HISTOGENICS CORP
Form 10-Q
May 12, 2016
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2016

OR

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

Commission File Number 001-36751

Histogenics Corporation

(Exact Name of Registrant as Specified in its Charter)

Delaware	**04-3522315**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
830 Winter Street, 3rd Floor	
Waltham, Massachusetts	**02451**
(Address of principal executive offices)	**(Zip Code)**

(781) 547-7900

(Registrant s telephone number, including area code)

Not Applicable

(Former name, former address and former fiscal year, if changed since last report)

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes x No ¨

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.

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

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

As of May 10, 2016, there were 13,274,407 outstanding shares of the registrant s common stock, $0.01 par value per share.

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HISTOGENICS CORPORATION

QUARTERLY REPORT ON FORM 10-Q

FOR THE QUARTERLY PERIOD ENDED MARCH 31, 2016

PART I FINANCIAL INFORMATION

PART II OTHER INFORMATION

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INFORMATION REGARDING FORWARD-LOOKING STATEMENTS

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

- the timing of enrollment, commencement and completion of our clinical trials;
- the timing and success of preclinical studies and clinical trials conducted by us and our development partners;
- our need for additional financing and our ability to raise additional funds on commercially reasonable terms;
- our securities or industry analysts expectations regarding the timing and success of enrollment in our clinical trials;
- the scope, progress and costs of developing and commercializing our product candidates;
- our expectations regarding our expenses and revenues, the sufficiency of our cash resources, the timing of our future profitability;
- our technology manufacturing location and partners;
- our ability to adequately manufacture our product candidates and the raw materials utilized therein;
- the ability to obtain and maintain regulatory approval of our product candidates and the labeling for any approved products;
- our ability to obtain and maintain intellectual property protection for our product candidates and our regenerative medicine platform;

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 reimbursement and market acceptance of any of our product candidates;

our anticipated growth strategies;

the anticipated trends and challenges in our business and the market in which we operate;

our ability to establish and maintain development partnerships;

our ability to attract or retain key personnel;

our ability to operate our business in compliance with the covenants and restrictions that we are subject to under our loan and security agreement;

regulatory developments in the United States and foreign countries; and

our plans for the use of our cash and cash equivalents.

Any forward-looking statements in this Quarterly Report on Form 10-Q reflect our current views with respect to future events or to our future financial performance and involve known and unknown risks,

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uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by these forward-looking statements. Factors that may cause actual results to differ materially from current expectations include, among other things, those described in the sections titled Risk Factors and Management s Discussion and Analysis of Financial Condition and Results of Operations in this Quarterly Report on Form 10-Q and those described in the sections titled Risk Factors and Management s Discussion and Analysis of Financial Condition and Results of Operations in our Annual Report on Form 10-K filed on March 10, 2016. Given these uncertainties, you should not place undue reliance on these forward-looking statements. We specifically disclaim any obligation to update these forward-looking statements in the future, except as required by law.

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PART I FINANCIAL INFORMATION

Item 1. Financial Statements.

HISTOGENICS CORPORATION

CONDENSED CONSOLIDATED BALANCE SHEETS

(unaudited)

(in thousands, except share and per share data)

	March 31, 2016	December 31, 2015
ASSETS		
Current assets:		
Cash and cash equivalents	$ 22,897	$ 30,915
Prepaid expenses and other current assets	466	321
Total current assets	23,363	31,236
Property and equipment, net	4,815	5,213
Intangible asset, net	200	200
Restricted cash	137	137
Total assets	$ 28,515	$ 36,786
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 1,713	$ 2,024
Accounts payable due to Intrexon Corporation	260	229
Accrued expenses	981	1,444
Accrued expenses due to Intrexon Corporation	1,903	1,546
Current portion of deferred rent	128	126
Current portion of deferred lease incentive	407	407
Current portion of equipment loan	583	583
Total current liabilities	5,975	6,359
Deferred rent, long-term	418	451
Deferred lease incentive, long-term	915	1,017
Equipment loan, long-term	615	761
Total liabilities	7,923	8,588
Commitments and contingencies (Note 5)		
Stockholders equity:		
	133	132

Common stock, $0.01 par value; authorized shares 100,000,000 at March 31, 2016 and December 31, 2015; 13,274,407 shares issued and outstanding at March 31, 2016 and 13,273,470 shares issued and outstanding at December 31, 2015		
Additional paid-in capital	193,942	193,631
Accumulated deficit	(173,483)	(165,565)
Total stockholders equity	20,592	28,198
Total liabilities and stockholders equity	$ 28,515	$ 36,786

See accompanying notes to unaudited condensed consolidated financial statements.

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HISTOGENICS CORPORATION

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(unaudited)

(in thousands, except share and per share data)

	Three Months Ended March 31,	
	2016	**2015**
Revenue	$	$
Operating expenses:		
Research and development	5,586	5,764
General and administrative	2,212	2,109
Total operating expenses	7,798	7,873
Loss from operations	(7,798)	(7,873)
Other expense:		
Interest expense, net	(19)	(62)
Other expense, net	(101)	(29)
Total other expense, net	(120)	(91)
Net loss	$ (7,918)	$ (7,964)
Net loss attributable to common stockholders basic and diluted	$ (7,918)	$ (7,964)
Net loss per common share basic and diluted	$ (0.60)	$ (0.60)
Weighted-average shares used to compute net loss per common share basic and diluted	13,269,021	13,201,186

See accompanying notes to unaudited condensed consolidated financial statements.

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HISTOGENICS CORPORATION

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(unaudited)

(in thousands)

	Three Months Ended March 31,	
	2016	2015
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (7,918)	$ (7,964)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	430	371
Deferred rent and lease incentive	(133)	73
Stock-based compensation	311	235
Non-cash consulting expense		9
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(145)	(33)
Accounts payable	(311)	(1,819)
Accounts payable due to Intrexon Corporation	31	226
Accrued expenses	(463)	(104)
Accrued expenses due to Intrexon Corporation	357	317
Net cash used in operating activities	(7,841)	(8,689)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchases of property and equipment	(32)	(915)
Net cash used in investing activities	(32)	(915)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from overallotment, net of issuance costs of $377		4,738
Repayments on equipment term loan	(146)	(13)
Proceeds from exercise of stock options	1	
Net cash (used in) provided by financing activities	(145)	4,725
Net decrease in cash and cash equivalents	(8,018)	(4,879)
Cash and cash equivalents Beginning of period	30,915	58,060
Cash and cash equivalents End of period	$ 22,897	$ 53,181

See accompanying notes to unaudited condensed consolidated financial statements.

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HISTOGENICS CORPORATION

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(unaudited)

(in thousands, except share and per share data)

1. NATURE OF BUSINESS

Organization

Histogenics Corporation (the Company) was incorporated under the laws of the Commonwealth of Massachusetts on June 28, 2000 and has its principal operations in Waltham, Massachusetts. In 2006, the Company s board of directors approved a corporate reorganization pursuant to which the Company incorporated as a Delaware corporation. The Company is a regenerative medicine company engaged in developing and commercializing products in the musculoskeletal segment of the marketplace. The Company combines cell therapy and tissue engineering technologies to develop products for tissue repair and regeneration focusing on patients suffering from 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 for consideration of $2,224 to enable it to create more effective solutions for tissue regeneration. ProChon s products combine cell regeneration technologies with proprietary growth factors and biocompatible scaffolds to restore injured or chronically damaged tissues. The acquisition of ProChon provided 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. The acquisition led to the initial recognition of goodwill, which was subsequently written off in 2011, and intangible assets including IPR&D and a licensing agreement which have been impaired as discussed in Note 2.

On December 18, 2014, the Company formed a wholly owned subsidiary, Histogenics Securities Corporation, under the laws of the Commonwealth of Massachusetts.

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

The condensed consolidated financial statements have been prepared on a going-concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. As shown in the accompanying condensed consolidated financial statements, the Company has incurred losses and cash flow deficits from operations for the three months ended March 31, 2016 and 2015. The Company has financed operations to date primarily through private placements of equity securities, the issuance of common stock in the initial public offering completed in December 2014, and borrowings under debt agreements. The Company has incurred losses and negative cash flows from operations resulting in an accumulated deficit at March 31, 2016 of $173.5 million. The Company

anticipates that it will continue to incur net losses for the next several years. The Company believes that our existing cash and cash equivalents will be sufficient to fund our projected cash needs into 2017. The Company will require additional capital to complete the enrollment of the NeoCart clinical trial, and for the further development of our existing product candidates.

The Company is subject to a number of risks. 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, successfully enrolling patients in its clinical trials in a timely manner, ability to obtain adequate financing, obtaining regulatory approval for any of its product candidates in any jurisdiction, compliance with government regulations, protection of proprietary therapeutics, 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 condensed consolidated financial statements are unaudited and have been prepared in conformity with accounting principles generally accepted in the United States of America (U.S. GAAP). However, they do not

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include all of the information and footnotes required by GAAP for complete financial statements. These interim condensed consolidated financial statements, in the opinion of the Company s management, reflect all normal recurring adjustments necessary for a fair presentation of the Company s financial position and results of operations for the interim periods ended March 31, 2016 and 2015. The results of operations for the interim periods are not necessarily indicative of the results of operations to be expected for the full year. These interim financial statements should be read in conjunction with the audited financial statements as of and for the year ended December 31, 2015, and the notes thereto, which are included in the Company s Annual Report on Form 10-K filed with the Securities and Exchange Commission (the SEC) on March 10, 2016.

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

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

During the three months ended March 31, 2016, there have been no material changes to the significant accounting policies described in the Company s audited financial statements as of and for the year ended December 31, 2015, and the notes thereto, which are included in the Annual Report on Form 10-K, except as noted below.

Reclassifications

The Company has reclassified certain prior period amounts to conform to the current period presentation. The amounts reclassified impact Accounts Payable due to Intrexon Corporation (Intrexon) for the three months ended March 31, 2015 and the year ended December 31, 2015.

Segment and Geographic Information

Information about the Company s operations in different geographic regions is presented in the tables below:

	March 31, 2016	December 31, 2015
Long-lived assets:		
United States	$ 4,807	$ 5,204
Israel	8	9
Total long-lived assets	$ 4,815	$ 5,213

Fair Value Measurements

The carrying amounts reported in the Company s condensed 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.

As a basis for determining the fair value of certain of the Company s financial instruments, the Company utilizes a three-tier value hierarchy, which prioritizes the inputs used in measuring fair value as follows:

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

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

Level 3: Pricing inputs are unobservable for the assets. Level 3 assets include private investments that are

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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.

The Company had no assets or liabilities classified as Level 1 or Level 2 as of March 31, 2016 and December 31, 2015, 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. The Company had no assets or liabilities classified as Level 3 as of March 31, 2016 and December 31, 2015. Transfers are calculated on values as of the transfer date. There were no transfers between Levels 1, 2 and 3 during the three months ended March 31, 2016 and 2015.

Cash and Cash Equivalents

The Company considers all highly liquid securities with original maturities of three months or less from the date of purchase to be cash equivalents. As of March 31, 2016, cash and cash equivalents comprise cash deposits of $3,120 and money market funds of $19,777.

The money market funds are measured at fair value on a recurring basis based on quoted market prices.

Description	Total	Quoted prices in active markets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
March 31, 2016				
Money market funds	$ 19,777	$ 19,777	$	$
	$ 19,777	$ 19,777	$	$
December 31, 2015				
Money market funds	$ 25,764	$ 25,764	$	$
	$ 25,764	$ 25,764	$	$

Intangible Asset

As of March 31, 2016 and December 31, 2015, the Company s intangible asset consists of acquired in-process research and development (IPR&D).

For the three months ended March 31, 2016 and 2015, the Company determined that there were no triggering events indicating impairment of its IPR&D.

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

	As of March 31, 2016			As of December 31, 2015		
	Cost	Accumulated Impairment	Net Book Value	Cost	Accumulated Impairment	Net Book Value
IPR&D	$ 630	$ (430)	$ 200	$ 630	$ (430)	$ 200
	$ 630	$ (430)	$ 200	$ 630	$ (430)	$ 200

Stock-Based Compensation

The Company accounts for stock options and restricted stock based on their grant date fair value and recognizes compensation expense on a straight-line basis over their vesting period. The Company estimates the fair value of stock options as of the date of grant using the Black-Scholes option pricing model, with the exception of stock options that include a market condition, and of restricted stock based on the fair value of the underlying common stock as of the date of grant or the value of the services provided, whichever is

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more readily determinable. The expense is adjusted for actual forfeitures at year end. Stock-based compensation expense recognized in the condensed consolidated financial statements is based on awards that are ultimately expected to vest. Stock-based compensation expense is classified as research and development or general and administrative based on the grantee s respective compensation classification.

For stock option grants with vesting triggered by the achievement of performance-based milestones, the expense is recorded over the remaining service period after the point when the achievement of the milestone is probable or the performance condition has been achieved. For stock option grants with both performance-based milestones and market conditions, expense is recorded over the derived service period after the point when the achievement of the performance-based milestone is probable or the performance condition has been achieved. For stock option grants with market conditions, the expense is calculated using the Monte Carlo model based on the grant date fair value of the option and is recorded on a straight line basis over the requisite service period, which represents the derived service period and accelerated when the market condition is satisfied. The Company did not issue awards with market conditions during the three months ended March 31, 2016. 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.

Recent Accounting Pronouncements

In March 2016, the Financial Accounting Standards Board (the FASB) issued Accounting Standards Update (ASU) No. 2016-09, Compensation-Stock Compensation (Topic 718): Improvements to Employee Shared-Based Payment Accounting. This standard provides guidance on accounting for employee share-based payments. This guidance addresses several aspects of the accounting for share-based payment award transactions, including: (a) income tax consequences; (b) classification of awards as either equity or liabilities; and (c) classification on the statement of cash flows. This standard will be effective for fiscal years beginning after December 15, 2016, including interim periods within those fiscal years. The Company is evaluating the impact of this guidance on the presentation of its results of operations, financial position or disclosures.

In November 2014, the FASB issued ASU 2014-16, Derivatives and Hedging (Topic 815): Determining Whether the Host Contract in a Hybrid Financial Instrument Issued in the Form of a Share Is More Akin to Debt or to Equity. This standard provides guidance to eliminate the existing diversity in practice in accounting for hybrid financial instruments issued in the form of a share. A hybrid financial instrument consists of a host contract into which one or more derivative terms have been embedded. This guidance requires an entity to consider the terms and features of the entire financial instrument, including the embedded derivative features, in order to determine whether the nature of the host contract is more akin to debt or to equity. This guidance is effective for fiscal years and interim periods beginning after December 15, 2015, with early adoption permitted. A reporting entity should apply this guidance using a modified retrospective approach by recording a cumulative-effect adjustment to equity as of the beginning of the annual period of adoption. Retrospective application is permitted to all relevant prior periods. The Company has concluded that this guidance has no impact on the presentation of its results of operations, financial position or disclosures.

In August 2014, the FASB issued ASU No. 2014-15, Presentation of Financial Statements-Going Concern (Subtopic 205-40): Disclosure of Uncertainties about an Entity s Ability to Continue as a Going Concern. This standard provides guidance that requires management to assess an entity s ability to continue as a going concern every reporting period, and provide certain disclosures if management has substantial doubt about the entity s ability to operate as a going concern, or an express statement if not, by incorporating and expanding upon certain principles that are currently in U.S. auditing standards. This guidance is effective for the annual period ending after December 15, 2016, and for annual periods and interim periods thereafter. Early application is permitted. The adoption of this guidance is not

expected to have an impact on the Company s financial position or results of operations.

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In June 2014, the FASB issued ASU No. 2014-12, Compensation-Stock Compensation (Topic 718): Accounting for Share-Based Payments When the Terms of an Award Provide That a Performance Target Could be Achieved after the Requisite Service Period. This standard provides guidance requiring when there is a performance target that affects vesting of equity awards granted and could be achieved after the requisite service period to be treated as a performance condition. A reporting entity should apply existing guidance on stock-based compensation, as it relates to such awards. This guidance is effective for annual periods and interim periods within those annual periods beginning after December 15, 2015 with early adoption permitted using either of two methods: (i) prospective to all awards granted or modified after the effective date; or (ii) retrospective to all awards with performance targets that are outstanding as of the beginning of the earliest annual period presented in the financial statements and to all new or modified awards thereafter, with the cumulative effect of applying this guidance as an adjustment to the opening retained earnings balance as of the beginning of the earliest annual period presented in the financial statements. The Company issued performance-based awards during the year ended December 31, 2015. The Company adopted this guidance on a prospective basis and there have not been any performance-based awards since the effective date of the guidance.

In May 2014, the FASB issued ASU No. 2014-09, Revenue from Contracts with Customers (Topic 606), which requires an entity to recognize the amount of revenue to which it expects to be entitled for the transfer of promised goods or services to customers. ASU 2014- 09 will replace most existing revenue recognition guidance in U.S. GAAP when it becomes effective. In July 2015, the FASB issued a one-year deferral of the effective date of the new revenue recognition standard. The new guidance will be effective for the Company s first quarter of fiscal year 2018 and early application for fiscal year 2017 would be permitted. The Company s adoption of this guidance is not expected to have a material impact on the consolidated financial statements.

3. LOSS PER COMMON SHARE

The Company computes basic and diluted loss per share using a methodology that gives effect to the impact of outstanding participating securities (the two-class method). As the three month periods ended March 31, 2016 and 2015 resulted in net losses, there is no income allocation required under the two-class method or dilution attributed to the weighted-average shares outstanding in the calculation of diluted loss per share.

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):

	Three Months Ended March 31,	
	2016	2015
Restricted stock and options to purchase common stock	1,405,396	842,492
Warrants exercisable into common stock	166,403	170,102

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4. PROPERTY AND EQUIPMENT

Property and equipment consisted of the following:

	March 31, 2016	December 31, 2015
Office equipment	$ 539	$ 539
Laboratory equipment	4,345	4,337
Leasehold improvements	7,683	7,683
Construction in progress	571	547
Software	96	96
Total property and equipment	13,234	13,202
Less: accumulated depreciation	(8,419)	(7,989)
Property and equipment, net	$ 4,815	$ 5,213

Depreciation expense related to property and equipment amounted to $430 and $371 for the three months ended March 31, 2016 and 2015, respectively.

5. COMMITMENTS AND CONTINGENCIES

Operating Leases

The Company leases its office and research facilities in Waltham and Lexington, Massachusetts under non-cancellable operating leases that expire at various dates through year 2023. Terms of the agreements generally provide for an initial rent-free period and future rent escalation, and provide that in addition to minimum lease rental payments, the Company is responsible for a pro-rata share of common area operating expenses. The Company s wholly-owned subsidiary, ProChon, also leases a facility in Woburn, Massachusetts which expires during the second quarter of 2016. The Company does not plan to renew the lease.

Rent expense under operating lease agreements amounted to approximately $258 and $291 for the three months ended March 31, 2016 and 2015, respectively.

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 towards the total cost of tenant improvements. The Company has recorded these costs in the condensed 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.

As an inducement to enter into its Lexington facility lease, the lessor agreed to provide the Company with a construction allowance of up to $996 towards the total cost of tenant improvements. The Company has recorded these costs in the condensed 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.

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

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Agreement). As of March 31, 2016, the Company has paid an aggregate $3,200 in commercialization milestones under the terms of the Hydrogel License Agreement, which have been expensed to research and development.

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

A one-time $3,000 payment upon approval of an eligible product by the FDA; and

Single digit royalties on the net sales of NeoCart and certain other future products.

Tissue Regeneration License

In April 2001, the Company entered into an exclusive license agreement with The Board of Trustees of the Leland Stanford Junior University (Stanford University) for the use of certain technology to develop, manufacture and sell licensed products in the field of growth and regeneration of cartilage (Tissue Regeneration License Agreement). The term of the Tissue Regeneration License Agreement extends to the expiration date of Stanford University s last to expire domestic or foreign patents. As of March 31, 2016, the Company has paid an aggregate $721 in patent reimbursement costs, royalty fees, and commercialization milestone payments under the terms of the Tissue Regeneration License Agreement, which have been recorded to research and development expense.

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

A one-time $300 payment upon approval of an eligible product by the FDA;

An annual minimum non-refundable royalty fee of $10 for the life of the license that may be used to offset up to 50% of each earned royalty described below; and

Low single digit royalties on net sales.

Honeycomb License

In March 2013, the Company entered into a license agreement with Koken Co., Ltd. (Koken) and paid a fee 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). 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 also entitled to low single digit royalties on net sales of the licensed products and on 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 of all of the Company s sublicensing receipts.

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Tissue Processor Sub-License

In December 2005, the Company entered into an exclusive agreement to sub-license certain technology from Purpose, Co. (Purpose), which is owned by a stockholder of the Company (Sub-License Agreement). Purpose entered into the original license agreement (Original Agreement) with Brigham and Women s Hospital, Inc. (Brigham and Women s) in August 2001. The Original Agreement shall remain in effect for the licensed patents owned by Brigham and Women s unless extended or terminated as provided for in the agreement. The technology is to be used to develop, manufacture, use and sell licensed products that cultivate cell or tissue development. The Sub-License Agreement extends to the expiration date of the last to expire domestic or foreign patents covered by the agreement. As of March 31, 2016, the Company has paid an aggregate $991 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 condensed 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 the sole supplier of equipment the Company uses in its manufacturing processes, and granted Purpose distribution rights of the Company s products for certain territories. In exchange, Purpose allowed for the use of its technology (owned or licensed) and manufactured and serviced exogenous tissue processors used by the Company. Under the terms of the agreement, as amended, Purpose granted the Company (a) exclusive rights to all of Purpose s technology (owned or licensed) related to the exogenous tissue processors, (b) continued supply of exogenous tissue processors during the Company s clinical trials, and (c) rights to manufacture the exogenous tissue processors at any location the Company chooses. In exchange for such consideration, the Company granted Purpose an exclusive license in Japan for the use of all of the Company s technology and made a payment of $250 to reimburse Purpose for development costs on a next generation tissue processer.

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;

$200 in potential milestone payments; and

Low single digit royalties on net sales of a licensed product.

The OCS Agreement

In connection with its research and development, the Company 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% to 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 plus interest based on the LIBOR interest rate, depending on the percentage of the manufacturing of sponsored product that takes place outside of Israel.

Engineering Agreement

The Company entered into an agreement with a development corporation to purchase a multi-unit bioreactor system. Pursuant to the agreement, as of March 31, 2016, the Company has made payments of $377 with a remaining $190 due upon the Company s acceptance of the system, which is expected in second quarter of 2016.

Collagen Supply Agreement

In September 2015, the Company entered into an agreement with Collagen Solutions (UK) Limited (the

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Supplier) to purchase soluble collagen that meets specifications provided by the Company. The initial term of the agreement is three years and will automatically renew from year to year thereafter unless otherwise terminated with at least 180 days notice by either party. Pursuant to the agreement, starting 12 months after entering into the agreement, the Company will be required to order a minimum amount of material and/or services totaling $150 from the Supplier in each calendar year until the expiration of the initial term of the agreement. The Company also committed to pay a non-refundable payment totaling $123 by the end of 2015. This expense was recorded to research and development expense as of December 31, 2015. As of March 31, 2016, the Company has paid $93 under the terms of the agreement. The remaining amount of $30 is expected to be paid in 2016 per agreement with the supplier.

6. WARRANTS

Consulting Agreement Warrant

In March 2015, in connection with a consulting agreement entered into for an interim chief financial officer, the Company issued a common stock warrant as compensation to the consulting firm. The warrant provides the holder with the right to purchase an aggregate of 7,398 shares of the Company s common stock at a per share exercise price of $9.75, the closing price of the Company s common stock on the date of issuance. The warrant vests and becomes exercisable in monthly installments over 24 months beginning March 31, 2015. The warrant expires on the tenth anniversary of issuance. The warrant is equity classified and accounted for using the fair value approach. The fair value of the warrant is estimated using the Black-Scholes option pricing model and is subject to re-measurement at each reporting period until the measurement date is reached. On December 21, 2015 the Company terminated the consulting agreement resulting in the forfeiture of 50% (3,699) of the shares eligible for exercise under the warrant. The remaining 3,699 shares were vested and exercisable on December 31, 2015.

The related warrant expense is included in general and administrative expenses on a straight-line basis over the expected service period, which is the vesting period.

Affiliates of an Advisor Warrant

In connection with the issuance of the Series A Preferred Stock 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 161,977 shares of the Company s common stock at a per share exercise price of $0.01. The warrants are exercisable, in whole or in part, immediately and may be exercised on a cashless basis. The warrants expire on the tenth anniversary of issuance. The fair value of the warrants of $117 was estimated using the Black-Scholes option pricing model and was recorded as a reduction to Series A Preferred Stock and a credit to additional paid-in capital. On December 8, 2014, the Company completed its initial public offering and warrants for 5,839 shares of common stock were surrendered to partially settle the Other Liability and common stock was issued by the Company to Purpose for the warrant shares surrendered. As of March 31, 2016 and 2015, warrants to purchase an aggregate of 156,138 shares of the Company s common stock at an exercise price of $0.01 are outstanding.

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Equipment Line of Credit Warrant

The Company granted Silicon Valley Bank a warrant to purchase 6,566 shares of common stock at a per share exercise price of $7.99. The warrant is exercisable, in whole or in part, immediately and may be exercised on a cashless basis and expires on the tenth anniversary of issuance. The fair value of the warrant as of July 9, 2014 was estimated at $51 with the following inputs: (a) risk-free interest rate of 2.58%; (b) implied volatility of the Company s common stock of 87%; (c) the expected term of 10 years. The fair value of the warrant was recorded as a debt issuance cost with a corresponding credit to additional paid-in capital.

7. STOCK-BASED COMPENSATION

Stock option activity under the Company s 2012 Equity Incentive Plan (the 2012 Plan) and 2013 Equity Incentive Plan (the 2013 Plan) for the three months ended March 31, 2016 is summarized as follows:

	Number of Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2015	1,230,838	$ 7.32		
Granted	194,040	2.56		
Exercised	(937)	0.76		
Cancelled	(23,735)	7.30		
Outstanding at March 31, 2016	1,400,206	$ 6.66	9.0	$ 95
Vested and expected to vest at March 31, 2016	1,282,478	$ 6.68	8.9	$ 95
Exercisable at March 31, 2016	268,244	$ 6.95	7.9	$ 85

As of March 31, 2016, the unrecognized compensation cost related to outstanding options was $3,538 and is expected to be recognized as expense over approximately 2.60 years. As of March 31, 2016, the weighted average grant date fair value of vested options was $5.26 and the weighted average grant date fair value of shares outstanding was $4.080.

The weighted average grant date fair value per share of employee option grants within the period was $1.43 and $4.51 for the three months ended March 31, 2016 and 2015, respectively.

Restricted stock awards under the 2012 Plan and 2013 Plan for the three months ended March 31, 2016 are summarized as follows:

	Number of Shares	Weighted Average Grant Date Fair Value
Unvested at December 31, 2015	5,190	$ 1.07
Vesting of restricted stock		
Unvested at March 31, 2016	5,190	$ 1.07

As of March 31, 2016, the unrecognized compensation cost related to restricted stock awards was $2 and is expected to be recognized as expense over approximately 0.95 years.

Stock-Based Compensation Expense

The Company granted stock options to employees during the three months ended March 31, 2016 and 2015. The Company estimates the fair value of stock options as of the date of grant using the Black-Scholes option pricing model and restricted stock based on the stock price, with the exception of those stock options

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that included a market condition. The Company estimates the fair value of stock options that include a market condition using the Monte-Carlo model. Stock options and restricted stock issued to non-board member, non-employees are accounted for using the fair value approach and are subject to periodic revaluation over their vesting terms.

Stock-based compensation expense amounted to $311 and $235 for the three months ended March 31, 2016 and 2015, respectively.

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

	For the Three Months Ended March 31,	
	2016	2015
Research and development	$ 115	$ 100
General and administrative	196	135
Total stock-based compensation expense	$ 311	$ 235

Stock-based compensation by award type is as follows:

	For the Three Months Ended March 31,	
	2016	2015
Stock options	$ 310	$ 234
Restricted stock	1	1
Total stock-based compensation expense	$ 311	$ 235

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:

	For the Three Months Ended March 31,	
	2016	2015
Risk-free interest rate	1.40%	1.60%
Expected volatility	59.6%	65.8%
Expected term (in years)	6.08	6.09
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:

	For the Three Months Ended March 31,	
	2016	2015
Risk-free interest rate	1.66%	0.56%
Expected volatility	64.7%	59.7%
Expected term (in years)	7.08	2.22
Expected dividend yield	0.0%	0.0%

8. INCOME TAXES

Deferred tax assets and deferred tax liabilities are recognized based on temporary differences between the financial reporting and tax basis of assets and liabilities using statutory rates. A valuation allowance is

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recorded against deferred tax assets if it is more likely than not that some or all of the deferred tax assets will not be realized. Due to the uncertainty surrounding the realization of the favorable tax attributes in future tax returns, the Company has recorded a full valuation allowance against the Company s otherwise recognizable net deferred tax assets.

9. EQUIPMENT LOAN PAYABLE

As of March 31, 2016, the Company had the following outstanding borrowing obligations (in thousands):

	Balance at March 31, 2016	Balance at December 31, 2015
Silicon Valley Bank Equipment Loan Payable	$ 1,198	$ 1,344
Total long-term debt	1,198	1,344
Less: current portion	583	583
Long-term debt, net	$ 615	$ 761

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

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

The equipment line of credit includes customary operating but non-financial covenants, including limitations on the Company s ability to incur additional indebtedness, issue dividends, sell assets, engage in any business other than its current business, merge or consolidate with other entities, create liens on our assets, make investments, repurchase stock in certain instances, enter into transactions with affiliates, make payments on subordinated indebtedness and transfer or encumber any collateral securing the debt. As of March 31, 2016 and December 31, 2015, $1.20 million and $1.34 million, respectively, of borrowings were outstanding under the line of credit and the Company was in compliance with all required covenants.

The scheduled maturities of the Company s long-term debt are as follows (in thousands):

December 31, 2016	$ 437
December 31, 2017	583
December 31, 2018	178

	$ 1,198

10. Subsequent Events

On May 10, 2016, the Company acquired the development and commercialization rights to NeoCart for the Japanese market from its long-time development partner Purpose. Under the terms of the agreement, the Company assumes sole responsibility for and rights to the development and commercialization of NeoCart in Japan. In exchange for the transfer of development and commercialization rights, the Company will pay a success-based milestone to Purpose upon conditional approval of NeoCart in Japan, as well as commercial milestones and a low single digit royalty on Japanese sales of NeoCart, upon full approval, if any, in Japan.

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

You should read the following discussion and analysis of our financial condition and results of operations in conjunction with the financial statements and the notes thereto included elsewhere in this Quarterly Report on Form 10-Q and with our audited financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2015, filed with the SEC on March 10, 2016. Some of the information contained in this discussion and analysis, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks, uncertainties and assumptions. You should read the Risk Factors and Information Regarding Forward-Looking Statements sections of this Quarterly Report on Form 10-Q for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Overview

Histogenics Corporation (we, our or Histogenics) is a regenerative medicine company focused on developing and commercializing products in the musculoskeletal segment of the marketplace. Our first product candidate, NeoCart®, is being investigated in a Phase 3 clinical trial. NeoCart utilizes various aspects of our regenerative medicine platform to develop an innovative tissue implant intended to treat tissue injury in the field of orthopedics, specifically cartilage damage in the knee. 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 defect can expand in size and progress to debilitating arthritis, ultimately necessitating a joint replacement procedure. NeoCart is based on our regenerative medicine platform, which combines expertise in the following areas:

Our regenerative medicine platform combines expertise in the following areas:

- Cell therapy and processing: the handling of a tissue biopsy and the extraction, isolation and expansion of the cells;
- Biomaterials and Scaffold: three-dimensional biomaterials 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 biomaterials to improve or replace biological functions; and
- Bioadhesives: natural, biocompatible materials that act as adhesives for biological tissue and allow for natural cell and tissue infiltration and integration with native cells.

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 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, through commercial bank debt and the proceeds of our

initial public offering.

We have never been profitable and have incurred net losses in each year since inception. Our accumulated deficit was $173.5 million as of March 31, 2016. Substantially all of our net losses resulted from costs incurred in connection with our research and development programs and from general and administrative costs associated with our operations. 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:

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conduct clinical trials of our product candidates;

continue scale up and improvement of our manufacturing processes;

continue with the transition of our manufacturing technology transfer;

continue our research and development efforts;

manufacture preclinical study and clinical trial materials;

hire additional clinical, quality control and technical personnel to conduct our clinical trials;

hire additional scientific personnel to support our product development efforts;

maintain, expand and protect our intellectual property portfolio;

seek regulatory approvals for our product candidates that successfully complete clinical trials;

implement operational, financial and management systems; and

hire additional general and administrative personnel to operate as a public company.

We do not expect to generate any future revenue from 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, a Delaware corporation, at our facilities in Waltham and Lexington, Massachusetts, and ProChon Biotech Ltd. (ProChon) in Tel Aviv, Israel. We own 100% of the voting shares of ProChon. As the nature of the products, customers and methods to distribute products are the same and the nature of the regulatory environment, the production processes and historical and estimated future margins are similar, the two operations have been aggregated into one reporting segment.

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. The ProChon acquisition was accounted for as a business combination. 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.

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

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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 condensed consolidated financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles. The preparation of these condensed 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 condensed 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.

There have been no material changes to our critical accounting policies from those described in Management s Discussion and Analysis of Financial Condition and Results of Operations included in our Annual Report on Form 10-K for the year ended December 31, 2015, filed with the SEC on March 10, 2016.

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 total $47.2 million at December 31, 2015.

At December 31, 2015, we had U.S. federal NOL of $55.7 million, which may be available to offset future taxable income. The U.S. federal NOL carryforwards begin to expire in 2035.

As of March 31, 2016, we have provided a full valuation allowance for deferred tax assets.

JOBS Act

On April 5, 2012, the Jumpstart Our Business Startups Act (JOBS Act) was enacted. Section 107 of the JOBS Act permits an emerging growth company 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)

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providing an auditor s attestation report on our system of internal control over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act and (2) complying with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor s report providing additional information about the audit and the financial statements, known as the auditor discussion and analysis. We will remain an emerging growth company until the earliest of (a) the last day of the fiscal year in which we have total annual gross revenue of $1.0 billion or more, (b) December 31, 2019, the last day of our fiscal year following the fifth anniversary of the date of the completion of our initial public offering (IPO), (c) the date on which we have issued more than $1.0 billion in non-convertible debt during the previous three years and (d) the date on which we are deemed to be a large accelerated filer under the rules of the SEC.

Results of Operations

Three Month Periods Ended March 31, 2016 and 2015

The following table summarizes the results of our operations for the three month periods ended March 31, 2016 and 2015:

	Three Months Ended March 31,		Change	
	2016	2015	$	%
	(in thousands)			
Research and development expenses	$ 5,586	$ 5,764	$ (178)	-3%
General and administrative expenses	2,212	2,109	103	5
Other (expense), net	(120)	(91)	(29)	32

Research and Development Expenses. Research and development expenses were $5.6 million for the three month period ended March 31, 2016 as compared to $5.8 million for the three month period ended March 31, 2015. The decrease in expense of $178,000 was a result of purchases made in the three months ended March 31, 2015 of $413,000 for raw materials for our ongoing clinical trial that were not repeated in the three months ended March 31, 2016 and a reduction in consulting expense of $105,000 in the three months ended March 31, 2016 as compared to the three months ended March 31, 2015. These amounts were partially offset by increases in salary related costs of $140,000 for new hires and increases in clinical trial costs of $216,000 in the three months ended March 31, 2016.

General and Administrative Expenses. General and administrative expenses were $2.2 million for the three month period ended March 31, 2016 as compared to $2.1 million for the three month period ended March 31, 2015. The increase in expense of $103,000 was primarily due to approximately $75,000 of increased recruiting fees, and approximately $60,000 related to stock-based compensation expense from new option grants partially offset by a decrease in directors and officers liability insurance.

Other (Expense), Net. Net other expense was $120,000 for the three month period ended March 31, 2016 as compared to net other expense of $91,000 for the three month period ended March 31, 2015. The $29,000 change was primarily due to an increase in Delaware franchise tax.

Liquidity and Capital Resources

We have incurred losses and negative cash flows from operations resulting in an accumulated deficit at March 31, 2016 of $173.5 million. We anticipate that we will continue to incur net losses for the next several years.

Through March 31, 2016, we have funded our consolidated operations primarily through the funds raised in

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our IPO, 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. In May 2014, we issued 955,565 shares of our Series A-1 Preferred Stock for net proceeds of $10.3 million in cash. In December 2014, we closed our IPO whereby we sold 6,374,091 shares of our common stock (inclusive of 465,000 shares of common stock sold pursuant to partial exercise of the overallotment option granted to the underwriters in connection with the offering) for net proceeds of $61.3 million in cash. As of March 31, 2016, we had cash and cash equivalents of $22.9 million.

We believe that our existing cash and cash equivalents will be sufficient to fund our projected cash needs into 2017. We will require additional capital to complete the enrollment of the NeoCart clinical trial, and for the further development of our existing product candidates.

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

	March 31,		Change	
	2016	2015	$	%
	(in thousands)			
Net cash used in operating activities	$ (7,841)	$ (8,689)	$ 848	-10%
Net cash used in investing activities	(32)	(915)	883	(97)
Net cash (used in) provided by financing activities	(145)	4,725	(4,870)	(103)
Net decrease in cash and cash equivalents	$ (8,018)	$ (4,879)	$ (3,139)	64%

Operating Activities

Cash used in operating activities decreased $0.8 million to $7.8 million for the three month period ended March 31, 2016 from $8.7 million for the three month period ended March 31, 2015. During the three month period ended March 31, 2016, the net cash used for operating activities of $7.8 million consisted primarily of our net loss of $7.9 million, non-cash expenses of $0.6 million partially offset by a $0.5 million net change in operating assets and liabilities. During the three months ended March 31, 2015, the net cash used for operating activities of $8.7 million consisted primarily of our net loss of $8.0 million and a $1.4 million net change in operating assets and liabilities partially offset by non-cash expenses of $0.7 million.

Investing Activities

Cash used in investing activities decreased $0.9 million to $32,000 for the three month period ended March 31, 2016 from $915,000 for the three month period ended March 31, 2015. The decreased use of cash was related to a reduction in purchases of property and equipment, primarily lab equipment partially offset by an increase in leasehold improvements.

Financing Activities

Cash provided by financing activities decreased $4.9 million to $145,000 for the three month period ended March 31, 2016 from $4.7 million for the three month period ended March 31, 2015. During the three months ended March 31, 2016, we made payment on our equipment line of credit of $146,000 which was partially offset by proceeds of $1,000 from exercise of an option to purchase our common stock by an employee. During the three months ended March 31, 2015, we received net proceeds of $4.7 million from the partial exercise of the underwriters overallotment option.

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Operating Capital Requirements

Historically, we have generated minimal 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 expect to generate significant revenue from therapeutic product sales unless and until we obtain regulatory approval for 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 risks inherent in the development of new therapeutic products, and we may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. We have incurred additional costs associated with operating as a public company. We anticipate that we will need substantial additional funding in the future 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. 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 that our financial resources will be adequate to support our operations into 2017 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 manufacturing technology transfer;
- 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;

any plans to expand our research and development activities, including our need and ability to hire additional employees;

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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.

Loan and Security Agreements

Equipment Line of Credit

In July 2014, we entered into a loan and security agreement with Silicon Valley Bank, which provides for a line of credit to finance certain equipment purchases up to an aggregate of $1.75 million through March 31, 2015. The line has been fully drawn and is payable in 36 monthly installments of principal and interest commencing six months following the date of the draw with an annual interest rate of 2.75% plus the greater of 3.25% and the prime rate in effect at the time of each draw. The outstanding balance on the line of credit is secured by a first priority lien over all equipment purchased using the line of credit.

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

The equipment line of credit includes customary operating but non-financial covenants, including limitations on our ability to incur additional indebtedness, issue dividends, sell assets, engage in any business other than our current business, merge or consolidate with other entities, create liens on our assets, make investments, repurchase our stock in certain instances, enter into transactions with affiliates, make payments on subordinated indebtedness and transfer or encumber any collateral securing the debt. As of March 31, 2016 and 2015, $1.20 million and $1.34 million, respectively, of borrowings were outstanding under the line of credit and we were in compliance with all required covenants.

Off-Balance Sheet Arrangements

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

Item 3. Quantitative and Qualitative Disclosures about Market Risk.

Not applicable.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

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

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In connection with the preparation of this Quarterly Report on Form 10-Q, we completed an evaluation, as of March 31, 2016, under the supervision of and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, as to the effectiveness of our disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act).

It should be noted that any system of controls, however well designed and operated, can provide only reasonable, and not absolute, assurance that the objectives of the system will be met. In addition, the design of any control system is based in part upon certain assumptions about the likelihood of future events. Based upon the evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that, as of March 31, 2016, our disclosure controls and procedures were effective.

Changes in Internal Control Over Financial Reporting

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

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PART II OTHER INFORMATION

Item 1. Legal Proceedings.

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

Item 1A. Risk Factors.

The following description of risk factors include any material changes to, and supersedes the description of, risk factors associated with our business previously disclosed in Part I, Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2015, filed with the Securities and Exchange Commission (SEC) on March 10, 2016, under the heading Risk Factors. Our business, financial condition and operating results can be affected by a number of factors, whether current known or unknown, including but not limited to those described below, any one or more of which could, directly or indirectly, cause our actual operating results and financial condition to vary materially from past, or anticipated future, operating results and financial condition. Any of these factors, in whole or in part, could materially and adversely affect our business, financial condition, operating results and the price of our common stock.

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

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

Risks Related to 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, besides our current ongoing Phase 3 clinical trial we have never conducted clinical trials of a size required for regulatory

approvals. Further, we have not yet demonstrated an ability to successfully

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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 enrolling and completing our clinical trial program for NeoCart;
- manufacture NeoCart and constituent products contained in NeoCart for our ongoing Phase 3 clinical trial of 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;
- secure additional funding as may be needed;
- obtain required regulatory approvals for the manufacturing and 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;
- recruit and retain qualified executive management personnel;
- build and maintain appropriate research and development, clinical, sales, manufacturing, financial reporting, distribution and marketing capabilities on our own or through third parties;
- expand potential indications of NeoCart and our regenerative medicine platform;
- 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 $22.8 million in 2014 and $32.0 million in 2015. As of December 31, 2015 and March 31, 2016, we had an accumulated deficit of $165.5 million and $173.5 million, respectively. We expect to continue to incur substantial losses for the next several years, and we expect these losses to increase as we continue our development of and seek regulatory approval for, NeoCart and our future product candidates. In addition, if we receive regulatory approval to market NeoCart or any of our future product candidates, we will incur additional losses as we scale our manufacturing operations and build an internal sales and marketing organization to commercialize any approved products. In addition, we expect our expenditures to increase as we add infrastructure and personnel to support our operations as a public company. We anticipate that our net losses and accumulated deficit for the next several years will be significant as we conduct our planned operations.

Because of the numerous risks and uncertainties associated with regenerative medicine product development, we are unable to accurately predict the timing or amount of the development and clinical expenses or when, or if we will be able to achieve, or maintain, profitability. In addition, our expenses could increase if we are required by the FDA or comparable foreign regulatory authorities to perform preclinical or clinical studies or trials in addition to those currently expected, or if there are any delays in

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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 will 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. We will require substantial additional capital in order to complete the clinical development of, create additional manufacturing capacity for 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 scope, timing and costs of manufacturing NeoCart implants for use in 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, or in third party facilities at our direction, 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, related to our status as a public company; and

the costs associated with being a public company.

Many of these factors are outside of our control. 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 into the first quarter 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 or other unanticipated increases in spending related to circumstances outside of our control, including, without limitations, costs associated with

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litigation, hiring of additional personnel or procurement of additional raw materials. Our existing cash and cash equivalents 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. 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.

Our fundraising efforts to secure additional financing 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 completing 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. 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 source, preparation and collagen honeycomb scaffold, which are used in the production of NeoCart.

We have also entered into a supply agreement with Collagen Solutions (UK) Limited (Collagen Solutions) pursuant to which we will oversee the manufacture of additional collagen used in our manufacture of NeoCart. We currently do not anticipate using any collagen produced by Collagen Solutions during our Phase 3 clinical trial, but anticipate needing additional supplies of collagen above those we anticipate being able to produce in-house upon commercialization, if ever. Therefore, we have engaged Collagen Solutions in order to establish a relationship and work with the FDA as appropriate to complete any necessary comparability approvals in advance of commercialization, if ever.

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 our facility, and which may be manufactured under our direction in third party facilities (including, without limitation, facilities operated by Collagen Solutions) 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. For example, in April 2016, the FDA approved our submission which provided equivalence data for the collagen manufactured at our Westview, Massachusetts facility, meaning that the collagen manufactured at such facility will require no further additional data or actual patience equivalence studies.

In the future, 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, or the sites of third parties under our direction, 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.

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Additionally, our manufacturing sites, or those of third party sites under our direction, 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 are required to identify and enroll a sufficient number of patients that meet inclusion criteria under investigation for NeoCart. We will need to enroll the remaining patients in a timely manner in order to complete the trial. 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. For example, in November 2015 we changed our guidance for the completion of patient enrollment in the NeoCart Phase 3 clinical trial from June 2016 to June 2017 based on enrollment trends in November 2015 not meeting our expectations. 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 competing 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 our NeoCart Phase 3 clinical trial;

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 in our NeoCart Phase 3 clinical trial;

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.

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A number of companies in the regenerative medicine industry have suffered significant setbacks or difficulty enrolling patients 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 in the future, 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 (BLA) 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 and produce NeoCart implants for 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

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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 NeoCart or any of our future 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 clinical 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.

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The technologies on which our channel partnering agreement with Intrexon Corporation is based are currently in preclinical and clinical stages of development.

We have an Exclusive Channel Collaboration Agreement (the ECC) with Intrexon Corporation (Intrexon) that provides for the worldwide exclusive use of Intrexon s proprietary synthetic biology technology platform for the development and commercialization of allogeneic genetically modified chondrocyte cell therapeutics for the treatment or repair of damaged articular hyaline cartilage in humans. Such technologies have a limited history of use in the design and development of human therapeutic product candidates and may therefore involve unanticipated risks or delays. We cannot assure that any product candidates developed from this collaboration will result in nonclinical results sufficient to warrant the expense of clinical testing in human clinical trials.

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 (NDA) or a BLA 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.

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We and our contract manufacturers must comply with the current Good Manufacturing Practices (cGMP) regulations and guidelines promulgated by the FDA. We and our contract manufacturers may encounter difficulties in achieving quality control and quality assurance and may experience shortages in qualified personnel. We and our contract manufacturers 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, clinical enrollment 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 recently completed a facility for our cGMP manufacturing in Lexington, Massachusetts which we plan to further 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 BLA approval, delaying BLA approval and resulting in added cost to mitigate issues identified during inspection.

The Lexington, Massachusetts site for production of key raw materials 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 met with the FDA in December 2014 to obtain preliminary feedback and general acceptance of our raw material transition strategy, which the FDA approved in April 2015 with regard to our production of collagen. Additionally, we have entered into a supply agreement with Collagen Solutions pursuant to which we will oversee the manufacture of additional collagen used in our manufacture of NeoCart. Any raw materials manufactured or handled at facilities operated by Collagen Solutions will similarly need to be approved by the FDA for comparability, and the FDA may delay approval of the new raw material source or require additional studies to show comparability. We currently do not anticipate using any collagen produced by Collage Solutions during our Phase 3 clinical trial, but anticipate needing additional supplies of collagen above those we anticipate being able to produce

in-house upon commercialization, if ever. Therefore, we have engaged Collagen Solutions in order to establish a relationship and work with the FDA as appropriate to complete necessary comparability approvals in advance of commercialization, if ever.

The raw material to be produced at our facilities or those of Collagen Solutions under our direction 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. Such delays may impact enrollment of our NeoCart Phase 3 clinical trial and FDA approval, if granted at all.

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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 and high unit costs, depending upon the length of the delay.

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

We are a party to technology licenses that are important to our business and we may enter into additional licenses in the future. We currently hold material licenses from Purpose Co., Ltd., Angiotech Pharmaceuticals (US), Inc., Angiodevice International GmbH, the Board of Trustees of The Leland Stanford Junior University, Yeda Research and Development Co., Ltd., Koken Co., Ltd., Intrexon and Advanced BioMatrix, Inc. The rights licensed under these agreements, including rights relating to our scaffolds, tissue processor, bioadhesives and growth factors, are material to our regenerative medicine platform and the continued development of NeoCart and our future product candidates. These licenses impose various commercial, contingent payment, royalty, insurance, indemnification and other obligations on us. If we fail to comply with these obligations, the licensor may have the right to terminate the license, in which event we would lose valuable rights under our license agreements and our ability to develop or commercialize product candidates. Any termination or reversion of our rights to under the foregoing agreements may have a material adverse effect on our business, prospects and results of operations. Our ECC with Intrexon provides that Intrexon may terminate such agreement if we do not perform certain specified requirements, including developing therapies considered demonstrably superior to existing therapies and those under development by us.

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.

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

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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 healthcare 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 scope, progress, expansion, costs and results of our preclinical and clinical trials;
- 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 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.

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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. 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 and our collaborative partners 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 manufacture raw materials for use in our clinical trials, including our Phase 3 clinical trial of NeoCart;
- 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 cost to manufacture and 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.

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We have a limited manufacturing capacity for NeoCart and our future product candidates, which could inhibit our revenues and the long-term growth prospects of our 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. While we believe these facilities provide us with sufficient capacity to meet our expected clinical demand and possibly our initial 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 we believe would alleviate the capacity restraints currently resulting from our single-unit processors and expect to 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 a 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

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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 will incur additional expenses in connection with our exclusive channel collaboration arrangement with Intrexon.

Pursuant to our ECC with Intrexon, we are responsible for future research and development expenses of product candidates developed under each such collaboration, the effect of which may increase the level of our overall research and development expenses going forward.

We have incurred $3.1 million and $3.8 million as of December 31, 2015 and March 31, 2016, respectively, in connection with our collaboration with Intrexon. In addition, because development activities are determined pursuant to a joint steering committee comprised of representatives of Intrexon and us, future development costs associated this program may be difficult to anticipate and may exceed our expectations. Our actual cash requirements may vary materially from our current expectations for a number of other factors that may include, but are not limited to, unanticipated technical challenges, changes in the focus and direction of our development activities or adjustments necessitated by changes in the competitive landscape in which we operate. If we are unable to continue to financially support such collaborations due to our own working capital constraints, we may be forced to delay our activities.

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;

manufacturing and 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 or the procurement of critical raw materials required for manufacturing a product candidate;

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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.

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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

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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:

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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

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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

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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 have also entered into a supply agreement with Collagen Solutions pursuant to which we will oversee the manufacture of additional collagen used in our manufacture of NeoCart. We currently do not anticipate using any collagen produced by Collagen Solutions during our Phase 3 clinical trial, but anticipate needing additional supplies of collagen above those we anticipate being able to produce in-house upon commercialization, if ever. Therefore, we have engaged Collagen Solutions in order to establish a relationship and work with the FDA as appropriate to

complete necessary comparability approvals in advance of commercialization, if ever.

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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 will 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 preclinical and 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.

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

If we fail to attract and keep senior management and key scientific personnel, 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.

We are highly dependent on members of our management and scientific teams, including Adam Gridley, our Chief Executive Officer and President; Jonathan Lieber, our Chief Financial Officer; Gloria Matthews, DVM, Ph.D., DACVS, our Chief Medical Officer; and Stephen Kennedy, our Chief Technology Officer. The loss of the services of any of these persons could impede the achievement of our research, development and commercialization objectives. We do not maintain key person insurance for any of our executives or other employees.

Recruiting and retaining qualified scientific, clinical, manufacturing, sales and marketing personnel will also be critical to our success. We may not be able to attract and retain these personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us.

We may not be able to manage our business effectively if we are unable to attract and retain key personnel and consultants.

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

Our industry has experienced high turnover of management personnel in recent years. We are highly dependent on the development, regulatory, commercialization and business development expertise of our senior management team. The loss of Mr. Gridley or one or more additional executive officers or key employees, could seriously harm our ability to implement our business strategy successfully. While we have entered into employment contracts with each of our executive officers, 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;

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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.

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 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 we are no longer a smaller reporting company or an emerging growth company, each as defined under the Exchange Act. When and if we are a large accelerated filer or an accelerated filer and are no longer a smaller reporting company or an emerging growth company, 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 five 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 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 are also subject to complex tax laws, regulations, accounting principles and interpretations thereof. The preparation of our financial statements requires us to interpret accounting principles and guidance and make estimates and judgments that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported revenue generated and expenses incurred during the reporting periods. Our interpretations, estimates and judgments are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for the preparation of our financial statements. U.S. generally accepted accounting principles presentation is subject to

interpretation by the SEC, the Financial Accounting Standards Board and various other bodies formed to interpret and create appropriate accounting principles and guidance. In the event that one of these bodies disagrees with our accounting recognition,

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measurement or disclosure or any of our accounting interpretations, estimates or assumptions, it may have a significant effect on our reported results and may retroactively affect previously reported results. The need to restate our financial results could, among other potential adverse effects, result in us incurring substantial costs, affect our ability to timely file our periodic reports until such restatement is completed, divert the attention of our management and employees from managing our business, result in material changes to our historical and future financial results, result in investors losing confidence in our operating results, subject us to securities class action litigation, and cause our stock price to decline.

We may identify material weaknesses in the future that may cause us to fail to meet our reporting obligations or result in material misstatements of our financial statements.

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

We cannot assure you that we will not have material weaknesses or significant deficiencies in our internal control over financial reporting. If we 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.

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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 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, our ability to utilize our net operating loss carryforwards could be further limited.

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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

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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.

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

We are subject to the reporting requirements of the Exchange Act and the other rules and regulations of the SEC. 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

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destroyed, we may not be able to quickly or inexpensively replace our manufacturing capacity. In addition, natural disasters could affect our third-party service providers and manufacturers ability to perform services and provide materials for us on a timely basis. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, our efforts to obtain regulatory approvals for, and to commercialize, our product candidates may be delayed or prevented. For example, if a central laboratory holding all of our clinical product supply were to suffer a catastrophic loss of their facility, we would be required to delay our clinical trials. In addition, acts of terrorism could cause disruptions in our business or the business of our third-party service providers, partners, customers or the economy as a whole.

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

We are party to a loan and security agreement with Silicon Valley Bank, which provides for a line of credit of up to $1.75 million in the aggregate to finance certain equipment purchases. Borrowings under this agreement are secured by a first priority lien over all equipment purchased using the line of credit. This agreement restricts our ability to, among other things:

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

The operating covenants and restrictions in the loan and security agreement, as well as covenants and restrictions in any future financing agreements that we may enter into, may restrict our ability to finance our operations, engage in business activities or expand or fully pursue our business strategies. Our ability to comply with these covenants may be affected by events beyond our control, and we may not be able to meet those covenants. A breach of any of these

covenants could result in a default under the loan and security agreement or any future financing agreement, which could cause all of the outstanding indebtedness under the facility to become immediately due and payable and terminate all commitments to extend further credit.

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

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

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

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

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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 NDAs and BLAs 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

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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.

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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.

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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

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composition-of-matter patents will not be found invalid or unenforceable if challenged. Method-of-use patents protect the use of a product for the specified method. This type of patent does not prevent a competitor from making and marketing a product that is identical to our product for a use that is outside the scope of the patented method. Moreover, even if competitors do not actively promote their product for our targeted indications, physicians may prescribe these products off-label. Although off-label prescriptions may infringe or contribute to the infringement of method-of-use patents, the practice is common and such infringement is difficult to prevent or prosecute.

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

- The U.S. Patent and Trademark Office and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent process. There are situations in which noncompliance can result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, competitors might be able to enter the market earlier than would otherwise have been the case.

- Patent applications may not result in any patents being issued.

- Patents that may be issued or in-licensed may be challenged, invalidated, modified, revoked, circumvented, found to be unenforceable, or otherwise may not provide any competitive advantage.

- Our competitors, many of whom have substantially greater resources than we do and many of whom have made significant investments in competing technologies, may seek or may have already obtained patents that will limit, interfere with, or eliminate our ability to make, use and sell our potential product candidates.

- There may be significant pressure on the U.S. government and international governmental bodies to limit the scope of patent protection both inside and outside the United States for treatments that prove successful, as a matter of public policy regarding worldwide health concerns.

- Countries other than the United States may have patent laws less favorable to patentees than those upheld by U.S. courts, allowing foreign competitors a better opportunity to create, develop, and market competing product candidates.

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

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

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

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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.

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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

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outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our product candidates and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

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

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

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

We completed our initial public offering in December 2014 at an initial price to the public of $11.00 per share. Subsequently, as of May 10, 2016, our common stock has traded as low as $1.39 per share. The realization of any of the risks described in these risk factors or other unforeseen risks could have a dramatic and adverse effect on the market price of our common stock. The trading price of our common stock is likely to continue to be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control. These factors include those discussed elsewhere in this Risk Factors section and others such as:

- the delay or failure in initiating, enrolling 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;

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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;

changes in our operating results;

any changes in the financial projections we may provide to the public, our failure to meet these projections, or changes in recommendations by any securities analysts that elect to follow our common stock;

any change in securities analysts estimates of our performance, or our failure to meet analysts expectations;

the expiration of market standoff or contractual lock-up agreements;

sales or potential sales of substantial amounts of our common stock; and

price and volume fluctuations in the overall stock market or resulting from inconsistent trading volume levels of our shares.

In recent months and years, the stock market in general, and the market for pharmaceutical and biotechnological companies in particular, has experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to changes in the operating performance of the companies whose stock is experiencing those price and volume fluctuations. Broad market and industry factors may seriously affect the market price of our common stock, regardless of our actual operating performance.

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.

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 currently have limited research coverage by securities analysts. If no additional securities or industry analysts commence coverage of our company, the trading price for our stock could suffer. In the event we obtain additional 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.

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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.

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 May 10, 2016, our executive officers, directors, holders of more than 5% of our capital stock and their respective affiliates beneficially owned 74.6% of our outstanding capital stock. These stockholders have the ability to influence us through their ownership position. These stockholders are able to determine all matters requiring stockholder approval. For example, these stockholders are 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, including pursuant to our equity incentive plans, 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. As of May 10, 2016, we have 13,247,407 outstanding shares of common stock, 4,568,655 of which are beneficially owned by directors, executive officers and other affiliates and will be subject to volume and other limitations under Rule 144 under the Securities Act.

The 1,405,942 shares that are subject to outstanding options as of May 10, 2016 will become eligible for sale in the public market to the extent permitted by the provisions of various vesting 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 4,479,418 shares of our common stock. 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 have registered an additional 1,648,334 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, contractual lock-up agreements, or Rule 144 transfer restrictions applicable to affiliates.

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

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

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

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

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

We are an emerging growth company. Under the Jumpstart Our Business Startups Act, emerging growth companies can delay adopting new or revised accounting standards until such time as those standards apply to private companies.

We plan to avail ourselves of this exemption from new or revised accounting standards and, therefore, we may not be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

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

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

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

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

Sales of Unregistered Securities

None.

Use of Proceeds

On December 8, 2014, we closed our IPO whereby 5,909,091 shares of common stock were sold at a public offering price of $11.00 per share for an aggregate offering price of $65.0 million. On January 6, 2015, an additional 465,000 shares of common stock were sold at the IPO price of $11.00 per share following the underwriters exercise in part of their overallotment option (Underwriters Option). The offer and sale of all of the shares in the IPO and pursuant to the Underwriters Option were registered under the Securities Act pursuant to a registration statement on Form S-1 (File No. 333- 199202), which was declared effective by the SEC on December 2, 2014. The offering commenced as of December 2, 2014 and did not terminate before all of the securities registered in the registration statement were sold. The syndicate of underwriters was led by Cowen and Company, Needham & Company and Canaccord Genuity as joint book-running managers and BTIG, LLC as co-manager. We raised approximately $61.3 million in net proceeds after deducting underwriting discounts and commissions and other offering expenses. No payments were made by us to directors, officers or persons owning ten percent or more of our common stock or to their associates, or to our affiliates, other than payments in the ordinary course of business to officers for salaries and to non-employee directors as compensation for board committee service.

There has been no material change in the planned use of proceeds from our IPO as described in our prospectus dated December 2, 2014, filed with the SEC pursuant to Rule 424(b)(4) under the Securities Act.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not Applicable.

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Item 5. Other Information.

None.

Item 6. Exhibits.

A list of the exhibits filed as part of this Quarterly Report on Form 10-Q is set forth on the Exhibit Index, which is incorporated herein by reference.

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SIGNATURES

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

Histogenics Corporation

Dated: May 12, 2016

/s/ Adam Gridley
Adam Gridley
President and Chief Executive Officer

(Principal Executive Officer)

Dated: May 12, 2016

/s/ Jonathan Lieber
Jonathan Lieber
Chief Financial Officer

(Principal Financial Officer and Principal Accounting Officer)

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EXHIBIT INDEX

Exhibit	Description
3.1	Sixth Amended and Restated Certificate of Incorporation (filed as Exhibit 3.1 to the Registrant s Current Report on Form 8-K as filed on December 8, 2014, and incorporated herein by reference)
3.2	Amended and Restated Bylaws (filed as Exhibit 3.2 to the Registrant s Current Report on Form 8-K as filed on December 8, 2014, and incorporated herein by reference)
31.1*	Certification of the Chief Executive Officer, as required by Section 302 of the Sarbanes-Oxley Act of 2002
31.2*	Certification of the Chief Financial Officer as required by Section 302 of the Sarbanes-Oxley Act of 2002
32.1*	Certifications of the Chief Executive Officer and Chief Financial Officer as required by 18 U.S.C. 1350
101.INS*	XBRL Instance Document
101.SCH*	XBRL Taxonomy Extension Schema Document
101.CAL*	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	XBRL Taxonomy Extension Presentation Linkbase Document

* Filed herewith

The certifications attached as Exhibit 32.1 that accompany this Quarterly Report on Form 10-Q is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Histogenics Corporation under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Quarterly Report on Form 10-Q, irrespective of any general incorporation language contained in such filing.