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As confidentially submitted to the Securities and Exchange Commission on April 11, 2014. This third 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	**3842**	**04-3522315**
(State or Other Jurisdiction of Incorporation or Organization)	**(Primary Standard Industrial Classification Code Number)**	**(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)

Kevin McArdle
Chief Financial 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-2 of the Exchange Act. (Check one):

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☐ (Do not check if a smaller reporting company)	Smaller reporting company	☒

CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities to be Registered	**Proposed Maximum Aggregate Offering Price[(1)]**	**Amount of Registration Fee[(2)]**
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 over-allotments, 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.

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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 April 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

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. We leverage our regenerative medicine platform, described below, to provide solutions that can be utilized individually or in concert to treat musculoskeletal-related conditions, which are disorders that can affect muscles, joints, tendons, bones, ligaments and nerves. 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 collagen 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.

Our first product candidate, NeoCart, utilizes our platform to produce an innovative tissue implant intended to treat tissue injury in the field of orthopedics, specifically cartilage damage in the knee. 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 allows the cells to organize and function like cartilage cells. 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. The process results in a well-affixed implant with the potential to facilitate earlier weight-bearing and accelerated recovery than is typical with current therapies.

NeoCart has not been approved in any jurisdiction, including the United States. We are currently enrolling a Phase 3 clinical trial for NeoCart in the United States 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. In a Phase 2 clinical trial of 30

patients, NeoCart showed statistically better clinical outcomes when compared directly to microfracture on measures of pain and function as of the first and second anniversary of the procedure. If 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 a statistically significant improvement, meaning that sufficient data exist to indicate the outcome is unlikely to have occurred by chance, in clinical efficacy based on pain and function measures as compared to microfracture in our Phase 2 clinical trial. We believe positive Phase 1 and Phase 2 clinical data generated by NeoCart is a direct result of our regenerative medicine platform and the elements comprising our platform.

The goal of our Phase 3 clinical trial is to demonstrate significant 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. 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. 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.

Our regenerative medicine platform gives us the ability to develop a strong pipeline. We believe 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. 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 anticipate that we will continue to incur substantial losses for the next several years.
- 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 $ million, assuming an 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. If the underwriters' option to purchase additional shares in this offering is exercised in full, we estimate that our net proceeds will be $ million. We intend to use the net proceeds of this offering primarily to develop and advance NeoCart through clinical trials, as well as for working capital and general corporate purposes. 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 45,344,052 shares outstanding as of March 31, 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 March 31, 2014, at an exercise price of $0.001 per share;
- 3,187,440 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 $0.28 per share;
- 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
- 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 March 31, 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 March 31, 2014, to acquire shares of common stock at an exercise price of $0.001 per share;

- 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. Our historical results are not necessarily indicative of the results to be expected for any future 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,	
	2012	2013
Consolidated Statement of Operations Data:	(in thousands, except share and per share amounts)	
Revenue	$ 26	$ 8
Operating expenses:		
Research and development	11,941	11,946
Selling, general and administrative	3,053	4,847
Impairment of goodwill and intangible assets	—	60
Total operating expense	14,994	16,853
Loss from operations	(14,968)	(16,845)
Interest expense, net	(798)	—
Other expense, net	(13)	(52)
Gain on extinguishment of debt	687	—
Change in fair value of note payable to stockholder	(17)	—
Change in fair value of warrant liability and other liability	(1,826)	(8,815)
Net loss	$ (16,935)	$ (25,712)
Earnings (loss) per common share[1]:		
Basic	$ 1.00	$ (8.94)
Diluted	$ 0.26	$ (8.94)
Weighted-average shares used to compute earnings (loss) per common share[1]:		
Basic	2,818,293	6,264,690
Diluted	12,898,629	6,264,690
Pro forma earnings (loss) per common share[1]:		
Basic	$	$
Diluted	$	$
Pro forma weighted-average common shares outstanding[1]:		
Basic		
Diluted		

(1) 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 December 31, 2013		
	Actual	Pro Forma	Pro Forma As Adjusted
	(in thousands)		
Consolidated Balance Sheet Data:			
Cash and cash equivalents	$ 8,734		
Working capital[2]	5,259		
Total assets	14,796		
Other long-term liabilities	28,192		
Convertible redeemable preferred stock	57,071		
Total stockholders' equity (deficit)	(75,554)		

(2) 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 and $25.7 million in 2013. As of December 31, 2013, we had an accumulated deficit of $110.8 million. 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. 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. and Koken Co., Ltd. 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. We are in the process of identifying a chief executive officer to succeed Mr. Greenleaf, and we expect to continue to expand our management team in the future. Our future performance will depend significantly on our ability to hire a qualified chief executive officer and successfully integrate 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 a 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. Our board of directors will appoint a successor to our current president and chief executive officer and has initiated the search for a new president chief executive officer but we may not be able to hire a qualified new chief executive officer within the foreseeable future. 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. Greenleaf 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, 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.

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 March 31, 2014, our executive officers, directors, holders of more than 5% of our capital stock and their respective affiliates beneficially owned 84.7% 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 March 31, 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 March 31, 2014, after the contractual lock-up agreements pertaining to this offering expire 180 days from the date of this prospectus, up to an additional 45,344,052 shares will be eligible for sale in the public market, 38,402,816 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 3,187,440 shares that were subject to outstanding options as of March 31, 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 38,926,019 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, including a new chief executive officer;
- 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 $ million, assuming an 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. If the underwriters' option to purchase additional shares in this offering is exercised in full, we estimate that our net proceeds will be $ million.

The principal purposes of this offering are to obtain additional capital, create a public market for our common stock and facilitate our future access to the public equity markets. We intend to use the net proceeds of this offering primarily to develop and advance NeoCart through clinical trials, as well as for working capital and general corporate purposes.

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. 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, general business conditions and other factors that our board of directors may deem relevant.

CAPITALIZATION

The table below sets forth our capitalization as of December 31, 2013 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 December 31, 2013		
	Actual	Pro Forma	Pro Forma As Adjusted
	(in thousands, except share and per share amounts)		
Long-term liabilities, including current portion	28,656		
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	35,188		
Deficit accumulated during the development stage	(110,748)		
Total stockholders' (deficit) equity	(75,554)		
Total capitalization	$ 10,173	$	$

The table above excludes each of the following as of December 31, 2013:

- 5,287,144 shares issuable upon the exercise of options outstanding under our 2012 Equity Incentive Plan as of December 31, 2013, at a weighted average exercise price of $0.28 per share;

- 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
- 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 December 31, 2013, the historical net tangible book deficit of our common stock was $(76.1) million, or $(11.86) 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 December 31, 2013.

As of December 31, 2013, 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 pro forma as adjusted net tangible book value of our common stock as of December 31, 2013 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 December 31, 2013	$(11.86)	
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 December 31, 2013, 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 Purchased		Total Consideration		Average Price Per Share
	Number	Percent	Amount	Percent	
Existing stockholders		%		%	$
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:

- 5,287,144 shares issuable upon the exercise of options outstanding under our 2012 Equity Incentive Plan as of December 31, 2013, at a weighted average exercise price of $0.28 per share;
- 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
- 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. Our historical results are not necessarily indicative of the results to be expected for any future 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,	
	2012	2013
	(in thousands, except per share amounts)	
Consolidated Statement of Operations Data:		
Revenue	$ 26	$ 8
Operating expenses:		
Research and development	11,941	11,946
Selling, general and administrative	3,053	4,847
Impairment of goodwill and intangible assets	—	60
Total operating expense	14,994	16,853
Loss from operations	(14,968)	(16,845)
Interest expense, net	(798)	—
Other expense, net	(13)	(52)
Gain on extinguishment of debt	687	—
Change in fair value of note payable to stockholder	(17)	—
Change in fair value of warrant liability and other liability	(1,826)	(8,815)
Net loss	$ (16,935)	$ (25,712)
Earnings (loss) per common share[1]		
Basic	$ 1.00	$ (8.94)
Diluted	$ 0.26	$ (8.94)
Weighted-average shares used to compute earnings (loss) per common share[1]		
Basic	2,818,293	6,264,690
Diluted	12,898,629	6,264,690
Pro forma earnings (loss) per common share[1]:		
Basic		
Diluted		
Pro forma weighted-average common shares outstanding[1]:		
Basic		
Diluted		

[1] 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,	
	2012	2013
	(in thousands)	
Stock-based Compensation Expense:		
Selling, general and administrative	$ 14	$ 158

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

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. We leverage our regenerative medicine platform, described below, to provide solutions that can be utilized individually or in concert to treat musculoskeletal-related conditions, which are disorders that can affect muscles, joints, tendons, bones, ligaments and nerves. 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 collagen 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.

Our first product candidate, NeoCart, utilizes our platform to produce an innovative tissue implant intended to treat tissue injury in the field of orthopedics, specifically cartilage damage in the knee. 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 $110.7 million for the period from inception to December 31, 2013. 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 December 31, 2013, 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. 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 and $8,000 of collaboration revenue for the years ended December 31, 2012 and 2013, respectively.

From inception to December 31, 2013, 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 December 31, 2013, we incurred $56.7 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 December 31, 2013, we incurred $37.4 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 December 31, 2013.

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, 2013. The impairment charge of $330,000 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 December 31, 2012 or through December 31, 2013, 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 year ended December 31, 2012 and 2013, the weighted-average assumptions used in the Black-Scholes option pricing model to determine the fair value of those grants were as follows:

	Years Ended December 31,	
	2012	2013
Risk-free interest	0.93%	1.01%
Expected volatility	89.0%	87.9%
Expected term (in years)	6.08	5.36
Expected dividend yield	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, the weighted-average assumptions used in the Black-Scholes option pricing model to determine the fair value of those grants were as follows:

	Year Ended December 31, 2013
Risk-free interest	0.23%
Expected volatility	145.2%
Expected term (in years)	0.98
Expected dividend yield	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 December 31, 2013, 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 and December 31, 2013, the unrecognized compensation cost related to outstanding options was $130,000 and $1.0 million, respectively, and is expected to be recognized as expense over 3.28 years and 3.21 years, respectively.

As of December 31, 2012 and December 31, 2013, the unrecognized compensation cost related to restricted stock awards was $4,000 and $14,000, respectively, and is expected to be recognized as expense over 3.84 years and 3.14 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	Common Stock Fair 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

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 and $0.82 as of December 31, 2012, March 31, 2013, June 30, 2013, September 30, 2013, December 6, 2013 and December 31, 2013, 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
Acquisition scenarios						
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
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%
Time to event	2.25 years	2.75 years	2.84 years	2.58 years	2.40 years	3.5 years
IPO scenarios						
Pre-money valuation	$ 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%
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
Probability of liquidation scenario	20%	20%	20%	20%	10%	5%
Discount for lack of marketability	28%	31%	32%	31%	15%	15%

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.

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. 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
Acquisition scenarios		
Liquidity value	$50 to $250 million	$50 to $250 million
Probability of occurrence	10.00% to 50.00%	5.00% to 10.00%
Time to event	2.25 years	3.5 years
IPO scenarios		
Pre-money valuation	$75 to $150 million	$81 to $150 million
Probability of occurrence	0.67% to 3.33%	5.00% to 38.00%
Time to event	1.25 to 2.25 years	0.5 to 3.5 years
Probability of liquidation scenarios	20%	5%
Discount for lack of market ability	28%	15%

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 December 31, 2013, 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:

	Tax Positions (in 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.

JOBS Act

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

For so long as we are an “emerging growth company,” we intend to rely on exemptions relating to: (1) providing an auditor’s attestation report on our system of internal control over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act and (2) complying with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor’s report providing additional information about the audit and the financial statements, known as the auditor discussion and analysis. We will remain an emerging growth company until the earliest of (a) the last day of the fiscal year in which we have total annual gross revenue of $1.0 billion or more, (b) 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

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 December 31, 2013, we had an accumulated deficit of $110.7 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 December 31, 2013, we had cash and cash equivalents of $8.7 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,	
	2012	2013
	(in thousands)	
Net cash used in operating activities	$ (12,232)	$ (15,282)
Net cash used in investing activities	(79)	(554)
Net cash provided by financing activities	26,688	9,854
Net increase (decrease) in cash and cash equivalents	$ 14,377	$ (5,982)

Operating Activities

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 $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 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:

	Total	Less than 1 year	1-3 years	3-5 years	More than 5 years
			(in thousands)		
Operating lease obligations	$4,101	$ 1,135	$ 1,998	$ 968	$ —
Research and development contract obligations	345	107	64	64	110
Severance contract obligations	59	59	—	—	—
Engineering obligations	417	417	—	—	—
Total	$4,922	$ 1,718	$ 2,062	$ 1,032	$ 110

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 approval by 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 our former chief executive officer whose employment ended in March 2013.

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.

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 December 31, 2013, we had cash and cash equivalents of $8.7 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. We leverage our regenerative medicine platform, described below, to provide solutions that can be utilized individually or in concert to treat musculoskeletal-related conditions, which are disorders that can affect muscles, joints, tendons, bones, ligaments and nerves. 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 collagen 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.

Our first product candidate, NeoCart, utilizes our platform to produce an innovative tissue implant intended to treat tissue injury in the field of orthopedics, specifically cartilage damage in the knee. 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 allows the cells to organize and function like cartilage cells. 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. The process results in a well-affixed implant with the potential to facilitate earlier weight-bearing and accelerated recovery than is typical with current therapies.

NeoCart has not been approved in any jurisdiction, including the United States. We are currently enrolling a Phase 3 clinical trial for NeoCart in the United States 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. In a Phase 2 clinical trial of 30 patients, NeoCart showed statistically better clinical outcomes when compared directly to microfracture on measures of pain and function as of the first and second anniversary of the procedure. If 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 a statistically significant improvement, meaning that sufficient data exist to indicate the outcome is unlikely to have occurred by chance, in clinical efficacy based on pain and function measures as compared to microfracture in our Phase 2 clinical trial. We believe positive Phase 1 and Phase 2 clinical data generated by NeoCart is a direct result of our regenerative medicine platform and the elements comprising our platform.

The goal of our Phase 3 clinical trial is to demonstrate significant 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. In anticipation of potential approval of NeoCart, we have begun to scale our internal current Good Manufacturing Practices (cGMP) manufacturing capabilities and transition the manufacture of all our products in-house at our facilities located in the greater Boston area. 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.

Our regenerative medicine platform gives us the ability to develop a strong pipeline. We believe 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. 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 collagen 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 collagen 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 March 31, 2014, we had 20 active sites across the United States, with an additional ten 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 first half of 2017. Upon receiving approval from the FDA, if at all, 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 identifying and 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.

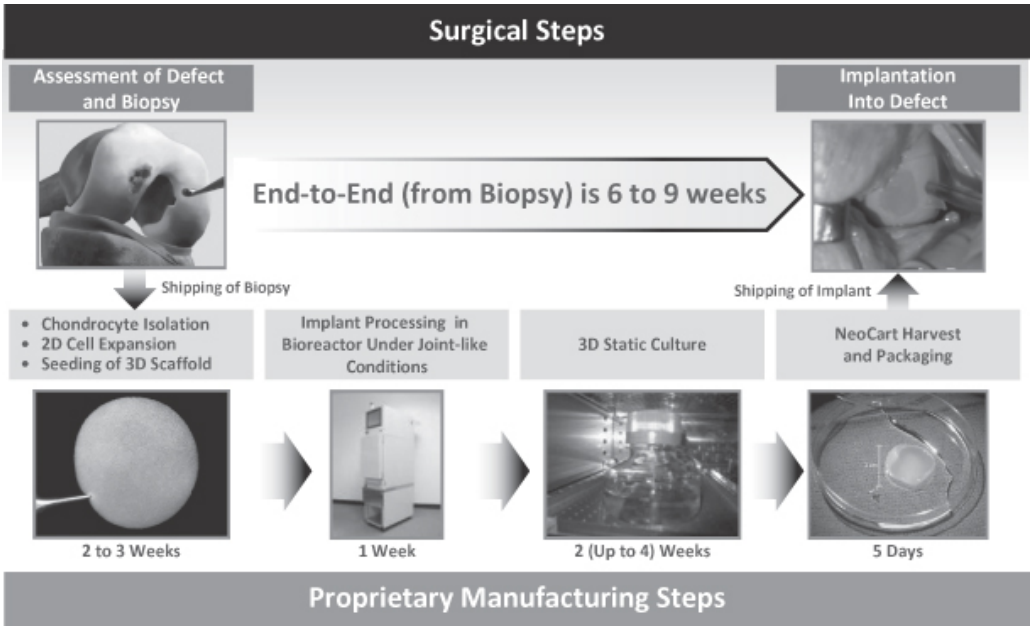
- ***Leverage Our Core Technology Platform to Expand into Additional Therapeutic Applications.*** We believe a significant unmet market need and commercial opportunity exist for NeoCart to treat cartilage defects in other joints such as ankles, shoulders and hips. Further, we plan to exploit our regenerative 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 in-licensing 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 study, 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.

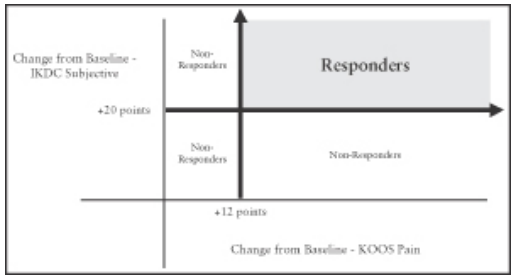
Under our SPA, the primary endpoint for approval is superiority at one year in the proportion of responders in the NeoCart patient group compared to the proportion of responders in the microfracture patient group in a dual-threshold responder analysis utilizing the Knee Injury and Osteoarthritis Outcome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

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 215 patients by the first half of 2016.

Phase 2 Clinical Trial

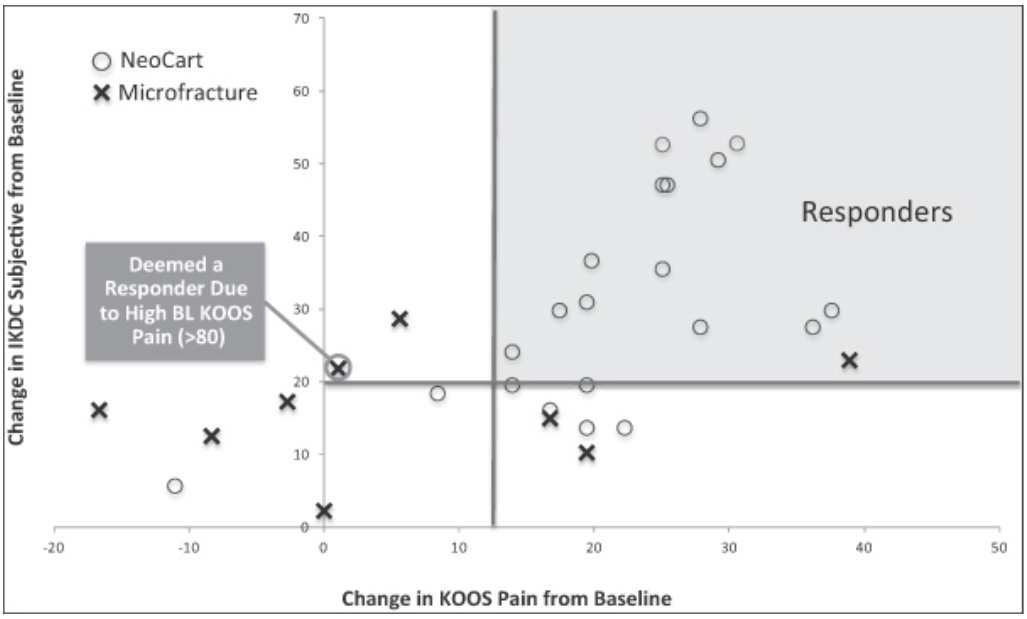
Our NeoCart Phase 2 clinical trial was initiated in 2007 to evaluate further the positive safety and early efficacy signals demonstrated in our Phase 1 clinical trial of NeoCart for articular cartilage damage in the knee. We also sought to identify clinically meaningful endpoints and identify appropriate 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. Twenty-one patients were randomized to receive a NeoCart implant and nine patients were randomized to undergo a microfracture procedure.

At every measurement interval between three months and three years, those patients receiving a NeoCart implant achieved statistically significant improvement, meaning that sufficient data exist to indicate the outcome is unlikely to have occurred by chance, compared to its baseline pain and function assessments using the KOOS pain and symptoms subscales, the IKDC Subjective assessment and a visual analog pain scale. Furthermore, when this improvement from baseline was compared to the improvement of microfracture from baseline, NeoCart’s improvement was statistically significantly better 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.

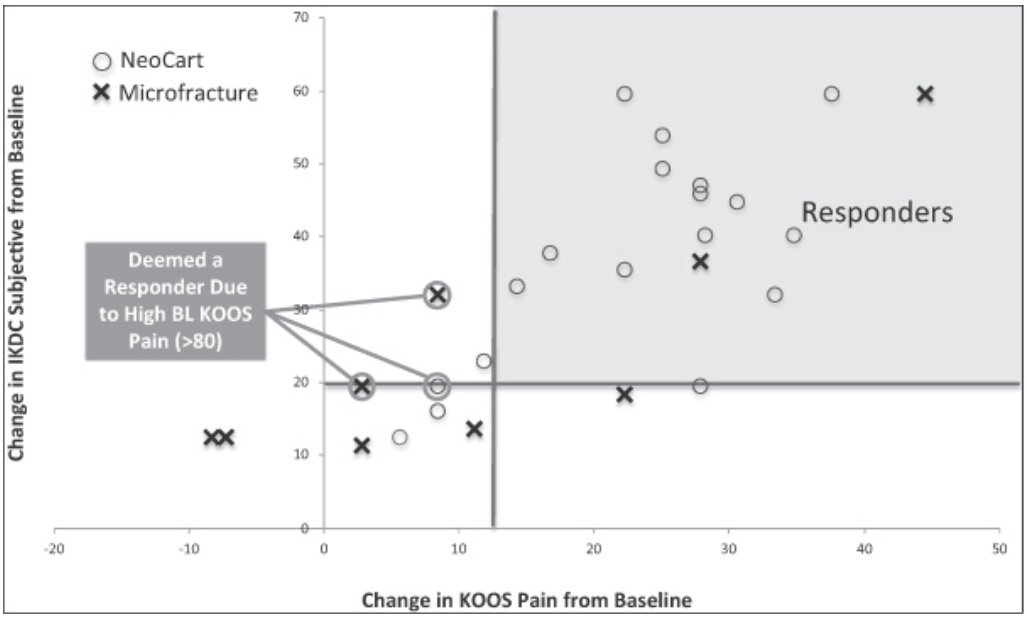
RESPONDER RATE ANALYSIS AT YEAR 1



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.

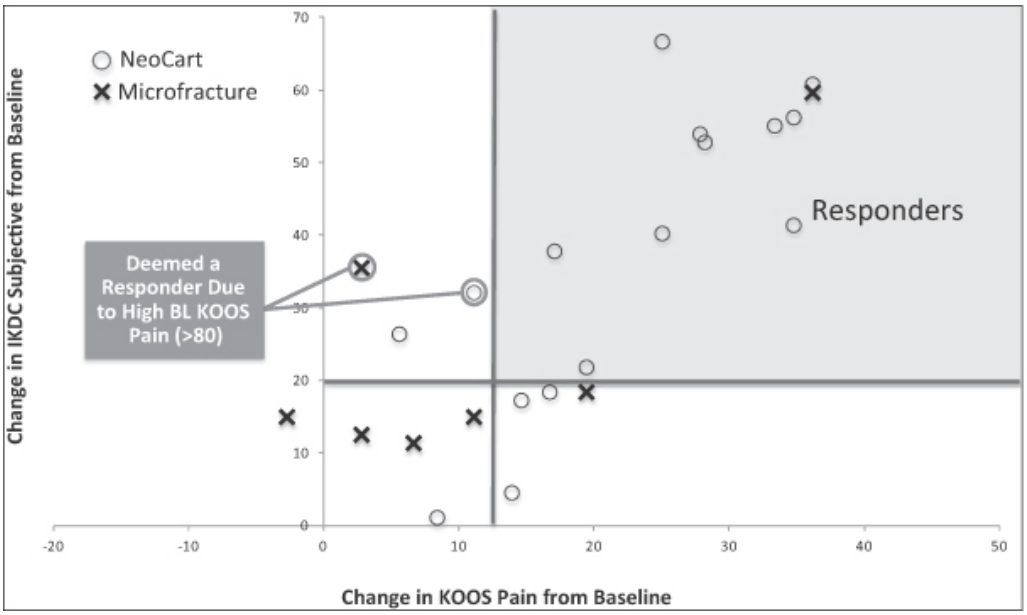
RESPONDER RATE ANALYSIS AT YEAR 2



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.

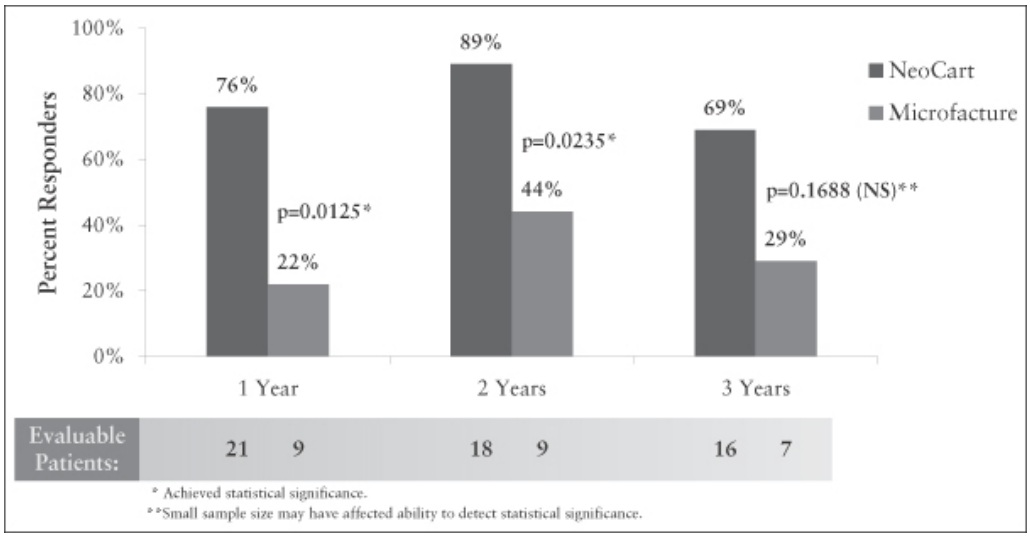
RESPONDER RATE ANALYSIS AT YEAR 3



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

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. 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 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 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 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. 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 24 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 22 issued patents and 12 pending patent applications relating to an exogenous tissue processor. Through this agreement, we have a sublicense to three issued U.S. patents and one issued Japanese patent 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 2020 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 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 shares issued to certain of our stockholders. Based on an assumed initial public offering price of $ per share, the midpoint of the initial public offering price range on the cover of this prospectus, and our estimated offering expenses, we or our stockholders would be required to issue or transfer 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. 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 December 31, 2013. 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 December 31, 2013. 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 December 31, 2013, $366,000 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 December 31, 2013. 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).

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 ever-increasingly active population. Worldwide, many products are commercially available, but the majority of these products are currently only available in the EEA, with Carticel, 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, but their early clinical data has not been published in highly regarded peer-reviewed journals. Although minimally-modified cells such as DeNovo NT 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 EMA.

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

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, notwithstanding the submission of any requested additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

The FDA also has authority to require a Risk Evaluation and Mitigation Strategy (REMS) from manufacturers to ensure that the benefits of a biological product outweigh its risks. A sponsor may also voluntarily propose a REMS as part of the BLA 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 cell-based medicinal product. The EU Member States have transposed the Tissues and Cells Directive into their national laws.

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

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

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 are in the process of leasing office and laboratory space in the Waltham, Massachusetts area. We anticipate that this facility will include clean room space that is utilized for production of our CT3 adhesive components. We also anticipate that this facility will include necessary space for quality operations, including quality control testing. We plan to further utilize this facility for manufacturing of key components of NeoCart, including collagen and scaffolding.

Employees

As of December 31, 2013, we employed 32 full-time employees, including two in research and development, seven in clinical development, two in regulatory, 16 in manufacturing and quality control and assurance, and five 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 March 31, 2014, are set forth below:

Name	Age	Position
Executive officers:		
Kevin McArdle	42	Chief Financial Officer
Nancy Lynch, M.D.	49	Chief Medical Officer
Stephen Kennedy	57	Senior Vice President of Manufacturing, Operations and Supply Chain
Other key employees:		
Laura Mondano	52	Vice President of Regulatory and Quality
Non-employee directors:		
Joshua Baltzell[1][2]	44	Director
John H. Johnson[1][3]	56	Director
Garheng Kong, M.D., Ph.D.[2]	38	Director, Chairman of the Board
Michael Lewis[2]	55	Director
Kevin Rakin[1][3]	53	Director

(1) Member of Compensation Committee.
(2) Member of Nominating and Corporate Governance Committee.
(3) Member of Audit Committee.

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

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 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

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 expect to apply 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. In order to be considered 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 director will be Michael Lewis, and his term 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. We expect that our new chief executive officer will be appointed to the board as a Class II director.

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($)[2][3]	Option Awards($)[2][3]	Total($)
Joshua Baltzell	—	—	—
John H. Johnson[1]	—	52,000[5]	52,000
Garheng Kong, M.D., Ph.D.	—	—	—
Michael Lewis	—	—	—
Kevin Rakin	8,979[4]	—	8,979

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

(2) 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 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.

(4) 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.

(5) 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 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.

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.

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.

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

(1) Employment commenced on June 10, 2013. Mr. Greenleaf resigned his employment on February 28, 2014.
(2) Employment commenced on September 23, 2013.
(3) Employment commenced on August 5, 2013.
(4) Resigned his employment on March 5, 2013.
(5) Represents prorated salary due to the commencement or termination of the officer's employment during the year ended December 31, 2013.
(6) 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.
(7) 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.
(8) 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.
(9) 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.
(10) 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.

Narrative Explanation of Certain Aspects of the Summary Compensation Table

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

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

Base Salaries

For the year ended December 31, 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			
Name	Number of Securities Underlying Unexercised Options Exercisable(#)	Number of Securities Underlying Unexercised Options Unexercisable(#)	Option Exercise Price ($)	Option Expiration Date
Peter Greenleaf	—	2,099,704[1]	0.07	7/15/2023
Nancy Lynch, M.D.	—	300,000[2]	0.66	12/10/2023
Stephen Kennedy	—	300,000[3]	0.66	12/10/2023
Patrick O'Donnell	265,796	88,599[4]	0.07	6/17/2014

(1) 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.
(3) Option vests over four years of service following August 19, 2013, with 25% vesting upon completion of 12 months of service and in 36 equal monthly installments thereafter.
(4) 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, 2013.

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.

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.

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) 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 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:

- 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.

Eligibility. 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 shares in any calendar year.

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 $ 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 December 31, 2013, up to 5,883,847 shares of our common stock have been reserved for issuance under the 2012 Plan. As of December 31, 2013, options to purchase 5,287,144 shares of common stock were outstanding under the 2012 Plan, and 428,671 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 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:

- shares;
- % 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 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. 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 are 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 Preferred 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 provides 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 will terminate upon the completion of this offering.

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, LP.

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, provides for the escrowing of certain shares of our capital stock that will be sufficient 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).

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[1]	Number of Series A-1 Preferred Stock Shares	Number of Common Stock Shares[1]	Aggregate Purchase Price[2]
Altima Restructure Fund Limited	—	1,715,453	635,027	833,542	$ 3,198,305
Entities affiliated with Boston Millennia Partners	—	1,253,670	447,741	1,129,792	$ 2,850,563
ProChon Holdings BV	Michael Lewis	6,663,563	2,464,643	3,125,000	$ 12,306,758
Sofinnova Venture Partners VIII, L.P.[3]	—	8,750,000	3,125,000	—	$ 11,875,000
Split Rock Partners II, LP	Joshua Baltzell	5,833,333	2,083,334	—	$ 7,916,667

(1) 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.
(3) 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, LP. Under this agreement, we granted information and inspection rights that will terminate upon the closing of this offering. In addition, the holders of 38,926,019 shares of our common stock as of March 31, 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, LP. 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 March 31, 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 March 31, 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 45,344,052 shares of common stock outstanding as of March 31, 2014, which includes 38,926,019 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 March 31, 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.

Name and Address of Beneficial Owner	Number of Shares Beneficially Owned		Percentage of Shares Beneficially Owned	
	Before the Offering	After the Offering[11]	Before the Offering	After the Offering[11]
5% Stockholders				
ProChon Holdings BV[1] Stonehage SA, Rue du Puit-Godet 12, PO Box 126 2005 Neuchatel Switzerland	12,374,864		27.2%	
Sofinnova Venture Partners VIII, L.P.[2] 2800 Sand Hill Road, Suite 150 Menlo Park, CA 94025	12,032,413		26.4%	
Split Rock Partners II, LP[3] 1600 El Camino Real, Suite 290 Menlo Park, CA 94025	8,021,609		17.6%	
Altima Restructure Fund Limited[4] 11 Slingsby Place, 2nd Floor St. Martin's Courtyard WC2E 9AB London United Kingdom	3,215,353		7.1%	
Entities Affiliated with Boston Millennia Partners[5] 30 Rowes Wharf, Suite 400 Boston, MA 02110	2,853,757		6.3%	
Directors and Named Executive Officers				
Garheng Kong, M.D., Ph.D.	—		—	—
Joshua Baltzell[6]	8,021,609		17.6%	
Kevin Rakin[7]	345,342		*	
Michael Lewis[8]	12,374,864		27.2%	
John H. Johnson	—	—	—	—
Stephen Kennedy	—	—	—	—
Peter Greenleaf[9]	—	—	—	—
Nancy Lynch, M.D.	—	—	—	—
All current executive officers and directors as a group (8 persons)[10]	20,856,403		46.0%	

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

(1) Shareholdings consist of 9,128,206 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 8 below. ProChon Holdings has sole voting and investment power over the shares of capital stock owned.

(2) Shareholdings consist of 11,875,000 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 7,916,667 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 2,350,480 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

(footnotes continued on following page)

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. Mark Donegan, a citizen of the United Kingdom serves as chief investment officer of Altima Partners. Dominic Redfern, a citizen of the United Kingdom serves as a portfolio manager with ARF.

(5) Shareholdings consist of 1,412,717 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; 67,673 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; 201,172 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; 12,703 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 7,146 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.

(6) 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.

(7) 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 15,274 shares are or will be vested within 60 days of March 31, 2014, (b) 120,000 shares of common stock issuable upon conversion of preferred stock owned directly by Mr. Rakin, (c) 80,000 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 stock.

(8) 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 interest.

(9) 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) Shareholdings include 114,588 shares of common stock issuable upon the exercise of options exercisable within 60 days of March 31, 2014 and 229,224 shares of common stock issuable upon the exercise of warrants exercisable within 60 days of March 31, 2014.

(11) The following stockholders will deliver the indicated numbers of shares of common stock to Purpose immediately prior to 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).

Name of Beneficial Owner	Percentage of Consideration Allocated under Purpose Agreement	Number of Shares of Common Stock 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%	
Other Holders Not Listed Above	25.16%	

DESCRIPTION OF CAPITAL STOCK

General

Following the closing of this offering, our authorized capital stock will consist of shares of common stock, par value $0.001 per share, and 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 March 31, 2014, there were 45,344,052 shares of our common stock outstanding, held of record by 19 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 10,323,988 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 March 31, 2014, options to purchase 3,187,440 shares of our common stock were outstanding under our 2012 Plan at a weighted-average exercise price of $0.28 per share, of which 945,365 were vested and exercisable as of that date.

Warrants

As of March 31, 2014, warrants to purchase 2,266,841 shares of our common stock were outstanding at an exercise price of $0.0167 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 $0.01 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 $0.01 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 $, which is the midpoint of the range set forth on the cover of this prospectus. Upon exercise 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.

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 March 31, 2014, the holders of 38,926,019 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 March 31, 2014, the holders of 38,926,019 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 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 American Stock Transfer & Trust Company, LLC.

NASDAQ Global Market

We expect to apply 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 December 31, 2013. 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 December 31, 2013; 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 38,926,019 shares of our common stock and the holders of warrants to purchase up to 2,266,841 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.

Name	Number of Shares
Cowen and 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.

	Per Share	Without Option	With 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 expect to apply 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.

Hong Kong

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 of, any other applicable provision of the SFA, in each case subject to compliance with 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, Waltham, 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 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)

Index to Consolidated Financial Statements

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)

	December 31, 2012	December 31, 2013	Pro Forma December 31, 2013 (unaudited)
ASSETS			
Current assets:			
Cash and cash equivalents	$ 14,716	$ 8,734	
Prepaid expenses and other current assets	363	1,612	
Total current assets	15,079	10,346	
Property and equipment, net	2,315	2,283	
Intangible asset	630	570	
Noncurrent deferred tax assets, net	2,480	1,058	
Restricted cash	522	522	
Other assets	18	17	
Total assets	$ 21,044	$ 14,796	
LIABILITIES, CONVERTIBLE REDEEMABLE PREFERRED STOCK AND STOCKHOLDERS' DEFICIT			
Current liabilities:			
Accounts payable	$ 1,042	$ 2,530	
Accrued expenses	418	1,035	
Current portion of deferred rent	168	168	
Current portion of deferred lease incentive	296	296	
Deferred tax liabilities, net	2,480	1,058	
Total current liabilities	4,404	5,087	
Deferred rent, long-term	551	392	
Deferred lease incentive, long-term	1,184	888	
Net sales distribution payment liability	—	13,100	
Warrant liability	129	636	
Other liability	4,868	13,176	
Total liabilities	11,136	33,279	
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 December 31, 2013; issued and outstanding shares—28,602,031 at December 31, 2012 and December 31, 2013; liquidation preference of $29,619 at December 31, 2012 and $31,989 at December 31, 2013; no shares issued and outstanding, pro forma (unaudited)	29,619	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; issued and outstanding shares—none at December 31, 2012 and 10,323,988 at December 31, 2013; liquidation preference of $0 at December 31, 2012 and $10,354 at December 31, 2013; no shares issued and outstanding, pro forma (unaudited)	—	14,454	
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; 6,311,096 shares issued and outstanding at December 31, 2012 and 6,418,033 shares issued and outstanding at December 31, 2013; and issued and outstanding, pro forma (unaudited)	6	6	
Additional paid-in capital	65,319	35,188	
Deficit accumulated during the development stage	(85,036)	(110,748)	
Total stockholders' deficit	(19,711)	(75,554)	
Total liabilities, convertible redeemable preferred stock and stockholders' deficit	$ 21,044	$ 14,796	

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,		Period From June 28, 2000 (Date of Inception) to December 31, 2013
	2012	2013	
Revenue	$ 26	$ 8	$ 401
Total revenue	26	8	401
Operating expenses:			
Research and development	11,941	11,946	56,680
Selling, general and administrative	3,053	4,847	37,408
Impairment of goodwill and intangible assets	—	60	2,230
Total operating expenses	14,994	16,853	96,318
Loss from operations	(14,968)	(16,845)	(95,917)
Other (expense) income:			
Interest expense, net	(798)	—	(5,419)
Other expense, net	(13)	(52)	(133)
Gain on extinguishment of debt	687	—	687
Change in fair value of note payable to shareholder	(17)	—	(37)
Change in fair value of warrant liability and other liability	(1,826)	(8,815)	(9,929)
Total other expense, net	(1,967)	(8,867)	(14,831)
Net loss	$ (16,935)	$ (25,712)	$ (110,748)
Earnings (loss) attributable to common stockholders—basic (Note 3)	$ 2,805	$ (56,003)	
Earnings (loss) attributable to common stockholders—diluted (Note 3)	$ 3,402	$ (56,003)	
Earnings (loss) per common share (Note 3):			
Basic	$ 1.00	$ (8.94)	
Diluted	$ 0.26	$ (8.94)	
Weighted-average shares used to compute earnings (loss) per common share (Note 3):			
Basic	2,818,293	6,264,690	
Diluted	12,898,629	6,264,690	
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)

	2005 Series A Convertible Redeemable Preferred Stock $0.001 Par Value		2006 Series A-1 Convertible Redeemable Preferred Stock $0.001 Par Value		2008 Series B Convertible Redeemable Preferred Stock $0.001 Par Value		2011 Series A Convertible Redeemable Preferred Stock $0.001 Par Value		Series A Convertible Redeemable Preferred Stock $0.001 Par Value		Series A-1 Convertible Redeemable Preferred Stock $0.001 Par Value		Class A Common Stock $0.001 Par Value		Restricted Stock $0.001 Par Value		Additional Paid- In Capital	Deficit Accumulated During the Development Stage	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount			
Balance at Inception, June 28, 2000	$ —	$ —	—	$ —	—	$ —	—	$ —	—	$ —	—	$ —	—	$ —	—	$ —	$ —	$ —	$ —
Issuance of common stock	—	—	—	—	—	—	—	—	—	—	—	—	14,341	—	598	—	10,527	—	10,527
Issuance of common stock for services	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	8	—	8
Conversion of common stock to convertible redeemable preferred stock	500	7,500	—	—	—	—	—	—	—	—	—	—	(500)	—	—	—	(7,500)	—	(7,500)
Issuance of preferred stock on various dates, net of amounts allocated to issuance costs of $2,453	167	5,800	2,345	13,376	6,480	8,129	5,362,172	1,573	—	—	—	—	—	—	—	—	(3,299)	—	(3,299)
Re-Issuance of 2006 Series A-1 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	—	—	—	—	—	—	10,724,321	15,530	—	—	—	—	—	—	—	—	—	—	—
Issuance of warrant in exchange for license	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	1,088	—	1,088
Extinguishment of preferred stock liquidation value on various dates	—	(13,300)	(2,345)	(14,950)	—	—	—	—	—	—	—	—	—	—	—	—	28,250	—	28,250
Extinguishment of 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 stock	(667)	(14,988)	(2,345)	(28,546)	(6,480)	(15,608)	—	—	—	—	—	—	17,899	—	—	—	55,790	3,352	59,142
Repricing of stock warrant issued for licensing rights	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	163	—	163
Recapitalization of equity	—	—	—	—	—	—	—	(12,826)	—	—	—	—	—	—	(60)	—	13,697	—	13,697
Accruals of dividends 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, 2011	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	(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)

	2005 Series A Convertible Redeemable Preferred Stock $0.001 Par Value		2006 Series A-1 Convertible Redeemable Preferred Stock $0.001 Par Value		2008 Series B Convertible Redeemable Preferred Stock $0.001 Par Value		2011 Series A Convertible Redeemable Preferred Stock $0.001 Par Value		Series A Convertible Redeemable Preferred Stock $0.001 Par Value		Series A-1 Convertible Redeemable Preferred Stock $0.001 Par Value		Class A Common Stock $0.001 Par Value		Restricted Stock $0.001 Par Value		Additional Paid- In Capital	Deficit Accumulated During the Development Stage	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount			
Balance at December 31, 2011	—	—	—	—	—	—	16,086,493	28,169	—	—	—	—	32,180	—	—	—	27,057	(68,101)	(41,044)
Issuance of new Series A convertible redeemable preferred stock, net of amounts allocated to issuance costs and warrants of $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	—	—	—	—	—	—	—	725	—	3,163	—	—	—	—	—	—	(3,888)	—	(3,888)
Issuance of restricted common stock in October 2012	—	—	—	—	—	—	—	—	—	—	—	—	—	—	61,095	—	—	—	—
Stock-based compensation expense	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	14	—	14
Net loss	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	(16,935)	(16,935)
Balance at December 31, 2012	—	—	—	—	—	—	—	—	28,602,031	29,619	—	—	6,250,001	6	61,095	—	65,319	(85,036)	(19,711)
Accruals of dividends and accretion to redemption value	—	—	—	—	—	—	—	—	—	2,291	—	—	—	—	—	—	(2,291)	—	(2,291)
Extinguishment of Series A convertible redeemable preferred stock	—	—	—	—	—	—	—	—	(28,602,031)	(31,910)	—	—	—	—	—	—	(28,000)	—	(28,000)
Reissuance of Series A convertible redeemable preferred stock	—	—	—	—	—	—	—	—	28,602,031	42,617	—	—	—	—	—	—	—	—	—
Issuance of Series A-1 convertible redeemable preferred stock, net of issuance costs of $63	—	—	—	—	—	—	—	—	—	—	10,323,988	14,454	—	—	—	—	—	—	—
Issuance of restricted common stock	—	—	—	—	—	—	—	—	—	—	—	—	—	—	81,623	—	—	—	—
Vesting of restricted stock	—	—	—	—	—	—	—	—	—	—	—	—	15,274	—	(15,274)	—	—	—	—
Stock-based compensation expense	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	158	—	158
Exercise of common stock options	—	—	—	—	—	—	—	—	—	—	—	—	25,314	—	—	—	2	—	2
Net loss	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	(25,712)	(25,712)
Balance at December 31, 2013	—	$ —	—	$ —	—	$ —	—	$ —	28,602,031	$ 42,617	10,323,988	$14,454	6,290,589	$ 6	127,444	$ —	$ 35,188	$ (110,748)	$ (75,554)

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)

	Years Ended December 31,		Period From June 28, 2000 (Date of Inception) to December 31, 2013
	2012	2013	
CASH FLOWS FROM OPERATING ACTIVITIES:			
Net loss	$(16,935)	$(25,712)	$ (110,748)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation	638	566	5,759
Deferred rent and lease incentive	(464)	(455)	(1,486)
Impairment of goodwill and intangible asset	—	60	2,230
Loss on sale of property and equipment	—	20	8
Stock-based compensation	14	158	593
Non-cash interest expense	—	—	206
Write-off of shareholder note receivable	—	—	100
Change in fair value of note payable to stockholder	17	—	37
Gain on extinguishment of debt	(687)	—	(687)
Non-cash consideration for licensed technology	3,115	—	4,367
Change in fair value of warrants	1,826	8,815	9,929
Amortization of deferred financing costs	196	—	919
Amortization of debt discount	—	—	1,936
Issuance of stock for services	—	—	8
Other non-cash items	—	—	9
Changes in operating assets and liabilities:			
Prepaid expenses and other current assets	230	(156)	(340)
Other non-current assets	41	1	(538)
Accounts payable	(228)	804	5
Accrued expenses	5	617	2,797
Net cash used in operating activities	(12,232)	(15,282)	(84,896)
CASH FLOWS FROM INVESTING ACTIVITIES:			
Purchases of property and equipment	(79)	(604)	(4,611)
Proceeds from sale of property and equipment	—	50	68
Advances on shareholder notes receivable	—	—	(100)
Cash acquired during ProChon acquisition	—	—	1,318
Net cash used in investing activities	(79)	(554)	(3,325)
CASH FLOWS FROM FINANCING ACTIVITIES:			
Proceeds from the issuance of term note	—	—	1,500
Borrowings under equipment term loan	—	—	1,400
Repayments of term note and equipment term loan	—	—	(2,900)
Issuance of Series A convertible promissory notes	—	—	14,387
Issuance of Series B convertible promissory notes	59	—	12,000
Issuance of Series A-1 convertible promissory notes	5,950	—	5,950
Issuance of common stock to investors	—	—	10,525
Issuance of 2005 Series A preferred stock	—	—	2,500
Issuance of 2006 Series A-1 preferred stock, net of issuance costs of $1,574	—	—	13,628
Issuance of 2008 Series B preferred stock, net of issuance costs of $879	—	—	8,351
Issuance of Series A preferred stock, net of issuance costs of $1,973	20,679	—	20,679

	Years Ended December 31,		Period From June 28, 2000 (Date of Inception) to December 31, 2013
	2012	2013	
Issuance of Series A-1 preferred stock, net of issuance costs of $63	—	10,261	10,261
Costs associated with Initial Public Offering	—	(409)	(409)
Deferred financing costs	—	—	(919)
Proceeds from the exercise of common stock options	—	2	2
Net cash provided by financing activities	26,688	9,854	96,955
Net increase (decrease) in cash and cash equivalents	14,377	(5,982)	8,734
Cash and cash equivalents—Beginning of period	339	14,716	—
Cash and cash equivalents—End of period	$14,716	$ 8,734	$ 8,734
Supplemental disclosure of noncash investing and financing activities			
Conversion of common stock to 2005 Series A preferred stock	$ —	$ —	$ 7,500
Conversions of preferred stock into common stock	$ —	$ —	$ 59,142
Recapitalization	$42,025	$ —	$ 55,722
Warrant issued to an advisor in connection with the issuance of Series A Preferred Stock	$ 117	$ —	$ 117
Warrants issued to investors in connection with the issuance of Series A Preferred Stock	$ 56	$ —	$ 56
Accretion of dividends and redemption value on convertible preferred stock	$ 3,888	$ 2,291	$ 75,700
Conversion of convertible notes payable and accrued interest into preferred stock	$19,081	$ —	$ 35,052
Issuance of 2011 Series A Preferred Stock and common stock to acquire ProChon	$ —	$ —	$ 1,574
Issuance of a note payable as part of the consideration to acquire ProChon	$ —	$ —	$ 650
Extinguishment of Series A Preferred Stock (Note 10)	$ —	$28,000	$ 28,000
Leasehold improvements acquired through lease incentive	$ —	$ —	$ 3,184

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

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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 December 31, 2012 and December 31, 2013, had a deficit accumulated during the development stage of $85,036

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and $110,748, 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 December 31, 2013, 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.

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

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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 Pro Forma Balance Sheet and Earnings (Loss) per Share Information

The unaudited pro forma consolidated balance sheet information as of December 31, 2013 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 December 31, 2013. 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.

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,		Period from June 28, 2000 (Inception) to December 31, 2013
	2012	2013	
Revenues:			
United States	$ —	$ —	$ 244
Israel	26	8	157
Total Revenues	$ 26	$ 8	$ 401

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	As of December 31,	
	2012	2013
Long-lived assets:		
United States	$ 2,179	$ 2,266
Israel	136	17
Total long-lived assets	$ 2,315	$ 2,283

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 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.

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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 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.

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, the carrying amount of cash and cash equivalents was $14,716 and $8,734, 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

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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 extend the lives of existing assets are capitalized. The Company provides for depreciation and amortization using the straight-line method over the estimated useful lives of the assets, which are as follows:

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

Upon retirement or sale, the cost of assets disposed and the related accumulated depreciation 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.

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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.

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, 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, 2012, 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

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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.

Intangible assets, net of accumulated amortization and impairment charges, are summarized as follows:

	As of December 31, 2012			As of December 31, 2013		
	Cost	Accumulated Amortization and Impairments	Net Book Value	Cost	Accumulated Amortization and Impairments	Net Book Value
IPR&D	$630	$ —	$ 630	$630	$ (60)	$ 570
	$630	$ —	$ 630	$630	$ (60)	$ 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.

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.

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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:

	Years Ended December 31,		Period from June 28, 2000 (Inception) to December 31, 2013
	2012	2013	
Revenues:			
Collaboration Revenue	$ 26	$ 8	$ 104
Product Revenue	—	—	53
Grant Revenue	—	—	244
Total Revenues	$ 26	$ 8	$ 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.

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

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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 in-licensed products; employee-related expenses, including salaries, benefits and travel; expenses incurred under agreements with contract research organizations and investigative sites that conduct clinical trials and preclinical studies; the cost of acquiring, developing and manufacturing clinical trial materials; facilities, depreciation and other expenses, which include direct and allocated expenses for rent and maintenance of facilities, insurance and other supplies; and costs associated with preclinical activities and regulatory operations.

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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 December 31, 2013.

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.

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.

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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.

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.

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3. EARNINGS (LOSS) PER COMMON SHARE

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

	Years Ended December 31,	
	2012	2013
Numerator:		
Net loss	$ (16,935)	$ (25,712)
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)
Loss (earnings) attributable to participating restricted stock and preferred stock shareholders	(17,960)	—
Earnings (loss) attributable to common stockholders—basic	2,805	(56,003)
Effect of convertible notes	597	—
Earnings (loss) attributable to common stockholders—diluted	$ 3,402	$ (56,003)
Denominator:		
Weighted-average number of common shares used in earnings (loss) per share—basic	2,818,293	6,264,690
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
Earnings (loss) per share—basic	$ 1.00	$ (8.94)
Effect of convertible preferred stock dividends	(0.12)	—
Effect of convertible notes	(0.40)	—
Effect of warrants to purchase common stock	(0.22)	—
Earnings (loss) per share—diluted	$ 0.26	$ (8.94)

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,	
	2012	2013
Convertible redeemable preferred stock and dividends	—	38,926,019
Restricted stock and options to purchase common stock	1,054,702	5,414,588
Warrants	—	1,750,000

The Company also had certain warrants and other liabilities outstanding for the years ended December 31, 2012 and 2013 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, 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

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satisfied during the years ended December 31, 2012 and 2013, 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 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 December 31,	
	2012	2013
Employee benefits	$ 200	$ —
Deposits	10	290
Undelivered laboratory and office equipment	—	57
Insurance	23	11
IPO costs	—	1,093
Prepaid rent	—	128
Other current assets	130	33
Prepaid expenses and other current assets	$ 363	$ 1,612

5. PROPERTY AND EQUIPMENT

Property and equipment consisted of the following:

	As of December 31,	
	2012	2013
Office equipment	$ 454	$ 460
Laboratory equipment	1,644	1,838
Leasehold improvements	5,364	5,489
Construction in progress	—	145
Total property and equipment	7,462	7,932
Less: accumulated deprecation	(5,147)	(5,649)
Property and equipment, net	$ 2,315	$ 2,283

Depreciation expense related to property and equipment amounted to $638, $566 and $5,759 for the years ended December 31, 2012 and 2013 and the period from June 28, 2000 (inception) to December 31, 2013, respectively.

6. ACCRUED EXPENSES

Accrued expenses consisted of the following:

	As of December 31,	
	2012	2013
Accrued compensation	$ 320	$ 128
Accrued professional fees	2	667
Other	96	240
Total accrued expenses	$ 418	$ 1,035

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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. The Company's wholly-owned subsidiary, ProChon, leases facilities in Woburn, Massachusetts and Israel. Aggregate minimum annual lease commitments of the Company under its non-cancellable operating leases as of December 31, 2013 are as follows:

Year Ending December 31,	
2014	$1,135
2015	1,013
2016	985
2017	968
Thereafter	—
Total minimum lease payments	$4,101

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 and $4,164 for the years ended December 31, 2012 and 2013 and the period from June 28, 2000 (inception) to December 31, 2013, 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. 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 December 31, 2013, the Company has received $337 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 $247.

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.

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License Agreements

From time to time, the Company enters into various licensing agreements whereby the Company may use certain technologies in conjunction with its product research and development.

Licensing agreements and the Company's commitments under the agreements are as follows:

Hydrogel License

In May 2005, the Company entered into an exclusive license agreement with Angiotech Pharmaceuticals (US), Inc. for the use of certain patents, patent 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 December 31, 2013, 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 fees of $50 for 2011, 2012 and 2013 totaling $150.

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 December 31, 2013, the Company has paid an aggregate $601 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 $366; 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;

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- 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.

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 December 31, 2013, the Company has paid an aggregate $724 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)

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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 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 and $13,176 at December 31, 2012 and December 31, 2013, 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.

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Severance Agreement

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 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 December 31, 2013, the remaining accrual was $59.

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 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.

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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 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.

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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.

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.

	Fair Value as of		Weighted Average Exercise Price Per Share
	December 31, 2012	December 31, 2013	
Warrant liability	$ 129	$ 636	$ 0.07
Other Liability	4,868	13,176	n/a
Net Sales Distribution Payment Liability	—	13,100	n/a
Total fair value	$ 4,997	$ 26,912	

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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
Acquisition scenarios		
Liquidity value	$50 to $250 million	$50 to $250 million
Probability of occurrence	10.00% to 50.00%	5.00% to 10.00%
Time to event	2.25 years	3.5 years
IPO scenarios		
Pre-money valuation	$75 to $150 million	$81 to $150 million
Probability of occurrence	0.67% to 3.33%	5.00% to 38.00%
Time to event	1.25 to 2.25 years	0.5 to 3.5 years
Probability of liquidation scenarios	20%	5%
Discount for lack of marketability	28%	15%

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.

Liabilities measured at fair value on a recurring basis are as follows:

Description	Total	Quoted prices in active markets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
December 31, 2012				
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	$ —	$ —	$ 26,912

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

	Years ended December 31,	
	2012	2013
Beginning balance	$ 670	$ 4,997
Issuance of warrants, Other Liability and Net Sales Distribution Payment Liability	3,171	13,100
Change in fair value of warrant liability and Other Liability	1,843	8,815
Extinguishment of note payable	(687)	—
Ending balance	$ 4,997	$ 26,912

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 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.

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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 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.

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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.

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 December 31,	
	2012	2013
Conversion of Series A Preferred	28,602,031	28,602,031
Conversion of Series A-1 Preferred	—	10,323,988
Vesting of restricted stock	61,095	127,444
Options to purchase common stock	2,797,253	5,287,144
Common stock warrant (equity)	1,750,000	1,750,000
Common stock warrants (liability)	516,841	516,841
Total	33,727,220	46,607,448

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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 and $3,307 as of December 31, 2012 and December 31, 2013, respectively. The following describes each series of convertible redeemable preferred stock issued.

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

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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.

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

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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.

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.

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3% Net Sales Distribution Payment

Within 45 days of the end of each calendar year, the Company shall pay each Royalty Recipient 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 $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 December 31, 2013, of which 469,259 are outstanding. 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.

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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.

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)	—	$ —		
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
Vested and expected to vest at December 31, 2013	4,856,238	$ 0.23	9.4	$ 2,844
Exercisable at December 31, 2013	1,038,950	$ 0.07	9.0	$ 779

As of December 31, 2012 and 2013, the unrecognized compensation cost related to outstanding options was $130 and $1,002, respectively, and is expected to be recognized as expense over approximately 3.28 years and 3.21 years, respectively.

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As of December 31, 2013, the weighted average fair value of vested options was $0.08.

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

	As of December 31,	
	2012	2013
Weighted-average grant date fair value per share of employee option grants	$ 0.05	$ 0.23
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)	—	$ —
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	—	—
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	—	—
Unvested at December 31, 2013	127,444	$ 0.10

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

As of December 31, 2012, no restricted stock options had vested.

Stock-Based Compensation Expense

The Company granted stock options to employees for the years ended December 31, 2012 and 2013. The Company estimates the fair value of stock options as of the date of grant using the Black-Scholes option pricing model and restricted stock based on the fair value of the award. Stock options and restricted stock issued to non-board member, non-employees are accounted for using the fair value approach and are subject to periodic revaluation over their vesting terms.

For all periods from inception to date, stock-based compensation for all options granted and restricted stock awards are classified as selling, general and administrative expense. Stock compensation expense amounted to $14, $158, and $593 for the years ended December 31, 2012 and 2013 and the period from June 28, 2000 (inception) to December 31, 2013, respectively.

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Stock-based compensation by award type is as follows:

	Years Ended December 31,		Period from June 28, 2000 (Inception) to December 31, 2013
	2012	2013	
Stock options	$ 14	$ 155	$ 225
Restricted stock	—	3	368
Total stock-based compensation expense	$ 14	$158	$ 593

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 December 31,	
	2012	2013
Risk-free interest rate	0.93%	1.01%
Expected volatility	89.0%	87.9%
Expected term (in years)	6.08	5.36
Expected dividend yield	0.0%	0.0%

The weighted-average assumptions used in the Black-Scholes option pricing model to determine the fair value of the non-employee stock option grants were as follows, noting the Company had no non-employee stock options granted for the year ended December 31, 2012:

	Years ended December 31,	
	2012	2013
Risk-free interest rate	—	0.23%
Expected volatility	—	145.2%
Expected term (in years)	—	0.98
Expected dividend yield	—	0.0%

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

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

Expected Term. The expected term represents the period of time that options are expected to be outstanding. Because the Company does not have historical exercise behavior, through December 31, 2013 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.

Histogenics Corporation
(A Development Stage Company)

Notes to Consolidated Financial Statements
(In thousands, except share and per share data)

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 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 December 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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(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 December 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	$ —	$ —

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 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.

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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 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.

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.

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(In thousands, except share and per share data)

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 and $584 for the years ended December 31, 2012 and 2013 and the period from June 28, 2000 (inception) to December 31, 2013, respectively. At December 31, 2013, $46 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.

15. SUBSEQUENT EVENTS

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. The Company has concluded that no subsequent event has occurred that requires disclosure, except as noted below:

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.

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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.

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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

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	*

* 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 April [·], 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; and (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.

(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.

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), (3) and (4) 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.

Exhibit	Description
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)

Exhibit	Description
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
4.2‡	Second Amended and Restated Investors' Rights Agreement dated as of December 18, 2013
4.3‡	Second Amended and Restated Stockholders' Agreement dated as of December 18, 2013
5.1*	Opinion of Gunderson Dettmer Stough Villeneuve Franklin & Hachigian, LLP
10.1‡	Form of Indemnity Agreement for directors and officers
10.2+‡	Employment Agreement, dated June 5, 2013, between the Registrant and Peter Greenleaf
10.3+‡	Offer letter, effective as of May 15, 2011, between the Registrant and Kevin McArdle
10.4+‡	Offer letter, dated September 23, 2013, between the Registrant and Nancy Lynch, M.D.
10.5+‡	Offer letter, effective as of August 5, 2013, between the Registrant and Stephen Kennedy
10.6+‡	2012 Equity Incentive Plan, as amended, and form of option agreement thereunder
10.7+*	2013 Equity Incentive Plan and form of option agreement thereunder
10.8+*	2013 Employee Stock Purchase Plan
10.9+*	Independent Director Compensation Policy
10.10†‡	License Agreement dated as of May 12, 2005 among the Registrant and Angiotech Pharmaceuticals (US), Inc. and Angiodevice International GmbH
10.11†‡	Amendment to License Agreement dated as of August 31, 2007 among the Registrant and Angiotech Pharmaceuticals (US), Inc. and Angiodevice International GmbH
10.12†‡	Second Amendment to License Agreement dated as of January 1, 2008 among the Registrant and Angiotech Pharmaceuticals (US), Inc. and Angiodevice International GmbH
10.13†‡	Third Amendment to License Agreement dated as of April 15, 2008 among the Registrant and Angiotech Pharmaceuticals (US), Inc. and Angiodevice International GmbH
10.14†‡	Fourth Amendment to License Agreement dated as of November 1, 2008 among the Registrant and Angiotech Pharmaceuticals (US), Inc. and Angiodevice International GmbH
10.15†‡	Fifth Amendment to License Agreement dated as of August 6, 2010 among the Registrant and Angiotech Pharmaceuticals (US), Inc. and Angiodevice International GmbH
10.16†‡	Reinstatement Agreement and Sixth Amendment to License Agreement dated as of February 8, 2011 among the Registrant and Angiotech Pharmaceuticals (US), Inc. and Angiodevice International GmbH
10.17†‡	Seventh Amendment to License Agreement dated as of March 31, 2011 among the Registrant and Angiotech Pharmaceuticals (US), Inc. and Angiodevice International GmbH
10.18†‡	Eighth Amendment to License Agreement dated as of June 29, 2012 among the Registrant and Angiotech Pharmaceuticals (US), Inc. and Angiodevice International GmbH
10.19†‡	Paid-up License Agreement dated as of March 6, 2013 between the Registrant and Koken Co., Ltd.
10.20†‡	Agreement dated as of June 22, 2012 between the Registrant and Purpose Co., Ltd. f/k/a Takagi Sangyo Co. Ltd. and f/k/a Takagi Industrial Co., Ltd.
10.21†‡	Exclusive Agreement dated as of April 15, 2001 between the Registrant and The Board of Trustees of The Leland Stanford Junior University
10.22†‡	First Amendment to Exclusive Agreement dated as of October 26, 2005 between the Registrant and The Board of Trustees of The Leland Stanford Junior University

Exhibit	Description
10.23†‡	Second Amendment to Exclusive Agreement dated as of January 15, 2006 between the Registrant and The Board of Trustees of The Leland Stanford Junior University
10.24†‡	Amendment No. 3 to the License Agreement Effective 4/15/2001 dated as of May 1, 2009 between the Registrant and The Board of Trustees of The Leland Stanford Junior University
10.25†‡	Amendment No. 4 to the License Agreement Effective 4/15/2001 dated as of April 29, 2010 between the Registrant and The Board of Trustees of The Leland Stanford Junior University
10.26†‡	License Agreement dated as of January 6, 2008 between the Registrant (ProChon Biotech Ltd.) and Yeda Research and Development Company Limited
10.27†‡	Amendment to License Agreement dated as of March 23, 2010 between the Registrant (ProChon Biotech Ltd.) and Yeda Research and Development Company Limited
10.28‡	Lease Agreement dated of June 9, 2006 between the Registrant and Intercontinental Fund III 830 Winter Street LLC
10.29‡	First Amendment to Lease dated as of October 1, 2009 between the Registrant and Intercontinental Fund III 830 Winter Street LLC
10.30	Separation Agreement, dated February 28, 2014, between the Registrant and Peter Greenleaf
21.1‡	List of Subsidiaries
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.

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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: _____

President 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 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:

Signature	Title	Date
_____	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	

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EXHIBIT INDEX

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10.6+‡	2012 Equity Incentive Plan, as amended, and form of option agreement thereunder
10.7+*	2013 Equity Incentive Plan and form of option agreement thereunder
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10.9+*	Independent Director Compensation Policy
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10.14†‡	Fourth Amendment to License Agreement dated as of November 1, 2008 among the Registrant and Angiotech Pharmaceuticals (US), Inc. and Angiodevice International GmbH
10.15†‡	Fifth Amendment to License Agreement dated as of August 6, 2010 among the Registrant and Angiotech Pharmaceuticals (US), Inc. and Angiodevice International GmbH
10.16†‡	Reinstatement Agreement and Sixth Amendment to License Agreement dated as of February 8, 2011 among the Registrant and Angiotech Pharmaceuticals (US), Inc. and Angiodevice International GmbH
10.17†‡	Seventh Amendment to License Agreement dated as of March 31, 2011 among the Registrant and Angiotech Pharmaceuticals (US), Inc. and Angiodevice International GmbH
10.18†‡	Eighth Amendment to License Agreement dated as of June 29, 2012 among the Registrant and Angiotech Pharmaceuticals (US), Inc. and Angiodevice International GmbH

Exhibit	Description
10.19†‡	Paid-up License Agreement dated as of March 6, 2013 between the Registrant and Koken Co., Ltd.
10.20†‡	Agreement dated as of June 22, 2012 between the Registrant and Purpose Co., Ltd. f/k/a Takagi Sangyo Co. Ltd. and f/k/a Takagi Industrial Co., Ltd.
10.21†‡	Exclusive Agreement dated as of April 15, 2001 between the Registrant and The Board of Trustees of The Leland Stanford Junior University
10.22†‡	First Amendment to Exclusive Agreement dated as of October 26, 2005 between the Registrant and The Board of Trustees of The Leland Stanford Junior University
10.23†‡	Second Amendment to Exclusive Agreement dated as of January 15, 2006 between the Registrant and The Board of Trustees of The Leland Stanford Junior University
10.24†‡	Amendment No. 3 to the License Agreement Effective 4/15/2001 dated as of May 1, 2009 between the Registrant and The Board of Trustees of The Leland Stanford Junior University
10.25†‡	Amendment No. 4 to the License Agreement Effective 4/15/2001 dated as of April 29, 2010 between the Registrant and The Board of Trustees of The Leland Stanford Junior University
10.26†‡	License Agreement dated as of January 6, 2008 between the Registrant (ProChon Biotech Ltd.) and Yeda Research and Development Company Limited
10.27†‡	Amendment to License Agreement dated as of March 23, 2010 between the Registrant (ProChon Biotech Ltd.) and Yeda Research and Development Company Limited
10.28‡	Lease Agreement dated of June 9, 2006 between the Registrant and Intercontinental Fund III 830 Winter Street LLC
10.29‡	First Amendment to Lease dated as of October 1, 2009 between the Registrant and Intercontinental Fund III 830 Winter Street LLC
10.30	Separation Agreement, dated February 28, 2014, between the Registrant and Peter Greenleaf
21.1‡	List of Subsidiaries
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.

Exhibit 10.30

HISTOGENICS CORPORATION
830 Winter Street
Waltham, MA 02451

February 28, 2014

Mr. Peter Greenleaf

Dear Peter:

This letter (this "Agreement") is to confirm the agreement between you and Histogenics Corporation (the "Company") in connection with your resignation as an employee of the Company.

1. **Resignation Date**. Effective as of February 28, 2014 (the "Resignation Date"), you have resigned from all positions as an officer, director and employee of the Company.

2. **Effective Date and Revocation**. You have up to 21 days after you receive this Agreement to review it. You are advised to consult an attorney of your own choosing before signing this Agreement. Furthermore, you have up to seven days after you sign this Agreement to revoke it. If you wish to revoke this Agreement after signing it, you may do so by delivering a letter of revocation to me. If you do not revoke this Agreement, the eighth day after the date you sign it will be the "Effective Date." Because of the seven-day revocation period, no part of this Agreement will become effective or enforceable until the Effective Date.

3. **Salary and Vacation Pay**. The Company will promptly pay you all of your unpaid salary earned through the Resignation Date and all of your accrued but unused vacation time or PTO (less applicable withholding taxes and other deductions). You acknowledge that the only payments and benefits that you are entitled to receive from the Company in the future are those specified in this Agreement.

4. **Stock Option**. On July 16, 2013, you were granted an option to purchase up to 2,099,704 shares of the Company's common stock at a purchase price of $0.07 per share (the "Option"). You acknowledge that no portion of the Option was vested as of the Resignation Date and that the Company will cancel the Option as of the Resignation Date.

5. **Release of All Claims by You**. To the fullest extent permitted by law, you waive, release and promise never to assert any claims or causes of action, whether or not now known, against the Company or its predecessors, successors or past, present or future subsidiaries, stockholders, directors, officers, employees, consultants, attorneys, agents, assigns, insurers and employee benefit plans and their administrators and fiduciaries with respect to any matter, including (without limitation) any matter related to your employment with the Company or the termination of that employment, including (without limitation) claims to attorneys' fees or costs, claims of wrongful discharge, constructive discharge, emotional distress, defamation, invasion of privacy, fraud, breach of contract (express or implied) or breach of the covenant of good faith and fair

dealing, claims of discrimination, harassment retaliation and/or civil rights, claims relating to wages or compensation, claims under M.G.L. c. 149, §§148 and 150 (also known as the Massachusetts Wage Act), claims under Title VII of the Civil Rights Act of 1964, the Massachusetts Fair Employment Practices Act, the Age Discrimination in Employment Act of 1967, the Americans with Disabilities Act and all other laws and regulations relating to employment. However, this release covers only those claims that arose prior to the execution of this Agreement and only those claims that may be waived by applicable law. In addition, notwithstanding anything to the contrary herein, this release does not cover claims based on any fraud or intentional misconduct by the Company. Execution of this Agreement does not bar any claim that arises hereafter, including (without limitation) a claim for breach of this Agreement.

6. **Release of All Claims by the Company**. To the fullest extent permitted by law, the Company waives, releases and promises never to assert any claims or causes of action, whether or not now known, against you or your heirs, personal representatives, agents or assigns with respect to any matter, including (without limitation) any matter related to your employment with the Company or the termination of that employment, including (without limitation) claims to attorneys' fees or costs, claims of defamation, breach of contract (express or implied) or breach of the covenant of good faith and fair dealing. However, this release covers only those claims that arose prior to the execution of this Agreement and only those claims that may be waived by applicable law. In addition, notwithstanding anything to the contrary herein, this release does not cover claims based on any fraud or intentional misconduct by you. Execution of this Agreement does not bar any claim that arises hereafter, including (without limitation) a claim for breach of this Agreement.

7. **No Admission**. Nothing contained in this Agreement will constitute or be treated as an admission by you or the Company of liability, any wrongdoing or any violation of law.

8. **Severability**. If any term of this Agreement is held to be invalid, void or unenforceable, the remainder of this Agreement will remain in full force and effect and will in no way be affected, and the parties will use their best efforts to find an alternate way to achieve the same result.

9. **Choice of Law**. This Agreement will be construed and interpreted in accordance with the laws of the Commonwealth of Massachusetts (other than their choice-of-law provisions).

10. **Execution**. This Agreement may be executed in counterparts, each of which will be considered an original, but all of which together will constitute one agreement. Execution of a facsimile copy will have the same force and effect as execution of an original, and a facsimile signature will be deemed an original and valid signature.

Please indicate your agreement with the above terms by signing below.

Very truly yours,

HISTOGENICS CORPORATION

By: /s/ Kevin McArdle
Name: Kevin McArdle
Title: Chief Financial Officer

I agree to the terms of this Agreement, and I am voluntarily signing this release of all claims. I acknowledge that I have read and understand this Agreement, and I understand that I cannot pursue any of the claims and rights that I have waived in this Agreement at any time in the future.

Signed: /s/ Peter Greeleaf
Peter Greenleaf

Dated: 2/28/14

GUNDERSON DETTMER STOUGH
VILLENEUVE FRANKLIN & HACHIGIAN, LLP
850 WINTER STREET
WALTHAM, MA 02451
TELEPHONE: (781) 890-8800 FACSIMILE: (781) 622-1622

April 11, 2014

VIA EDGAR AND OVERNIGHT COURIER

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
Confidential Draft Registration Statement on Form S-1
CIK No. 00001372299

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 March 13, 2014 relating to the Company's Confidential Draft Registration Statement on Form S-1, confidentially submitted on February 14, 2014 (the "Draft Registration Statement").

On behalf of the Company, we are also confidentially 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.

1. ***Please supplementally provide us with any written materials that you or anyone authorized to do so on your behalf provides in reliance on Section 5(d) of the Securities Act to potential investors that are qualified institutional buyers or institutional accredited investors. Similarly, please supplementally provide us with any research reports about you that are published or distributed in reliance upon Section 2(a)(3) of the Securities Act of 1933 added by Section 105(a) of the Jumpstart Our Business Startups Act by any broker or dealer that is participating or will participate in your offering.***

RESPONSE TO COMMENT 1:

In response to the Staff's request, the Company has supplementally provided with this correspondence all of the written materials that were presented to potential investors in reliance on Section 5(d) of the Securities Act. Such materials were only made available for viewing by such potential investors during the Company's presentation. To the Company's knowledge, no research reports about the Company were published or distributed in reliance upon Section 2(a)(3) of the Securities Act by any broker or dealer that is participating or, to the Company's knowledge, will participate in the offering. To the extent any such research reports are published or distributed in the future, the Company will provide the Staff with any such communications or reports.

Overview, page 1

2. ***Your disclosure in the summary appears to rely excessively on jargon and may be difficult for an average investor to understand. Please revise your disclosure so that a non-medical field investor will be able to understand your product, business and market opportunity. For example, we note terms such as scaffolding, tissue engineering, bioadhesives microfracture, and fibroblast growth factor variants, among others. Please revise your summary.***

RESPONSE TO COMMENT 2:

The Company acknowledges the Staff's comment and has revised the applicable sections of the Registration Statement accordingly.

3. ***We note that you have provided in the summary a separate section on risks relating to your business. Rather than discussing the negative aspects in one area of your summary, your summary should provide a balanced, integrated discussion of the positive and negative aspects of your offering. For example, in your first paragraph, please clearly state that you are not yet approved to sell your product. In addition, please disclose that you have incurred net losses in each year since inception and quantify your net losses. Please revise your summary throughout.***

RESPONSE TO COMMENT 3:

The Company acknowledges the Staff's comment and has revised the section of the Registration Statement accordingly. Additionally, the Company has disclosed that it has incurred net losses in each year since inception and has quantified its net losses in the prospectus summary of the Registration Statement.

4. ***Please expand your description of your first product candidate "NeoCart" so that investors can understand what the product is and how and why you believe it demonstrates "clinical superiority" over the current standard of care.***

RESPONSE TO COMMENT 4:

The Company acknowledges the Staff's comment and has revised the section of the Registration Statement accordingly.

5. ***We note your statements regarding "statistically significant improvement in clinical efficacy based on pain and function measures as compared to microfracture" and "positive Phase 1 and Phase 2 clinical data." Please expand your disclosure to describe the purpose and size of the Phase 1 and Phase 2 trials, respectively, and how the data supports your claim of significant improvement and positive data.***

RESPONSE TO COMMENT 5:

The Company acknowledges the Staff's comment and has added additional disclosure to the Registration Statement as requested.

6. ***Please explain what it means when you state "NeoCart is currently enrolling a Phase 3 clinical trial in the United States under a Special Protocol Assessment with the U.S. Food and Drug Administration." How is this different from other Phase 3 clinical trials and why are you pursuing this type of trial? Please also disclose the size of the trial and its anticipated schedule.***

RESPONSE TO COMMENT 6:

The Company acknowledges the Staff's comment and has revised the section of the Registration Statement accordingly to implement the response above.

Impairment of Intangible Assets, page 60

7. ***We reference the discussion on page 60 that the suspension of the production and commercialization of BioCart was an indicator of potential impairment, and this resulted in $1.8 million impairment charge to goodwill. Please explain to us how this suspension was considered in your assessment of the recoverability of the intangible assets related to the acquisition of ProChon.***

RESPONSE TO COMMENT 7:

The Company advises the Staff that subsequent to the acquisition of ProChon, the Company reassessed its operating segments and reporting units under the applicable guidance from ASC 280 and ASC 350. The Company concluded that the Histogenics business and the ProChon business should be considered separate reporting units for the purpose of conducting its annual goodwill impairment assessment as of December 31, 2011. In performing the Company's goodwill impairment assessment for the year ended December 31, 2011, as a standalone reporting unit, ProChon would no longer expect to receive the anticipated synergies that would have resulted from the combination of two companies in the cartilage regeneration field. As a result, the Company recorded a goodwill impairment charge of $1.8 million during the year ended December 31, 2011.

The Company further advises the Staff that in the event that the development of Company's NeoCart product proves unsuccessful, the Company may reinitiate the development of BioCart. In its intangible asset impairment assessment as of December 31, 2011, the Company determined that the value of BioCart was not impaired due to its probability-adjusted future cash flow potential.

Stock Based Compensation, pages 60-66

8. ***Please tell us the estimated initial public offering price. To the extent that there is a significant difference between the estimated grant-date fair value of your common stock during the past twelve months and the estimated IPO price, please discuss for us each significant factor contributing to the difference.***

RESPONSE TO COMMENT 8:

The Company acknowledges the Staff's comments. At this time, the Company is not able to make a conclusive determination regarding the significant factors contributing to the difference between the estimated IPO price and the estimated grant-date fair value of the Company's common stock during the past twelve months because the price of the offering or a bona fide public offering price range is not yet known. The Company is currently working with the underwriters to determine an IPO price. The Company respectfully advises the Staff that it will provide the requested information prior to requesting effectiveness of the Registration Statement.

JOBS Act, page 68

9. ***Please clarify what you mean when you state that you "are in the process of evaluating the benefits of relying on other exemptions and reduced reporting requirements provided by the JOBS Act."***

RESPONSE TO COMMENT 9:

The Company acknowledges the Staff's comment and has revised the Registration Statement to remove such statement as it has elected to comply with certain reduced public company reporting requirements for this prospectus and future filings pursuant to the JOBS Act.

Business, page 76

10. ***Please provide copies of the reports, studies and industry data that you reference. Please clearly mark the relevant sections of these reports. For each report, please also tell us: how you confirmed that the data reflects the most recent available information; whether the data is publicly available; whether the data was prepared for use in the registration statement; whether the authors of the data consented to your use of it in the registration statement; and whether you paid for the compilation of the data. If you were affiliated with the preparation of the data in the studies, ensure that your disclosure clearly indicates the nature of all such affiliations.***

RESPONSE TO COMMENT 10:

The Company acknowledges the Staff's comments, and it has attached to this correspondence a table that indicates the pages of the applicable reports, studies and industry data referenced in the Registration Statement as Annex A. The Company has supplementally provided copies of each report to the Staff with the couriered delivery of this letter. Each report has been marked to show the relevant sections that support the data included in the prospectus and to indicate the page number of the prospectus where the data has been used.

The Company advises the Staff that the sources of the cited data have all consented to the use of their names in the Registration Statement or were from publicly available materials where such consent would not be necessary. None of the reports were commissioned by the Company or prepared specifically for its use. The Company confirmed to its reasonable satisfaction that all of the information reflects the most recent available information by checking the original source for updates.

Limitations of Current Alternatives for Treating Cartilage Damage, page 78

11. ***Please ensure that your disclosure presents a balanced view of the benefits and drawbacks of current alternatives. For example, it is unclear why you state that microfracture "in theory" forms joint cartilage. Is this in doubt? Please clarify and revise.***

RESPONSE TO COMMENT 11:

The Company acknowledges the Staff's comment and has revised the Registration Statement accordingly.

Our Regenerative Medicine Platform, page 79

12. ***Please revise the discussion of your technology so that investors who may not be familiar with medical technology will be able to understand how you develop your product. Among many examples, it is unclear what it means when you state your tissue engineering processors incubate your implants under conditions of cyclic hydrostatic pressure and low oxygen tension. Please revise throughout the prospectus.***

RESPONSE TO COMMENT 12:

The Company acknowledges the Staff's comment and has revised the Registration Statement accordingly.

Our Business Strategy, page 80

13. ***Please describe more fully the steps involved in implementing your business strategy. Explain the steps, size and time involved in completing your Phase 3 clinical trial. For example, what is involved in "transferring production of critical raw materials in-house?" What does means to "invest strategically in a U.S. commercial infrastructure" to support a successful launch and commercialization of NeoCart?***

RESPONSE TO COMMENT 13:

The Company acknowledges the Staff's comment and has revised the section of the Registration Statement accordingly.

Our Phase 3 Product Candidate: NeoCart, page 81

14. ***Please expand your disclosure to explain the basis for your claim that your Phase 1 and Phase 2 trials "demonstrated very favorable safety and the potential for durable efficacy." Please also explain what you mean when you state that your data has been "published in well regarded peer-reviewed journals." Also, explain the meaning of the phrase "acceptance as Level 1 evidence".***

RESPONSE TO COMMENT 14:

The Company acknowledges the Staff's comment and has revised the section of the Registration Statement accordingly.

15. ***Please expand your graphics to show the "NeoCart Manufacturing Process" in more detail so that investors can understand the steps involved.***

RESPONSE TO COMMENT 15:

The Company acknowledges the Staff's comment and has revised the graphics on page 82 of the Registration Statement accordingly.

Phase 3 Clinical Trial, page 82

16. ***Please revise your disclosure so that investors who are not in your industry can understand the steps involved in the Phase 3 trial. Why do you believe the BLA pathway is "rigorous" and how does it differ from other FDA approval processes? Why do you believe it is appropriate to use a one year endpoint, when you state that one of microfractures drawbacks is its limited efficacy after two years? What do you mean when you describe "control arm" and "treatment arm" and what is a "dual-threshold responder analysis." Please also clarify your explanation of the schematic graphic you provide so it is clear.***

RESPONSE TO COMMENT 16:

The Company acknowledges the Staff's comment and has revised the Registration Statement accordingly to implement the explanations above.

Phase 2 Clinical Trial, page 83

17. ***Please disclose the size of the "treatment group" upon completion of the Phase 2 trial and describe how you determined the improvement was "statistically significant." Also, please tell us why you believe investors will be able to interpret and understand the tables you provide on pages 84 and 85. It is unclear why the tables are necessary and what they add to the information you are trying to convey.***

RESPONSE TO COMMENT 17:

The Company acknowledges the Staff's comment and has revised the section of the Registration Statement accordingly.

Phase I Clinical Trial, page 86

18. ***Please expand your disclosure regarding this trial to explain what it means when you refer to a "highly favorable safety profile." Also, please discuss in greater detail the "[e]fficacy signals" that were noted.***

RESPONSE TO COMMENT 18:

The Company acknowledges the Staff's comment and has revised the disclosure and added additional disclosure to the Registration Statement as requested.

NeoCart Manufacturing Process, page 87

19. ***We note your statement that your process is "organized with specific steps that [you] plan to control" through your supply chain strategy. Please explain the steps you intend to perform in-house and what steps require third party assistance.***

RESPONSE TO COMMENT 19:

The Company acknowledges the Staff's comment and has revised the section of the Registration Statement accordingly.

Purpose Co., Ltd, page 89

20. ***Please expand your discussion of the shares to be issued upon completion of an initial public offering to explain which investors would be issuing the shares to Purpose. Also, please disclose the specific royalty percentages to be paid to Purpose. In this regard, it is unclear why you describe the royalty as a "low single digits of our net sales."***

RESPONSE TO COMMENT 20:

The Company acknowledges the Staff's comment and has expanded is discussion of additional shares to be issued upon completion of the initial public offering to explain which investors would be issuing the shares to Purpose as requested. With regard to the disclosure of the specific royalty percentages to be paid to Purpose, the Company has revised the disclosure to more clearly describe the royalty. However, the Company notes that the specific royalty amount has not been disclosed as it has submitted a confidential treatment request with regard to this information.

Angiotech Pharmaceuticals…, page 90

21. ***Please disclose the specific royalty percentages to be paid to Angiotech. In this regard, it is unclear why you describe the royalty as a "low single digits of our net sales."***

RESPONSE TO COMMENT 21:

The Company acknowledges the Staff's comment and has revised the disclosure to more clearly describe the royalty. However, the Company notes that the specific royalty amount has not been disclosed as it has submitted a confidential treatment request with regard to this information.

Koken Co, Ltd, page 91

22. ***Please disclose the March 2013 fee paid to Koken and clarify whether there are other payment obligations.***

RESPONSE TO COMMENT 22:

The Company acknowledges the Staff's comment and respectfully notes that the specific fee paid to Koken in March 2013 has not been disclosed as the Company has submitted a confidential treatment request with regard to this information.

Certain Relationships and Related Party Transactions, page 124

23. ***The relationships of the parties described in this section are unclear. Please identify the related parties and provide additional disclosure as required by Item 404 of Regulation S-K.***

RESPONSE TO COMMENT 23:

The Company acknowledges the Staff's comment and has revised the section of the Registration Statement accordingly.

Financial Statements

Note 2. Restatement of Historical Financial Information, page F-11

24. ***We note that you identified certain material errors in the previously reported financial statements for the period from inception to December 31, 2009. Please explain to us in greater how you accounted for these errors and how the amounts in the table in Note 2 are reflected in your financial statements. Please also tell us where you have included the disclosures required by FASB ASC 250-10-50 related to these errors.***

RESPONSE TO COMMENT 24:

The Company advises the Staff that during the year ended December 31, 2009, the Company issued warrants to purchase 2008 Series B convertible redeemable preferred stock in connection with the issuance of convertible notes. The Company had initially utilized the Black Scholes

method to determine the fair value of these warrants in preparing its financial statements for the year ended December 31, 2009. The 2008 Series B preferred stock that the warrants were convertible to contained an anti-dilution protection provision. This protection provision provided that if a new security was issued at a lower conversion price than the original issuance cost of the Series B preferred stock, the Series B preferred stock would be adjusted and converted to common stock at the lower price. As the warrants were convertible into Series B preferred stock, the warrants were afforded this same right. As a result, the Company concluded that the Black Scholes valuation methodology was inappropriate and the Company engaged a third-party valuation specialist to develop a Probability Weighted Expected Return Methodology ("PWERM") valuation model that would more appropriately value the warrants.

The errors that are being corrected impact the inception to date information presented within the Company's consolidated statements of operations, consolidated statements of cash flows, and its consolidated statements of convertible redeemable preferred stock and stockholders' deficit through December 31, 2009. Prior to the Company's filing of the Draft Registration Statement, the Company last issued audited private company financial statements for the year ended December 31, 2009. As a result, the current periods presented in the Draft Registration Statement have not been previously stated. The purpose of the tables within Note 2 is to inform the reader of our consolidated financial statements of the correction amount that is included within the applicable inception to date information. Since the revised balances are embedded within the inception to date information, our footnote directs the reader to the applicable financial statement line item and current inception to date balances.

In preparing Note 2 of the Draft Registration Statement, the Company considered the disclosure requirements of ASC 250-10-50-7 through 50-9. In considering ASC 250-10-50-7(a), the Company's footnote includes the effect of the correction on each applicable financial statement line item. The correction for the error related to the fair market value of the warrant impacted net income for the year ended December 31, 2009, however, as a private company, the Company had not previously reported earnings-per-share information. As a result, the Company concluded that the earnings-per-share requirement of paragraph 50-7(a) was not applicable. ASC 250-10-50-7(b) requires disclosure of the cumulative effect of the change on retained earnings in the statement of financial position for the earliest period presented. The Company noted that the earliest period presented in its statements of financial position is as of December 31, 2011. The correction of the errors noted above was recorded in periods prior to fiscal year 2011, and therefore, the Company determined that this disclosure was also not applicable. The Company believes it met the disclosure requirements of ASC 250-10-50-8 and 50-9 through the information contained in the tables in Note 2 to the previously issued financial statements in the Draft Registration Statement.

Please note, however, that in reliance on ASC 250-10-50-10, the restatement-related disclosures within the audited financial statements as of and for each of the two years ended December 31, 2013 and 2012, and for the period from June 28, 2000 (date of inception) to December 31, 2013, do not include restatement disclosures for the error identified in the prior periods' audits. In order to provide transparent disclosure of the existence of the identified material weakness that triggered the restatement, we have retained the related risk factor regarding such material weakness and resulting restatement of prior periods.

Note 3. Revenue Recognition, page F-19

25. ***Please revise to separately disclose product, license fee and government grant revenue in your financial statements. Please explain to us the nature of government grant funding and clarify the reference to this as a qualifying therapeutic discovery project tax credit program. Please also clarify where the related reimbursable expenses are recorded.***

RESPONSE TO COMMENT 25:

The Company acknowledges the Staff's comment and has revised the financial statements of the Registration Statement accordingly.

Please note, however, that there were no reimbursable expenses recorded related to the government grant and therefore the Company has removed the reference to reimbursable expenses within the disclosure.

[Remainder of page intentionally left blank.]

* * * * *

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: Kevin McArdle
Richard Blake
Keith Scherer

Annex A

Statement	Page(s) on which the statement appears in the Registration Statement	Source	Page(s) on which statement appears in the industry report	Notes
Statement 1: "Cartilage damage is a leading cause of osteoarthritis, the condition most responsible for the estimated 750,000 knee replacements performed in the United States annually."	Pages 2 and 76	Source A: "Projections of Primary and Revision Hip and Knee Arthroplasty in the United States from 2005 to 2030" (Published in the *Journal of Bone and Joint Surgery*; Publication Date: April 2007; Authors: Sunny Kim, Ph.D., Jose Bosque, M.D., John P. Meehan, M.D., Amir Jamali, M.D. and Richard Marder, M.D.)	Pages 782-783	Publicly available.
Statement 2A: "Musculoskeletal conditions, including cartilage damage, are one of the most prevalent health problems in the United States." Statement 2B: "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."	Pages 2 and 78	Source B: "The Burden of Musculoskeletal Diseases in the United States: Prevalence, Societal and Economic Cost" (Published by the American Academy of Orthopaedic Surgeons (Second Edition, 2011) and available at http://www.boneandjointburden.org)	Pages 1, 2 and 9-20	Publicly available.
Statement 3: "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."	Page 77	Source C: "Tissue Engineering, Cell Therapy and Transplantation: Products, Technologies & Market Opportunities, Worldwide, 2009-2018" (Published by MedMarket Diligence, LLC; Publication Date: 2010).	Page 2	The Company used publicly available information from the 2010 MedMarket Diligence report and did not purchase the actual report.

Statement	Page(s) on which the statement appears in the Registration Statement	Source	Page(s) on which statement appears in the industry report	Notes
Statement 4A: "Based on recent publications, we estimate that 1,000,000 knee arthroscopies are performed each year in the United States…" Statement 4B: "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,…"	Pages 2, 75 and 77	Source D: "Increase in Outpatient Knee Arthroscopy in the United States: A Comparison of National Surveys of Ambulatory Surgery, 1996 and 2006" (Published in the *Journal of Bone and Joint Surgery*; Publication Date: June 1, 2011; Authors: Sunny Kim, Ph.D., Jose Bosque, M.D., John P. Meehan, M.D., Amir Jamali, M.D. and Richard Marder, M.D.)	Page 995, 997	Publicly available.
Statement 5A: "[W]e believe cartilage damage is likely to be identified in over 60% of those knew arthroscopies." Statement 5B: "[B]ased on a 2007 article published in *The Knee*, more than 60% of those arthroscopies may reveal cartilage damage."	Pages 2, 75-76 and 77	Source E: "Articular cartilage defects: Study of 25,124 knee arthroscopies" (Published in the *Knee*; Publication Date: February 20, 2007; Authors: W. Widuchowski, J. Widuchowski and T. Trzaska)	Pages 177-178 and 180	Publicly available.
Statement 6: "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."	Page 77	Source F: "Overview of Treatment Options for Articular Cartilage Repair: Past Present & Future" (presented at Cellular, Tissue and Gene Therapies Advisory Committee Meeting for the Food and Drug Administration on May 15, 2009 by Ken Zaslav, M.D.)	Pages 9-10, 30	Publicly available.
Statement 7: "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."	Page 78	Source G: "Clinical Efficacy of the Microfracture Technique for Articular Cartilage Repair in the Knee: An Evidence-Based Systematic Analysis" (Published in the *American Journal of Sports Medicine*; Publication Date: September 26, 2009; Authors: Kai Mithoefer, M.D., Timothy McAdams, M.D., Riley J. Williams, M.D., Peter C. Kreuz, M.D. and Bert R. Mandelbaum, M.D.)	Page 2057	Publicly available.

Statement	Page(s) on which the statement appears in the Registration Statement	Source	Page(s) on which statement appears in the industry report	Notes
Statement 8: "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."	Page 78	Source H: "Activity-Related Outcomes of Articular Cartilage Surgery: A Systematic Review" (Published in *Cartilage*; Publication Date: March 18, 2013; Authors: Peter N. Chambers, M.D., Hari Vigneswaran, B.S., Joshua D. Harris, M.D. and Brian J. Cole, M.D., M.B.A.) Source G: "Clinical Efficacy of the Microfracture Technique for Articular Cartilage Repair in the Knee: An Evidence-Based Systematic Analysis" (Published in the *American Journal of Sports Medicine*; Publication Date: September 26, 2009; Authors: Kai Mithoefer, M.D., Timothy McAdams, M.D., Riley J. Williams, M.D., Peter C. Kreuz, M.D. and Bert R. Mandelbaum, M.D.)	Pages 198-200 Pages 2057, 2059 and 2061-2062	Publicly available.
Statement 9: "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."	Page 78	Source I: "Autologous Cultured Chondrocytes: Adverse Events Reported to the United States Food and Drug Administration" (Published in the *Journal of Bone and Joint Surgery*; Publication Date: March 2006; Authors: Jennifer J. Wood, Ph.D., M.P.H.; Mark A. Malek, M.D., M.P.H.; Frank J. Frassica, M.D.; Jacquelyn A. Polder, B.S.N., M.P.H.; Aparna K. Mohan, M.D., Ph.D.; Eda T. Bloom, Ph.D.; M. Miles Braun, M.D., M.P.H.; Timothy R. Coté, M.D., M.P.H.)	Page 505	Publicly available.
Statement 10: "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 prestigious *Journal of Bone and Joint Surgery*, which accepted the Phase 2 data as a study that was designed, conducted, analyzed and reported with the highest degree of rigor possible."	Page 82	Source J: "NeoCart, an Autologous Cartilage Tissue Implant, Compared with Microfracture for Treatment of Distal Femoral Cartilage Lesions" (Published in the *Journal of Bone and Joint Surgery*; Publication Date: June 6, 2012; Authors: Dennis C. Crawford, M.D., Ph.D., Thomas M. DeBerardino, M.D. and Riley J. Williams III, M.D.)	Pages 984 and 987-988	Publicly available.

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		Source K: "An Autologous Cartilage Tissue Implant NeoCart for Treatment of Grade III Chondral Injury to the Distal Femur: Prospective Clinical Safety Trial at 2 Years" (Published in the *American Journal of Sports Medicine*; Publication Date: 2009; Authors: Dennis C. Crawford, M.D., Ph.D., Chelsea M. Heveran, W. Dilworth Cannon Jr., M.D., Li Foong Foo, M.D. and Hollis G. Potter, M.D.)	Pages 1337, 1339 and 1342	
Statement 11: "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."	Page 88	Source J: "NeoCart, an Autologous Cartilage Tissue Implant, Compared with Microfracture for Treatment of Distal Femoral Cartilage Lesions" (Published in the *Journal of Bone and Joint Surgery*; Publication Date: June 6, 2012; Authors: Dennis C. Crawford, M.D., Ph.D., Thomas M. DeBerardino, M.D. and Riley J. Williams III, M.D.)	Pages 983 and 985	Publicly available.
Statement 12: "The two-year results of our Phase 1 clinical trial were published in the *American Journal of Sports Medicine* in 2009."	Page 88	Source K: "An Autologous Cartilage Tissue Implant NeoCart for Treatment of Grade III Chondral Injury to the Distal Femur: Prospective Clinical Safety Trial at 2 Years" (Published in the *American Journal of Sports Medicine*; Publication Date: 2009; Authors: Dennis C. Crawford, M.D., Ph.D., Chelsea M. Heveran, W. Dilworth Cannon Jr., M.D., Li Foong Foo, M.D. and Hollis G. Potter, M.D.)	Page 1339	Publicly available.