order; (iv) as required in connection with Bank's examinations and audits; or (v) as Bank considers appropriate in exercising remedies under this Agreement. Confidential information does not include information that is either: (a) in the public domain or in Bank's possession when disclosed to Bank or becomes part of the public domain after disclosure to Bank; or (b) disclosed to Bank by a third party, if Bank does not know that the third party is prohibited from disclosing the information.

10. Mutual Waiver of Jury Trial. BORROWER AND BANK EACH WAIVE THEIR RIGHT TO A JURY TRIAL OF ANY CLAIM OR CAUSE OF ACTION ARISING OUT OF THIS AGREEMENT OR ANY RELATED DOCUMENT OR ANY TRANSACTION CONTEMPLATED HEREBY OR THEREBY, INCLUDING CONTRACT, TORT, BREACH OF DUTY AND ALL OTHER CLAIMS. THIS WAIVER IS A

# MATERIAL INDUCEMENT FOR BOTH PARTIES TO ENTER INTO THIS AGREEMENT. EACH PARTY HAS REVIEWED THIS WAIVER WITH ITS COUNSEL.

11. Right of Set Off. Borrower hereby grants to Bank, a lien, security interest and right of set off as security for all Obligations to Bank, whether now existing or hereafter arising upon and against all deposits, credits, collateral and property, now or hereafter in the possession, custody, safekeeping or control of Bank or any entity under the control of Bank (including a Bank subsidiary) or in transit to any of them. At any time after the occurrence and during the continuance of an Event of Default, without demand or notice, Bank may set off the same or any part thereof and apply the same to any liability or obligation of Borrower even though unmatured and regardless of the adequacy of any other collateral securing the Obligations. ANY AND ALL RIGHTS TO REQUIRE BANK TO EXERCISE ITS RIGHTS OR REMEDIES WITH RESPECT TO ANY OTHER COLLATERAL WHICH SECURES THE OBLIGATIONS, PRIOR TO EXERCISING ITS RIGHT OF SETOFF WITH RESPECT TO SUCH DEPOSITS, CREDITS OR OTHER PROPERTY OF BORROWER ARE HEREBY KNOWINGLY, VOLUNTARILY AND IRREVOCABLY WAIVED.

[Signature page follows.]

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be executed as a sealed instrument under the laws of the Commonwealth of Massachusetts as of the date initially set forth above.

BORROWER:

HISTOGENICS CORPORATION

By: /s/ Kevin McArdle
Name: Kevin McArdle
Title: Chief Financial Officer

**Address:** 830 Winter Street, 3rd Floor

Waltham, Massachusetts 02451

Attn: \_\_\_\_\_\_Facsimile: \_\_\_\_\_\_Email: \_\_\_\_\_\_

BANK:

#### SILICON VALLEY BANK

By: /s/ Matthew Griffiths
Name: Matthew Griffiths
Title: Vice President

**Address:** 275 Grove Street, Suite 2-200

Newton, Massachusetts 02466

Attn: Christina Zorzi Email: CZorzi@svb.com



#### SCHEDULE A LOAN TERMS

BORROWER: HISTOGENICS CORPORATION

**EQUIPMENT LOANS** 

**Equipment Loan Amount:** One Million Seven Hundred Fifty Thousand Dollars (\$1,750,000.00) (the "**Equipment Loan** 

Amount")

**Equipment Loan Draw Period:** The period of time commencing upon the Effective Date and ending on the earlier to occur of (a) March 31, 2015,

or (b) an Event of Default (the "Equipment Loan Draw Period")

**Maturity Date:** For each Loan, the Payment Date that is thirty-five (35) months after the applicable Amortization Date for such

Loan (the "Maturity Date").

**Equipment Loans:** Subject to the terms and conditions of this Agreement, during the Equipment Loan Draw Period, from time to time

and upon the delivery to Bank by Borrower of a completed and executed irrevocable LOAN

PAYMENT/ADVANCE REQUEST FORM (in a form acceptable to Bank), and any additional information as Bank may reasonably request (including copies of the invoices for the equipment to be financed) at least five (5) Business Days before the proposed funding date, Bank will make up to four (4) Loans, each in a minimum amount of One Hundred Thousand Dollars (\$100,000.00), the aggregate of which will not exceed the Equipment Loan

Amount.

The Loans may only be used to finance Eligible Equipment purchased on or after ninety (90) days before the date of each Loan and may not exceed one hundred percent (100%) of the equipment invoice, excluding taxes, shipping, warranty charges, freight discounts and installation expense. Notwithstanding the foregoing, the initial Loan hereunder may be used to reimburse Borrower for Eligible Equipment purchased on or after the date which is nine (9) months prior to the Effective Date, provided such Loan is made on the Effective Date and in a minimum amount of One Hundred Thousand Dollars (\$100,000.00). Transferable software licenses, leasehold improvements or other soft costs (including sales tax, freight and installation expenses) may constitute up to twenty-five percent (25%) percent of each Loan.

In addition to the LOAN PAYMENT/ADVANCE REQUEST FORM, Borrower shall provide Bank with (a) a UCC financing statement covering the Eligible Equipment, and (b) an opportunity to confirm that upon filing the UCC financing statement covering the Eligible Equipment Bank shall have a first priority perfected security interest in such Eligible Equipment.

Once repaid, Loans may not be re-borrowed.

Bank will be obligated to make a Loan, so long as (i) each of the representations and warranties in Section 3 of the Agreement is materially true on the date the LOAN PAYMENT/ADVANCE REQUEST FORM is submitted and on the effective date of such Loan (except to the extent they relate specifically to an earlier date, in which case such representation and warranties shall continue to have been true and accurate as of such specified date), and (ii)

no Event of Default shall have occurred and be continuing or result from such Loan.

**Repayment:** Commencing on the first Payment Date of the month following the month in which

the Funding Date of a Loan occurs, and continuing on each Payment Date thereafter, Borrower shall make monthly payments of interest, in arrears, on the principal amount of each Loan at the rate set forth below.

Commencing on the applicable Amortization Date, and continuing on each Payment Date thereafter, Borrower shall repay each Loan in (i) thirty-six (36) equal monthly installments of principal, plus (ii) monthly payments of accrued interest at the rate set forth below. The final payment due on the applicable Maturity Date shall include all outstanding principal and all accrued and unpaid interest under each Loan and all other outstanding Obligations with respect to each Loan.

Interest Rate:

Loans accrue interest on the outstanding principal balance at a per annum rate of two and three quarters of one percent (2.75%) above the Prime Rate, fixed at the time of the advance for each Loan. Interest is computed on a 360 day year for the actual number of days elapsed.

**Default Rate:** 

Any amounts outstanding during the continuance of an Event of Default shall bear additional interest at the rate of five percent (5.0%) per annum.

**Prepayment Upon an Event of Loss:** 

Borrower shall bear the risk of any loss, theft, destruction, or damage of or to the Financed Equipment. If, during the term of this Agreement, any item of Financed Equipment becomes obsolete or is lost, stolen, destroyed, damaged beyond repair, rendered permanently unfit for use, or seized by a governmental authority for any reason for a period ending beyond the Maturity Date with respect to such Financed Equipment (an "Event of Loss"), then, within ten (10) days following such Event of Loss, Borrower shall (i) pay to Bank on account of the Obligations all accrued interest to the date of the prepayment, plus all outstanding principal owing with respect to the Financed Equipment subject to the Event of Loss, plus the Prepayment Premium and the Final Payment; or (ii) if no Event of Default has occurred and is continuing, at Borrower's option, repair or replace any Financed Equipment subject to an Event of Loss provided the repaired or replaced Financed Equipment is of equal or like value to the Financed Equipment subject to an Event of Loss and provided further that Bank has a first priority perfected security interest in such repaired or replaced Financed Equipment. Any partial prepayment of Loan paid by Borrower on account of an Event of Loss shall be applied to prepay amounts owing for such Loan in inverse order of maturity.

**Mandatory Prepayment:** 

If the Loans are accelerated following the occurrence of an Event of Default or otherwise, Borrower shall immediately pay to Bank an amount equal to the sum of: (i) all outstanding principal and accrued interest under the Loans, (ii) the Prepayment Premium, (iii) the Final Payment, and (iv) all other sums, if any, that shall have become due and payable, including interest at the Default Rate with respect to any past due amounts.

**Permitted Prepayment:** 

Borrower shall have the option to prepay all (but not less than all) of the Loans provided Borrower (i) provides written notice to Bank of its election to prepay the Loans at least thirty (30) days prior to such prepayment, and (ii) pays, on the date of such prepayment (A) all outstanding principal and accrued interest under the Loans, (B) the Prepayment Premium, (C) the Final Payment, and (D) all other sums, if any, that shall have become due and payable, including interest at the Default Rate with respect to any past due amounts.

**Request to Debit Accounts:** 

Bank may debit any of Borrower's deposit accounts (including account number(s):

\_\_\_\_\_\_\_) for principal and interest payments or any amounts Borrower owes Bank when due. Bank will notify Borrower when it debits Borrower's accounts. Such debits are not a set-off. Payments received after 12:00 noon Eastern time are considered received at the opening of business on the next Business Day. When a payment is due on a day that is not a Business Day, the payment is due the next Business Day and additional interest shall accrue.

### LIMITATION TO BANK'S OBLIGATIONS Limitation: Bank's obligation to lend the undisbursed portion of the Loan will terminate if, in Bank's sole discretion, there has been any material impairment in t he general affairs, management, results of operation, condition (financial or otherwise) or the prospect of repayment of the Obligations, or there has been any material adverse deviation by Borrower from the most recent business plan of Borrower presented to and accepted by Bank prior to the execution of this Agreement. **FEES Final Payment:** Borrower will pay the Final Payment, when due hereunder. **Prepayment Premium:** Borrower will pay the Prepayment Premium, when due hereunder. **Commitment Fee:** Borrower will pay to Bank on the Effective Date a fully earned, non-refundable commitment fee of Five Thousand Dollars (\$5,000.00). WARRANT Warrant: Concurrently on the Effective Date, Borrower will execute, deliver and issue to Bank a warrant to purchase stock (the "Warrant"), pursuant to Bank's standard form of warrant. **BANKING MATTERS Banking Matters:** Borrower shall maintain all of its and all of its Subsidiaries' (if any) operating, depository, and securities accounts with Bank and Bank's affiliates. FINANCIAL REPORTING REQUIREMENTS **Financial Reports:** Borrower shall provide Bank: Monthly Financial Statements. Within thirty (30) days after the end of each month, monthly financial statements prepared by Borrower in accordance with GAAP, together with a Compliance Certificate signed by a Responsible Officer in the form of Schedule E

*Annual Audited Financial Statements.* Within one hundred eighty (180) days following the end of Borrower's fiscal year, annual, audited, consolidated financial statements prepared under GAAP, consistently applied, together with an unqualified opinion in the financial statements from independent public accountants acceptable to Bank; and

*Board-Approved Operating Plan.* As soon as available, but no later than sixty (60) days after the last day of Borrower's fiscal year, and contemporaneously with any updates or changes thereto, Board-approved operating plan (reflecting projections on a quarterly or monthly basis) as to the then-current fiscal year in a form acceptable to Bank.



#### SCHEDULE B COLLATERAL

The Collateral consists of all right, title and interest of Borrower in and to the following:

Each item of equipment, or personal property financed with a "Loan" pursuant to that certain Loan and Security Agreement, dated as of July 9, 2014 (the "Loan Agreement"), by and between Borrower and Bank, including, without limitation, the property described in Annex A hereto, whether now owned or hereafter acquired, together with all substitutions, renewals or replacements of and additions, improvements, and accessions to any and all of the foregoing, and all proceeds from sales, renewals, releases or other dispositions thereof.

Pursuant to the terms of a certain negative pledge arrangement with Bank, Borrower has agreed not to encumber any of its copyright rights, copyright applications, copyright registrations and like protections in each work of authorship and derivative work, whether published or unpublished, any patents, patent applications and like protections, including improvements, divisions, continuations, renewals, reissues, extensions, and continuations-in-part of the same, trademarks, service marks and, to the extent permitted under applicable law, any applications therefor, whether registered or not, and the goodwill of the business of Borrower connected with and symbolized thereby, know-how, operating manuals, trade secret rights, rights to unpatented inventions, and any claims for damage by way of any past, present, or future infringement of any of the foregoing, without Bank's prior written consent.

ANNEX "A"

<u>Description of Equipment</u> <u>Make</u> <u>Model</u> <u>Serial #</u> <u>Invoice #</u>

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### SCHEDULE C DEFINITIONS

As used in this Agreement, the following words shall have the following meanings:

- "**Agreement**" is defined in the preamble hereof.
- "Amortization Date" is, for each Loan, the first Payment Date following the six (6) month anniversary of the Funding Date of such Loan.
- "Bank" is defined in the preamble hereof.
- "Bank Expenses" is defined in Section 8.2.
- "Board" means Borrower's board of directors.
- "Borrower" is defined in the preamble hereof.
- "Business Day" is defined in Section 3.6.
- "Collateral" is any and all properties, rights and assets of Borrower described on Schedule B.
- "Compliance Certificate" is that certain certificate in the form attached hereto as Schedule E.
- "Contract Threshold Amount" means One Hundred Thousand Dollars (\$100,000.00).
- "Effective Date" is defined in the preamble hereof.
- "Eligible Equipment" is the following to the extent it complies with all of Borrower's representations and warranties to Bank, is acceptable to Bank in all respects, is located at 830 Winter Street, 3rd Floor, Waltham, Massachusetts 02451, or such other location of which Bank has approved in writing, and is subject to a first priority lien in favor of Bank: new and used general purpose equipment, computer equipment, office equipment, test and laboratory equipment, furnishings, subject to the limitations set forth herein.
- "Equipment Loan Amount" is defined on Schedule A.
- "Equipment Loan Draw Period" is defined on Schedule A.
- "Event of Default" is defined in Section 5.
- "Event of Loss" is defined in Schedule A.
- "Final Payment" is, for each Loan, a payment (in addition to and not a substitution for the regular monthly payments of principal plus accrued interest) equal to the original principal amount of such Loan extended by Bank multiplied by the Final Payment Percentage, due on the earliest to occur of (a) the applicable Maturity Date, (b) the acceleration of any Loan, or (c) the prepayment of a Loan pursuant to this Agreement.
- "Final Payment Percentage" is, for each Loan, four percent (4.0%).
- "Financed Equipment" is all present and future Eligible Equipment in which Borrower has any interest which is financed by a Loan.

"Funding Date" is any date on which a Loan is made to or for the account of Borrower which shall be a Business Day.

"GAAP" is generally accepted accounting principles set forth in the opinions and pronouncements of the Accounting Principles Board of the American Institute of Certified Public Accountants and statements and pronouncements of the Financial Accounting Standards Board or in such other statements by such other Person as may be approved by a significant segment of the accounting profession, which are applicable to the circumstances as of the date of determination.

"Intellectual Property" means any copyright rights, copyright applications, copyright registrations and like protections in each work of authorship and derivative work, whether published or unpublished, any patents, patent applications and like protections, including improvements, divisions, continuations, renewals, reissues, extensions, and continuations-in-part of the same, trademarks, service marks and applications therefor, whether registered or not, and the goodwill of the business of Borrower connected with and symbolized thereby, know-how, operating manuals, trade secret rights, rights to unpatented inventions, and any claims for damage by way of any past, present, or future infringement of any of the foregoing.

"Loan" and "Loans" are defined in Section 1.

"Loan Documents" are, collectively, this Agreement, any subordination agreement, any note, or notes or guaranties executed by Borrower, and any other present or future agreement between Borrower and/or for the benefit of Bank in connection with this Agreement, all as amended, extended or restated.

"Material Adverse Change" means the occurrence of (a) any material impairment in the business, operations, or financial condition of the Borrower, (b) a material impairment of the prospect of repayment of any portion of the Obligations; or (c) a material impairment in the perfection or priority of Bank's security interest in the Collateral or in the value of such Collateral (other than normal depreciation) which is not covered by adequate insurance.

"Maturity Date" is defined in Schedule A.

"**Obligations**" is defined in Section 1.

"Ownership Threshold" means forty-nine percent (49.0%).

"Payment Date" is the first (1st) Business Day of each calendar month.

"Permitted Indebtedness" means (a) Borrower's indebtedness to Bank; (b) indebtedness existing on the Effective Date and shown on Schedule D; (c) indebtedness incurred by Borrower owed to a third-party subordinated to Borrower's indebtedness owed to Bank which subordination is reflected in a written agreement as accepted and approved by the Bank prior to the incurrence of such third-party indebtedness; (d) indebtedness to trade creditors incurred in the ordinary course of business; (e) indebtedness secured by Permitted Liens; (f) indebtedness arising from the endorsement of instruments in the ordinary course of business; and (g) extensions, refinancings, modifications, amendments and restatements of any items of Permitted Indebtedness described in (a) through (f) above, provided that the principal amount thereof is not increased or the terms thereof are not modified to impose materially more burdensome terms upon Borrower or its Subsidiaries, as the case may be.

"Permitted Investments" means (a) investments shown on Schedule D and existing on the Effective Date; (b) (i) marketable direct obligations issued or unconditionally guaranteed by the United States or its agency or any State maturing within one (1) year from its acquisition, (ii) commercial paper maturing no more than one (1) year after its creation and having the highest rating from either Standard & Poor's Ratings Service or Moody's Investors Service, Inc., (iii) Bank's certificates of deposit issued maturing no more than one (1) year after issue, (iv) investments permitted by Borrower's investment policy, as amended from time to time, provided that such investment policy (and such amendments thereto) has been approved by Bank in writing (which approval shall not be unreasonably withheld, conditioned or delayed); (c) investments consisting of the endorsement of negotiable instruments for deposit or collection or similar transactions in the ordinary course of business; (d) investments consisting of (i) travel advances and employee relocation loans and other employee loans and advances in the ordinary course of business, and (ii) loans to employees, officers or directors relating to the purchase of equity securities of Borrower or its Subsidiaries pursuant to employee stock purchase plans or agreements approved by Borrower's Board; (e) deposit and investment accounts of Borrower in which Bank has a lien prior to any other lien (other than liens securing customary fees and expenses (but no credit/debt relationship or margin account) of the depository or investment intermediary); and (f) investments not otherwise permitted in an aggregate amount of not more than One Hundred Thousand Dollars (\$100,000.00) in each fiscal year.

"Permitted Liens" means (a) liens in favor of Bank; (b) liens for taxes, fees, assessments or other government charges or levies, either not delinquent or being contested in good faith and for which Borrower maintains adequate reserves on its books, if they have no priority over any of Bank's security interests; and (c) statutory liens securing claims or demands of materialmen, mechanics, carriers, warehousemen, landlords and other Persons imposed without action of such parties, provided, they have no priority over any of Bank's security interests and the aggregate amount of such liens does not at any time exceed One Hundred Thousand Dollars (\$100,000.00).

"Permitted Transfer" means Transfers of (a) inventory in the ordinary course of business; (b) non-exclusive licenses and similar arrangements for the use of the property of Borrower or its Subsidiaries in the ordinary course of business and other non-perpetual licenses that may be exclusive in some respects, such as, by way of example, with respect to field of use or geographic territory, but that do not result, under applicable law, in a sale of all of Borrower's interest in the property that is the subject of the license; and (c) worn-out or obsolete equipment (that does not constitute Financed Equipment).

"**Person**" is any individual, sole proprietorship, partnership, limited liability company, joint venture, company association, trust, unincorporated organization, association, corporation, institution, public benefit corporation, firm, joint stock company, estate, entity or government agency.

"**Prepayment Premium**" shall be an additional fee payable to Bank in amount equal to: (a) for a prepayment made on or prior to the first (1st) anniversary of the Funding Date of such Loan, two percent (2.0%) of the then outstanding principal amount of such Loan as of the date immediately and prior to such prepayment, and (b) for a prepayment made after the first (1st) anniversary of the Funding Date of such Loan, one percent (1.0%) of the then outstanding principal amount of such Loan as of the date immediately and prior to such prepayment.

"**Prime Rate**" is the greater of (a) the rate of interest per annum from time to time published in the money rates section of The Wall Street Journal or any successor publication thereto as the "prime rate" then in effect; provided that if such rate of interest, as set forth from time to time in the money rates section of The Wall Street Journal, becomes unavailable for any reason as determined by Bank, the "Prime Rate" shall mean the rate of interest per annum announced by Bank as its prime rate in effect at its principal office in the State of California (such Bank announced Prime Rate not being intended to be the lowest rate of interest charged by Bank in connection with extensions of credit to debtors), and (b) three and one quarter of one percent (3.25%).

"Responsible Officer" is each of the Chief Executive Officer, the President, the Chief Financial Officer and the Controller of Borrower.

"Subsidiaries" is defined in Section 3.1.

"Transfer" is defined in Section 3.10.

"Warrant" is defined on Schedule A.



#### SCHEDULE D STATEMENT OF BORROWER'S INFORMATION

Borrower hereby represents and warrants, as of the date of the Agreement, subject to any updates provided to Bank as required under the Agreement: (If none, please indicate so. Attach additional pages, if necessary.)

- \*1. The exact legal name of Borrower, as set forth in its formation documents, is: Histogenics Corporation.
- \*2. Borrower currently operates and has operated during the previous five years under only the following names: Histogenics Corporation. In 2011, Borrower acquired ProChon Biotech Ltd., which operated under the name ProChon Biotech Ltd. prior to that time.
- \*3. Borrower is organized in the State of Delaware and is qualified to do business in the following states: Massachusetts.
- \*4. The following are all of Borrower's Subsidiaries and their respective states (or countries, if other than the U.S.) and dates of formation, as well as the percentage of total capital stock owned by Borrower:

Borrower owns 100% of the total capital stock of the following Subsidiaries:

Name of Wholly-Owned Subsidiary (Date of Organization) Histogenics Limited (2010) Prochon BioTech, Ltd. (1996)

<u>Jurisdiction of Organization</u> United Kingdom Israel Name under
which the subsidiary conducts
business
Histogenics Limited
Prochon BioTech, Ltd.

\*\*5. The following are all actions, suits, proceedings and investigations pending, or to Borrower's knowledge, currently threatened by or against Borrower, in which a likely adverse decision could reasonably be expected to cause a Material Adverse Change in Borrower's business, operations or financial condition:

None.

\*\*6. The following is a description of all returns, recoveries, disputes and claims of at least \$50,000 each, received by Borrower within the last thirty (30) days:

None.

\*\*\*7. The following are all of Borrower's copyrights or mask works registered with the United States Copyright Office:

None.

\*\*\*\*8. The following are all of Borrower's patents, trademarks and service marks, and all applications filed by Borrower in the United States Patent & Trademark Office for a patent or to register a trademark or service mark:

See IP Schedule attached hereto.

9. The following is all of the Borrower's indebtedness existing as of the date of the Agreement:

ThermoFisher Scientific Equipment Lease (\$10,915 as of May 31, 2014).

Series A-1 Preferred Stock Royalty Redemption Right - Beginning January 1, 2017 and ending December 31, 2019, holders of the Company's Series A-1 Preferred Stock (an any securities that such preferred stock is converted into) may redeem \$30M in cash or common stock in exchange for a 3% royalty right on future revenues of Borrower.

10. The following is all of the Borrower's investments (other than Subsidiaries) existing as of the date of the Agreement:

None. The Company holds its cash in cash and cash equivalent securities.

11. The following are all liens to which Borrower's assets and property are subject as of the date of the Agreement:

None

2. Other exceptions to representations and warranties under Section 3 of the Agreement:

None

Borrower must update Bank of any material change to information:

- \* at least thirty (30) days prior to the date of occurrence of the event necessitating such update.
- \*\* within five (5) days of the date of occurrence of the event necessitating such update.
- \*\*\* at least 15 days prior to the date of filing of any application with the United States Copyright Office.
- \*\*\*\* at least 30 days prior to the date of filing of any application with the United States Patent and Trademark Office.

#### SCHEDULE E COMPLIANCE CERTIFICATE

TO:

Title

Date

SILICON VALLEY BANK

FROM: HISTOGENICS CORPORATION		
Security Agreement between Borrower and Banl required covenants except as noted below and (ii In addition, the undersigned authorized officer of made adequate provision to pay, all material taxed documents supporting the certification. The Offic consistently applied from one period to the next	k (the "Agreement"), (i) Borrower is in comple) all representations and warranties in the Agree Borrower certifies that Borrower and each Ses, except those being contested in good faith correctifies that these are prepared in accordance except as explained in an accompanying letter lation that Borrower is not in compliance with	certifies that under the terms and conditions of the Loan and ete compliance for the period ending with all reement are true and correct in all material respects on this date ubsidiary has timely filed all required tax returns and paid, or with adequate reserves under GAAP. Attached are the required ince with Generally Accepted Accounting Principles (GAAP) or or footnotes. The Officer acknowledges that no borrowings any of the terms of the Agreement, and that compliance is
Please indicate compliance status by circling !	Yes/No under "Complies" column.	
Reporting Covenant Monthly financial statements + CC Annual (Audited) financial statements Board-approved operating plan Borrower only has deposit accounts located at th	Required Monthly within 30 days FYE within 180 days FYE within 60 days	Complies Yes No Yes No Yes No
Comments Regarding Exceptions: See Attach	ed.	BANK USE ONLY
Sincerely,		Y:AUTHORIZED SIGNER
HISTOGENICS CORPORATION		
Signature		AUTHORIZED SIGNER
	Date:	

Compliance Status:

No

Yes

#### LOAN PAYMENT/ADVANCE REQUEST FORM

#### DEADLINE FOR SAME DAY PROCESSING IS 12:00 NOON EASTERN TIME

Date: \_\_\_ Fax To: — LOAN PAYMENT: HISTOGENICS CORPORATION (Borrower) From Account # \_\_\_\_\_ To Account # \_\_\_\_\_ (Deposit Account #) (Loan Account #) Principal \$ \_\_\_ and/or Interest \$ \_\_\_ All Borrower's representations and warranties in the Loan and Security Agreement are true, correct and complete in all material respects up to and including the date of the transfer request for a loan payment, but those representations and warranties expressly referring to another date shall be true, correct and complete in all material respects as of that date: Authorized Signature: \_ Phone Number: \_\_ - LOAN ADVANCE: Complete Outgoing Wire Request section below if all or a portion of the funds from this loan advance are for an outgoing wire. To Account # \_\_\_\_ (Loan Account #) (Deposit Account #) Amount of Advance \$ All Borrower's representations and warranties in the Loan and Security Agreement are true, correct and complete in all material respects up to and including the date of the transfer request for an advance, but those representations and warranties expressly referring to another date shall be true, correct and complete in all material respects as of that date: **Authorized Signature:** Phone Number: — OUTGOING WIRE REQUEST Complete only if all or a portion of funds from the loan advance above are to be wired. Deadline for same day processing is 12:00 noon, Eastern Time. Amount of Wire: \$\_\_\_\_\_ Beneficiary Name: Beneficiary Bank: Account Number: City and State: Beneficiary Bank Transit (ABA) #:\_\_\_\_\_ Beneficiary Bank Code (Swift, Sort, Chip, etc.): (For International Wire Only) Transit (ABA) #: \_\_\_\_\_ Intermediary Bank: \_\_\_\_ For Further Credit to: \_\_\_\_\_ Special Instruction: \_\_\_\_ By signing below, I (we) acknowledge and agree that my (our) funds transfer request shall be processed in accordance with and subject to the terms and conditions set forth in the agreements(s) covering funds transfer service(s), which agreements(s) were previously received and executed by me (us).

Authorized Signature: \_\_\_\_\_\_Print Name/Title:

Telephone #

2nd Signature (If Required):

Telephone #

Print Name/Title:

ENDNOTE ANNOTATIONS FOR INTERNAL SVB USE ONLY

#### GUNDERSON DETTMER STOUGH VILLENEUVE FRANKLIN & HACHIGIAN, LLP ONE MARINA PARK DRIVE, SUITE 900 BOSTON, MA 02210

TELEPHONE: (617) 648-9100 FACSIMILE: (617) 648-9199

### VIA OVERNIGHT DELIVERY CONFIDENTIAL

July 11, 2014

U.S. Securities and Exchange Commission Division of Corporation Finance 100 F Street, N.E. Washington, D.C. 20549

Attention: Amanda Ravitz

Jay Mumford Daniel Morris

Re: Histogenics Corporation

Amendment No. 3 to Confidential Draft Registration Statement

on Form S-1 Submitted May 16, 2014

CIK No. 0001372299

Dear Ms. Ravitz:

On behalf of Histogenics Corporation (the "Company"), we submit this letter in response to comments from the staff (the "Staff") of the Securities and Exchange Commission (the "Commission") received by letter dated June 3, 2014 relating to the Company's Amendment No. 3 to Confidential Draft Registration Statement on Form S-1, confidentially submitted on May 16, 2014 (the "Draft Registration Statement").

On behalf of the Company, we are also submitting via EDGAR an amendment to the Draft Registration Statement on Form S-1 (the "Registration Statement"), and for the convenience of the Staff, we are providing to the Staff by overnight delivery copies of this letter and marked copies of the Registration Statement (against the Draft Registration Statement).

In this letter, we have recited the written comments from the Staff in italicized, bold type and have followed each comment with the Company's response.

#### Phase 3 Clinical Trial, page 8

We note your response to prior comment 8. Please clarify, if true, that the endpoint was deemed appropriate by the FDA.

#### **RESPONSE TO COMMENT 1:**

The Company acknowledges the Staff's comment. The Company would like to clarify that the U.S. Food and Drug Administration's Special Protocol Assessment (SPA) procedure can document the FDA's agreement that the design and planned analysis of a study adequately address objectives in support of a regulatory submission. Pursuant to the SPA process, the FDA agreed to

July 11, 2014 Page 2

the Company's Phase 3 protocol design, including the choice of a one-year superiority endpoint. The Company does note that final determinations for approval under an SPA are made after a complete review of a marketing application and are based on the entire data in the application.

#### Purpose Co., Ltd., page 93

2. We note your response to prior comment 10; however, it remains unclear how the transfer of shares will occur prior to effectiveness. Please expand your disclosure to explain in detail how you determined that "sufficient" shares are held in escrow and tell us how you have ensured that the "necessary number of shares of common stock can be quickly and easily transferred." Also, please address what will happen if the offering size changes after effectiveness and clarify whether the offering of shares by selling shareholders, if any, could change the number of shares transferred.

#### **RESPONSE TO COMMENT 2:**

The Company acknowledges the Staff's comment and has expanded its discussion of shares to be transferred upon completion of the initial public offering to explain which investors would be transferring the shares to Purpose as requested.

The Company holds in escrow an amount of shares in excess of the number of shares that would be necessary to transfer to Purpose based on the Company's current expectations of potential offering sizes. If the offering size changes after effectiveness, the number of shares to be transferred to Purpose will be adjusted appropriately by either transferring additional shares from the shares held in escrow or, if the escrow is exhausted, by further reallocation of additional shares from the stockholders obligated to reallocate shares pursuant to the Company's Second Amended and Restated Stockholders' Agreement dated as of December 18, 2013 and submitted as Exhibit 4.3 to the Registration Statement. No shares are being sold by selling shareholders as part of the offering.

#### Principal Stockholders, page 134

3. Also, with regard to prior comment 10, please tell us the basis for your belief that disclosure of the identity of the transferors and their percentage of consideration need only be disclosed for affiliates or beneficial owners of more than 5% of the registrant's shares.

#### **RESPONSE TO COMMENT 3:**

The Company acknowledges the Staff's comment and has expanded its discussion in the Principal Stockholders section of the Registration Statement to further describe the identity of the stockholders are required to transfer shares to Purpose. As previously indicated, the Company has not included the complete list of stockholders required to transfer shares to Purpose in the Registration Statement because this disclosure is not required by Regulation S-K as such stockholders are neither affiliates nor beneficial owners of five percent or more of the Company's outstanding Common Stock (on an as-converted basis), and the Company respectfully believes that it is not otherwise material to investors. Additionally, Exhibit 4.3 (Second Amended and Restated Stockholders' Agreement dated as of December 18, 2013) to the Registration Statement includes a breakdown of the percentage of consideration allocated to each applicable stockholder pursuant to the Company's agreement with Purpose.

July 11, 2014 Page 3

\* \* \* \* \*

Please do not hesitate to contact me at (781) 795-3555 if you have any questions or would like additional information regarding this matter.

Very truly yours,

## GUNDERSON DETTMER STOUGH VILLENEUVE FRANKLIN & HACHIGIAN LLP

By: /s/ Marc Dupré

cc: Adam Gridley

Kevin McArdle Richard Blake Keith Scherer

Nevin Fox

Albert Vanderlaan