HISTOGENICS CORP
Form 10-Q
May 14, 2015
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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, 2015

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 ¨ No x

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 13, 2015, there were 13,220,012 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, 2015

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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. We have based these forward-looking statements on our current expectations and projections about future events and trends that we believe may affect our financial condition, results of operations, strategy, short- and long-term business operations and objectives, and financial needs. These forward-looking statements are subject to a number of risks, uncertainties, assumptions and other important factors, including those described in the section titled Risk Factors and Management s Discussion and Analysis of Financial Condition and Results of Operations included in this Quarterly Report on Form 10-Q and our Annual Report on Form 10-K, filed on March 27, 2015. In light of these risks, uncertainties, assumptions and other factors, the forward-looking events and circumstances discussed in this Quarterly Report on Form 10-Q or Annual Report on Form 10-K may not occur, and actual results could differ materially and adversely from those anticipated or implied in the forward- looking statements. Given these uncertainties, you should not place undue reliance on these forward-looking statements.

Forward-looking statements include, but are not limited to, statements about:

- the timing and success of preclinical studies and clinical trials conducted by us and our development partners;
- our securities or industry analysts expectations regarding the timing and success of enrollment in our clinical trials;
- the ability to obtain and maintain regulatory approval of our product candidates and the labeling for any approved products;
- the scope progress and expansion and costs of developing and commercializing our product candidates;
- our expectations regarding our expenses and revenues, the sufficiency of our cash resources, our future profitability and needs for additional financing;
- our technology transfer and manufacturing location transition;
- our ability to adequately manufacture our product candidates and the raw materials utilized therein;

our ability to obtain and maintain intellectual property protection for our product candidates;

our expectations regarding competition;

the size and growth of the potential markets for our product candidates and the ability to serve those markets;

the rate and degree of 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;

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regulatory developments in the United States and foreign countries; and

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

Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, level of activity, performance or achievements. Any forward-looking statement made by us in this Quarterly Report on Form 10-Q speaks only as of the date of this report. Except as required by law, we disclaim any duty to update any of these forward-looking statements after the date of such statements are made, or to update the reasons actual results could differ materially from those anticipated in these forward-looking statements, even if new information becomes available in the future.

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PART I FINANCIAL INFORMATION

Item 1. Financial Statements.

HISTOGENICS CORPORATION

CONDENSED CONSOLIDATED BALANCE SHEETS

(in thousands, except share and per share data)

	March 31, 2015 (unaudited)	December 31, 2014
ASSETS		
Current assets:		
Cash and cash equivalents	$ 53,181	$ 58,060
Prepaid expenses and other current assets	829	796
Total current assets	54,010	58,856
Property and equipment, net	5,422	4,878
Intangible asset, net	510	510
Noncurrent deferred tax assets, net	1,034	651
Restricted cash	604	604
Total assets	$ 61,580	$ 65,499
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 3,293	$ 4,886
Accrued expenses	1,896	1,683
Current portion of deferred rent	224	219
Current portion of deferred lease incentive	514	407
Current portion of equipment loan	538	405
Deferred tax liabilities, net	1,034	651
Total current liabilities	7,499	8,251
Deferred rent, long-term	445	379
Deferred lease incentive, long-term	1,213	1,318
Equipment loan, long-term	1,199	1,345
Total liabilities	10,356	11,293
Commitments and contingencies (Note 5)		
Stockholders equity:		

Preferred stock, $0.01 par value; authorized shares 10,000,000 at December 31, 2014 and March 31, 2015; none issued and outstanding at December 31, 2014 and March 31, 2015		
Common stock, $0.01 par value; authorized shares 100,000,000 at December 31, 2014 and March 31, 2015; 12,755,012 shares issued and outstanding at December 31, 2014 and 13,220,012 shares issued and outstanding at March 31, 2015	132	127
Additional paid-in capital	192,597	187,620
Accumulated deficit	(141,505)	(133,541)
Total stockholders equity	51,224	54,206
Total liabilities and stockholders equity	$ 61,580	$ 65,499

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,	
	2015	**2014**
Operating expenses:		
Research and development	$ 5,764	$ 3,374
General and administrative	2,109	1,799
Total operating expenses	7,873	5,173
Loss from operations	(7,873)	(5,173)
Other income (expense):		
Interest expense, net	(62)	
Other income (expense), net	(29)	(2)
Change in fair value of warrant liability, other liability and net sales distribution payment liability		1,738
Total other income (expense), net	(91)	1,736
Net loss	$ (7,964)	$ (3,437)
Loss attributable to common stockholders basic and diluted	$ (7,964)	$ (3,437)
Loss per common share basic and diluted:	$ (0.60)	$ (5.90)
Weighted-average shares used to compute earnings per common share basic and diluted:	13,201,186	582,246

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,	
	2015	**2014**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (7,964)	$ (3,437)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	371	153
Deferred rent and lease incentive	73	(74)
Stock-based compensation	235	76
Non-cash consulting expense	9	
Change in fair value of liabilities		(1,738)
Amortization of deferred financing costs		(38)
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(33)	243
Accounts payable	(1,593)	34
Accrued expenses	213	(238)
Net cash used in operating activities	(8,689)	(5,019)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchases of property and equipment	(915)	(120)
Net cash used in investing activities	(915)	(120)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from overallotment, net of issuance costs of $377	4,738	
Payment on equipment term loan	(13)	
Costs associated with Initial Public Offering		(235)
Net cash provided by (used in) financing activities	4,725	(235)
Net change in cash and cash equivalents	(4,879)	(5,374)
Cash and cash equivalents Beginning of period	58,060	8,734
Cash and cash equivalents End of period	$ 53,181	$ 3,360

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 particular cartilage-derived pain and immobility. The Company is developing technology and products to reverse or prevent cartilage damage, including NeoCart for the repair of cartilage lesions. NeoCart is currently in a Phase 3 clinical trial in the United States under a special protocol assessment with the U.S. Food and Drug Administration (FDA) for the treatment of knee cartilage damage.

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

The Company is subject to a number of risks. Principal among these risks are the successful development of therapeutics, successfully enrolling patients in our clinical trials in a timely manner, protection of proprietary therapeutics, obtaining FDA approval and ongoing compliance with government regulations, ability to obtain adequate financing, fluctuations in operating results, dependence on key personnel and collaborative partners, adoption of the Company s products by the physician community, rapid technological changes inherent in the markets targeted, and substitute products and competition from larger companies.

Initial public offering

On December 8, 2014, the Company closed its initial public offering (IPO) whereby the Company sold 5,909,091 shares of common stock at a price of $11.00 per share for gross proceeds of $65,000. 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 for gross proceeds of $5,115. The shares began trading on The Nasdaq Global Market on December 3, 2014. Gross proceeds from the offering, inclusive of the overallotment, were $70,115. After giving effect to underwriting discounts and commissions and offering expenses payable by the Company, net proceeds were $61,277. In addition, each of the following occurred in connection with the completion of the IPO on December 8, 2014:

the conversion of all outstanding shares of the Company s convertible redeemable preferred stock and accrued dividends into 5,158,407 shares of common stock;

the conversion of $11,100 in convertible notes payable and accrued interest into 1,009,115 shares of common stock;

the net exercise of certain warrants into 44,531 shares of common stock and the surrender of 5,839 warrant shares to satisfy the contingent payment payable to Purpose Co., Ltd. (Other Liability), resulting in the settlement of the related warrant liability and Other Liability upon the closing of the IPO of $490 and $612, respectively, to additional paid-in capital;

the termination of the redemption provision of the net sales distribution payment; and

the Company is now authorized to issue 100,000,000 shares of common stock and 10,000,000 shares of preferred stock.

Basis of Presentation and Principles of Consolidation

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) for interim financial reporting. Accordingly, they do not 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, 2015 and 2014. The results of operations for the interim periods are not necessarily indicative of the

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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, 2014, 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 27, 2015.

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

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

The significant accounting policies described in the Company s audited financial statements as of and for the year ended December 31, 2014, and the notes thereto, which are included in the Annual Report on Form 10-K, have had no material changes during the three months ended March 31, 2015, except as noted below.

Reclassifications

The Company has reclassified certain prior period amounts to conform to the current period presentation. The amounts reclassified impact research and development expenses and general and administrative expenses for the three months ended March 31, 2014.

Segment and Geographic Information

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

	March 31, 2015	December 31, 2014
Long-lived assets:		
United States	$ 5,411	$ 4,866
Israel	11	12
Total long-lived assets	$ 5,422	$ 4,878

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

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

The Company had no assets or liabilities classified as Level 1 or Level 2 as of March 31, 2015 and December 31, 2014, other than the money market fund described in the Cash and Cash Equivalents section below, and there were no material re-measurements of fair value with respect to financial assets and liabilities during the periods presented, other than those assets and liabilities that are measured at fair value on a recurring basis. The Company had no assets or liabilities classified as Level 3 as of March 31, 2015 and December 31, 2014. Historically, the Company did have liabilities classified as Level 3 including a warrant liability, the Other Liability and the net sales distribution payment liability. These were all settled or terminated upon the closing of the IPO in December 2014.

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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, 2015 and 2014.

The Company has no liabilities classified as Level 3 that are measured by management at fair value on a quarterly basis as of March 31, 2015.

Cash and Cash Equivalents

The Company s cash equivalents, which consist of 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, 2015				
Money market	$ 49,750	$ 49,750	$	$
	$ 49,750	$ 49,750	$	$
December 31, 2014				
Money market	$ 49,750	$ 49,750	$	
	$ 49,750	$ 49,750	$	$

Intangible Asset

As of March 31, 2015 and December 31, 2014, the Company s intangible asset consists of acquired in-process research and development (IPR&D).

For the three months ended March 31, 2015 and 2014, 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, 2015			As of December 31, 2014		
	Cost	Accumulated Impairment	Net Book Value	Cost	Accumulated Impairment	Net Book Value
IPR&D	$ 630	$ (120)	$ 510	$ 630	$ (120)	$ 510
	$ 630	$ (120)	$ 510	$ 630	$ (120)	$ 510

Stock-Based Compensation

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

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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. Stock options with market conditions are valued using the Monte Carlo model. The Company issued awards with market conditions during the three months ended March 31, 2015.

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

There are no recent accounting standards that would impact the results reported in the unaudited condensed consolidated interim 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, 2015 and 2014 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 calculated 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,	
	2015	2014
Convertible redeemable preferred stock and dividends		3,603,308
Restricted stock and options to purchase common stock	842,492	287,711
Warrants exercisable into common stock	170,102	161,977

The Company also had certain warrants and other liabilities outstanding as of March 31, 2014 which could have obligated the Company, its stockholders, or both to issue shares of common stock upon the occurrence of various future events at prices and in amounts that were not determinable until the occurrence of those future events. For the three months ended March 31, 2014, these included the net sales distribution payment liability. Because the necessary conditions for the conversion or exercise of these instruments had not been satisfied as of March 31, 2014, the Company has excluded these instruments from the table above and the calculation of diluted net income per share for that period.

4. PROPERTY AND EQUIPMENT

Property and equipment consisted of the following:

	March 31,	December 31,

	2015	2014
Office equipment	$ 504	$ 467
Laboratory equipment	3,925	2,978
Leasehold improvements	7,644	7,503
Construction in progress		270
Software	96	35
Total property and equipment	12,169	11,253
less: accumulated depreciation	(6,747)	(6,375)
Property and equipment, net	$ 5,422	$ 4,878

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Depreciation expense related to property and equipment amounted to $371 and $153 for the three months ended March 31, 2015 and 2014, respectively.

5. COMMITMENTS AND CONTINGENCIES

Operating Leases

The Company leases its office and research facilities in Waltham, Massachusetts under a non-cancellable operating lease that expires in 2017. Terms of the agreement provide for an initial rent-free period and future rent escalation, and provide that in addition to minimum lease rental payments, the Company is responsible for a pro-rata share of common area operating expenses. In January 2014, the Company entered into an agreement with a third party to sublease an additional facility in Waltham, Massachusetts. The term of the sublease extends from February 1, 2014 through July 30, 2015. In June 2014, the Company entered into a lease agreement to rent a facility in Lexington, Massachusetts. The commencement date of the lease was July 9, 2014 with a term that extends through June 1, 2023. Terms of the lease agreement provide for an initial rent-free period and future rent escalation, and provide that in addition to minimum lease rental payments, the Company is responsible for a pro-rata share of operating expenses. The Company s wholly-owned subsidiary, ProChon, leases facilities in Woburn, Massachusetts and Israel.

Rent expense under operating lease agreements amounted to approximately $291 and $151 for the three months ended March 31, 2015 and 2014, respectively. In addition, the Company maintained a stand-by letter of credit in connection with the Waltham facility lease of $467 at March 31, 2015 and December 31, 2014. The Company also maintained a stand-by letter of credit in connection with the Lexington facility lease of $137 at March 31, 2015 and December 31, 2014. These amounts are classified as restricted cash in the condensed consolidated balance sheets.

As an inducement to enter into its Waltham facility lease, the lessor agreed to provide the Company with a construction allowance of up to $3,184 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 tenant improvement is recorded within leasehold improvements and included as a deferred lease incentive liability in the condensed consolidated balance sheet. Rent expense is recognized on a straight-line basis over the term of the lease and is reduced by the construction allowance.

License Agreements

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

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

Hydrogel License

In May 2005, the Company entered into an exclusive license agreement with Angiotech Pharmaceuticals (US), Inc. for the use of certain patents, patent application, and knowledge related to the manufacture and use of a hydrogel material in conjunction with NeoCart and certain other products (Hydrogel License Agreement). As of March 31,

2015, 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

Royalties in the single digits of the net sales of NeoCart and of certain other future products.

Tissue Regeneration License

In April 2001, the Company entered into an exclusive license agreement with The Board of Trustees of the Leland Stanford Junior University (Stanford University) for the use of certain technology to develop, manufacture and sell licensed products in the field of growth and regeneration of cartilage (Tissue Regeneration License Agreement). The length of the license agreement extends to the expiration date of Stanford University s last to expire domestic or foreign patents as set forth in the Tissue Regeneration License Agreement. As of March 31, 2015, the Company has paid an aggregate $640 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.

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

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

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

Royalties in the low single digits of net sales.

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 entitled a royalty fee of a low single digit percentage of net sales of the licensed products and of net sales for combination products (meaning the combination of the licensed product with at least one other active ingredient, material or medical device that would have a clinical effect if administered independently) and a low double digit percentage of all of the Company s sublicensing receipts.

Tissue Processor Sub-License

In December 2005, the Company entered into an exclusive agreement to sub-license certain technology from Purpose, Co. (Purpose), which is owned by a stockholder of the Company (Sub-License Agreement). The original license agreement (Original Agreement) was entered into in August 2001 with Brigham and Women s Hospital, Inc. (Brigham and Women s). The Original Agreement shall remain in effect for the licensed patents owned by Brigham and Women s unless extended or terminated as provided for in the agreement. The technology is to be used to develop, manufacture, use and sell licensed products that cultivate cell or tissue development. The Sub-License Agreement extends to the expiration date of the last to expire domestic or foreign patents covered by the agreement. As of March 31, 2015, the Company has paid an aggregate $941 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, which 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 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 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 milestone payments; and

Royalties in the low single digits of net sales of a licensed product.

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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, the Company will be required to make payments totaling $567, which are comprised of a deposit of $150 paid in May 2013 with the remaining $417 to be paid upon the Company s acceptance of the delivery of the system, which is expected in 2015.

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 and is subject to periodic revaluation over the vesting term.

The equity-classified warrant issued in March 2015 was valued using the Black-Scholes option pricing model (OM) and is subject to re-measurement at each reporting period until the measurement date is reached. Expense is recognized to 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 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 upon issuance and may be exercised on a cashless basis. The warrants expire on the tenth anniversary of issuance. The fair value of the warrants as of July 20, 2012 was estimated using the OM. with the following inputs: (a) risk-free interest rate of 0.22%; (b) implied volatility of the Company s common stock of 99%; and (c) the expected term to a liquidity event of 1.7 years. The fair value of the warrants as of July 20, 2012 was $117, which was recorded as a reduction to Series A Preferred and a credit to additional paid-in capital. On December 8, 2014, the Company completed its IPO 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, 2015 and December 31, 2014, warrants to purchase an aggregate of 156,138 shares of

the Company s common stock at an exercise price of $0.01 are outstanding.

Equipment Loan Warrant

On July 9, 2014, the Company entered into a loan and security agreement with Silicon Valley Bank for a loan to purchase equipment. The amount of the loan is $1,750 and bears interest at prime plus 2.75%, or 6.00% at each funding date, and is payable in equal monthly installments over 36 months beginning six months after the funding date, which ranged from August 2014 to November 2014.

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 in connection with entering into the loan and security agreement. The warrant is exercisable, in whole or in part, immediately upon issuance 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.

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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, 2015 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, 2014	537,683	$ 6.19		
Granted	389,050			
Cancelled	(92,734)			
Outstanding at March 31, 2015	833,999	$ 7.71	9.2	$ 1,814
Vested and expected to vest at March 31, 2015	769,853	$ 7.55	9.1	$ 1,879
Exercisable at March 31, 2015	180,198	$ 2.43	7.9	$ 1,362

As of March 31, 2015, the unrecognized compensation cost related to outstanding options was $3,615 and is expected to be recognized as expense over approximately 2.98 years. As of March 31, 2015, the weighted average grant date fair value of vested options was $2.05 and the weighted average grant date fair value of shares outstanding was $5.16.

For the three months ended March 31, 2015, the weighted average grant date fair value per share of employee option grants within the period was $4.51. There were no option grants for the three months ended March 31, 2014. No options were exercised for the three months ended March 31, 2015 or March 31, 2014.

Restricted stock awards under the 2012 Plan and 2013 Plan for the three months ended March 31, 2015 are summarized as follows:

	Number of Shares	Weighted-Average Grant Date Fair Value
Unvested at December 31, 2014	8,493	$ 1.04
Unvested at March 31, 2015	8,493	$ 1.04

As of March 31, 2015, the unrecognized compensation cost related to restricted stock awards was $6 and is expected to be recognized as expense over approximately 1.91 years.

Stock-Based Compensation Expense

The Company granted stock options to employees for the three months ended March 31, 2015 and 2014. The Company estimates the fair value of stock options as of the date of grant using the Black-Scholes option pricing model and restricted stock based on the stock price, with the exception of those stock options that included a market condition. The Company estimates the fair value of stock options that include a market condition using 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 compensation expense amounted to $235 and $76 for the three months ended March 31, 2015 and 2014, respectively.

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

	Three Months Ended March 31,	
	2015	2014
Research and development	$ 100	$ 27
General and administrative	135	49
Total stock-based compensation expense	$ 235	$ 76

Stock-based compensation by award type is as follows:

	Three Months Ended March 31,	
	2015	2014
Stock options	$ 234	$ 75
Restricted stock	1	1
Total stock-based compensation expense	$ 235	$ 76

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:

	Three Months Ended March 31,	
	2015	2014
Risk-free interest rate	1.60%	1.01%
Expected volatility	65.8%	87.9%
Expected term (in years)	6.09	5.36
Expected dividend yield	0.0%	0.0%

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

	Three Months Ended March 31,	
	2015	2014
Risk-free interest rate	0.56%	0.57%
Expected volatility	59.7%	109.9%
Expected term (in years)	2.22	2.13
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 recorded against

deferred tax assets if it is more likely than not that some or all of the deferred tax assets will not be realized. Due to the uncertainty surrounding the realization of the favorable tax attributes in future tax returns, the Company has recorded a full valuation allowance against the Company s otherwise recognizable net deferred tax assets. The Company has allocated its valuation allowance in accordance with the provisions of ASC 740, *Income Taxes*, which resulted in a non-current deferred tax asset of $1,034 and a current deferred tax liability of $1,034 as of March 31, 2015.

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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 our Annual Report on Form 10-K, filed with the SEC on March 27, 2015. 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

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

Our regenerative medicine platform combines expertise in the following areas:

Cell processing: the handling of a tissue biopsy, extraction of cells, and expansion of the cells;

Scaffold: three-dimensional structures that enable the proper distribution of cells and organize cells in their natural environment to support tissue formation;

Tissue engineering: the use of a combination of cells, engineering and materials to improve or replace biological functions; and

Bioadhesives: natural, biocompatible materials that act as adhesives for biological tissue.

NeoCart is a cartilage-like implant created using patient s own cartilage cells through a series of tissue engineering processes. We believe that the Phase 1 and Phase 2 clinical trials provide preliminary evidence for the safety of the NeoCart implant and improvement in pain and function in patients treated with NeoCart. We continued to make progress toward our goal of enrolling our Phase 3 clinical trial for NeoCart in the United States by the second quarter of 2016 to provide evidence of the safety and effectiveness of NeoCart, studying cartilage defects in the knees of 245 patients under a Special Protocol Assessment with the FDA.

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 $141.5 million as of March 31, 2015. 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:

conduct clinical trials of our product candidates;

continue scale up and improvement of our manufacturing processes;

transition our technology transfer and manufacturing location;

continue our research and development efforts;

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manufacture preclinical study and clinical trial materials;

maintain, expand and protect our intellectual property portfolio;

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

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

hire additional scientific personnel to support our product development efforts;

implement operational, financial and management systems; and

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

We do not expect to generate any future revenue from therapeutic product sales until we successfully complete development and obtain regulatory approval for one or more of our product candidates, which we expect will take a number of years. If we obtain regulatory approval for any of our product candidates, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution. Accordingly, we will seek to fund our operations through public or private equity or debt financings or other sources. However, we may be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all. Our failure to raise capital or enter into such other arrangements when needed would have a negative impact on our financial condition and ability to develop our product candidates.

Financial Operations Overview

We conduct operations in two geographic regions: Histogenics Corporation, a Delaware corporation, at our facility in Waltham, Massachusetts, and ProChon Biotech Ltd. (ProChon) in Tel Aviv, Israel. We own 100% of the voting shares of ProChon. As the nature of the products, customers and methods to distribute products are the same and the nature of the regulatory environment, the production processes and historical and estimated future margins are similar, the two 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. Unless otherwise indicated, the following information is presented on a consolidated basis to include our accounts and those of ProChon subsequent to the May 2011 acquisition. All intercompany transactions and balances are eliminated in consolidation.

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 filed with the SEC on March 27, 2015.

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

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results from a transaction or series of transactions over a three-year period resulting in an ownership change of more than 50 percentage points of the outstanding stock of a company by certain stockholders. We have completed a study to assess whether an ownership change has occurred or whether there have been multiple ownership changes since our formation. The results of this study indicated we experienced ownership changes, as defined by Section 382 of the Code, in each of 2006, 2011, 2012 and 2013. We have not recorded NOLs that as a result of these restrictions will expire unused. Accordingly, we have recorded NOL carryforwards net of these limitations, which are $47.2 million in 2013 and 2014.

At December 31, 2014, we had U.S. federal and Israeli NOL carryforwards of $31.2 million and $25.2 million, respectively, which may be available to offset future taxable income. The U.S. federal NOL carryforwards begin to expire in 2034 and the Israeli NOL carryforward does not expire.

As of March 31, 2015, 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) providing an auditor s attestation report on our system of internal control over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act and (2) complying with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor s report providing additional information about the audit and the financial statements, known as the auditor discussion and analysis. We will remain an emerging growth company until the earliest of (a) the last day of the fiscal year in which we have total annual gross revenue of $1.0 billion or more, (b) December 31, 2019, the last day of our fiscal year following the fifth anniversary of the date of the completion of our initial public offering, (c) the date on which we have issued more than $1.0 billion in non-convertible debt during the previous three years and (d) the date on which we are deemed to be a large accelerated filer under the rules of the SEC.

Results of Operations

Three Month Periods Ended March 31, 2015 and 2014

The following table summarizes the results of our operations for the three month periods ended March 31, 2015 and 2014:

	Three Months Ended March 31,		Change	
	2015	2014	$	%
Research and development expenses	$ 5,764	$ 3,374	$ 2,390	71%
General and administrative expenses	2,109	1,799	310	17%
Other income (expense), net	(91)	1,736	(1,827)	-105%

Research and Development Expenses. Research and development expenses were $5.8 million for the three month period ended March 31, 2015 as compared to $3.4 million for the three month period ended March 31, 2014. The increase in expense of $2.4 million was the result, in part, of incremental costs of enrolling patients in the NeoCart Phase 3 clinical trial of approximately $600,000, approximately $630,000 related to the Lexington facility and approximately $700,000 related to consulting, mainly due to the collaboration agreement with Intrexon that was entered into in September 2014, and approximately $460,000 related to an increase in headcount.

General and Administrative Expenses. General and administrative expenses were $2.1 million for the three month period ended March 31, 2015 as compared to $1.8 million for the three month period ended March 31, 2014. The increase in expense of $310,000 was the result, in part, of approximately $510,000 related to an increased headcount including our CEO, approximately $160,000 related to general liability insurance, approximately $30,000 related to facility and office expenses, partially offset by a reduction in professional fees of approximately $390,000.

Other Income (Expense), Net. Net other expense was $91,000 for the three month period ended March 31, 2015, compared to net other income of $1.7 million for the three month period ended March 31, 2014. The $1.8 million change

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was primarily due to the periodic fair value adjustment of warrant liability, Other Liability and net sales distribution payment liability, all of which were settled or terminated upon the closing of the IPO, which resulted in a gain of $1.7 million for the three month period ended March 31, 2014.

Liquidity and Capital Resources

We have incurred losses and negative cash flows from operations through March 31, 2015. Through March 31, 2015, we had an accumulated deficit of $141.5 million and anticipate that we will continue to incur net losses for the next several years.

Through March 31, 2015, we have funded our consolidated operations primarily through IPO funding and 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. On May 27, 2014, we issued 955,565 shares of our Series A-1 Preferred Stock for net proceeds of $10.3 million in cash. On December 8, 2014 we closed our initial public offering 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, 2015, we had cash and cash equivalents of $53.2 million.

We believe that the net proceeds from our initial public offering and our existing cash and cash equivalents will be sufficient to fund our projected cash needs into 2017. We will require additional capital for the further development of our existing product candidates and may also need to raise additional funds sooner to pursue other development activities related to additional product candidates.

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

	Three Months Ended March 31,	
	2015	2014
Net cash used in operating activities	$ (8,689)	$ (5,019)
Net cash used in investing activities	(915)	(120)
Net cash provided by (used in) financing activities	4,725	(235)
Net increase (decrease) in cash and cash equivalents	$ (4,879)	$ (5,374)

Operating Activities

Cash used in operating activities increased $3.7 million to $8.7 million for the three month period ended March 31, 2015 from $5.0 million for the three month period ended March 31, 2014. During the three month period 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 stock-based compensation expense of $235,000 a $73,000 charge for deferred rent and lease incentive, and depreciation expense of $371,000. During the three month period ended March 31, 2014, the net cash used for operating activities of $5.0 million consisted primarily of our net loss of $3.4 million adjusted for non-cash items including a gain of $1.7 million related to the change in fair value of warrants, other liability and net sales distribution payment liability, partially offset by depreciation expense of $153,000.

Investing Activities

Cash used in investing activities increased $795,000 to $915,000 for the three month period ended March 31, 2015 from $120,000 for the three month period ended March 31, 2014. The increased use of cash was related to purchases of property and equipment, primarily lab equipment and an increase in leasehold improvements.

Financing Activities

Cash provided by financing activities increased $5.0 million to $4.7 million for the three month period ended March 31, 2015 from cash used of $235,000 for the three month period ended March 31, 2014. During the three month period ended March 31, 2015, we received net proceeds of $4.7 million from the partial exercise of the underwriters overallotment option. During the three month period ended March 31, 2014, we incurred costs associated with the IPO of $235,000.

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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 know when, or if, we will generate any future revenue from therapeutic product sales. We do not expect to generate significant revenue from therapeutic product sales unless and until we obtain regulatory approval of and commercialize NeoCart or our future product candidates. We anticipate that we will continue to incur losses for the next several years, and we expect the losses to increase as we continue the development of, and seek regulatory approvals for, NeoCart and our future product candidates, and begin to commercialize any approved products. We are subject to all risks incident to the development of new therapeutic products, and we may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. We 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. In any event, we do not expect to achieve significant revenue from regenerative medicine product sales prior to the use of the net proceeds from our initial public offering. Additional capital may not be available on reasonable terms, if at all. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development or commercialization of one or more of our product candidates. If we raise additional funds through the issuance of additional debt or equity securities, it could result in dilution to our existing stockholders, increased fixed payment obligations and the existence of securities with rights that may be senior to those of our common stock. If we incur indebtedness, we could become subject to covenants that would restrict our operations and potentially impair our competitiveness, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. Any of these events could significantly harm our business, financial condition and prospects.

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

- the design, initiation, progress, size, timing, costs and results of preclinical studies and clinical trials for our product candidates;
- the outcome, timing and cost of regulatory approvals by the U.S. Food and Drug Administration (FDA) and comparable foreign regulatory authorities, including the potential for the FDA or comparable foreign regulatory authorities to require that we perform more studies than, or evaluate clinical endpoints other than those that we currently expect;
- the timing and costs associated with our technology transfer and manufacturing location transition;

the timing and costs associated with manufacturing NeoCart and our future product candidates for clinical trials, preclinical studies and, if approved, for commercial sale;

the number and characteristics of product candidates that we pursue;

the extent to which we are required to pay milestone or other payments under our in-license agreements and the timing of such payments;

the cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;

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

our need to implement additional infrastructure and internal systems and hire additional employees to operate as a public company;

the effect of competing technological and market developments; and

the cost of establishing sales, marketing and distribution capabilities for any products for which we may receive regulatory approval.

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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 Loan

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

In connection with the preparation of this Quarterly Report on Form 10-Q, we completed an evaluation, as of March 31, 2015, under the supervision of and with the participation of our management, including our Chief

Executive Officer and interim 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 interim Chief Financial Officer have concluded that, as of March 31, 2015, 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.

In our Annual Report on Form 10-K for the fiscal year ended December 31, 2014, filed with the SEC on March 27, 2015, we identify under Item 1A of Part I important factors which could affect our business, financial condition, results of operations and future operations and could cause our actual results for future periods to differ materially from our anticipated results or other expectations, including those expressed in any forward-looking statements made in this Form 10-Q. There have been no material changes in our risk factors subsequent to the filing of our Form 10-K for the fiscal year ended December 31, 2014. However, the risks described in our Annual Report Form 10-K are not the only risks we face. Additional risks and uncertainties that we currently deem to be immaterial or not currently known to us, as well as other risks reported from time to time in our reports to the SEC, also could cause our actual results to differ materially from our anticipated results or other expectations.

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

Sales of Unregistered Securities

Warrant Issuance to Danforth Advisors, LLC

In March 2015, in connection with entering into a consulting agreement with Danforth Advisors, LLC, we issued a warrant to Danforth Advisors, LLC exercisable for an aggregate of 7,398 shares of our common stock, subject to certain adjustments, at an exercise price of $9.75 per share. The shares underlying the warrant vest on a monthly basis over two years; provided that, 50% of the shares issuable upon exercise of the warrant shall become fully vested and exercisable if we terminate the consulting agreement for any reason other than for cause before March 12, 2016, and the remaining 50% of the shares issuable upon exercise of the warrant shall become fully vested and exercisable if we terminate the consulting agreement for any reason other than for cause upon the extension of the consulting agreement after March 12, 2016.

No underwriters were involved in the foregoing sale of securities. The issuances of the securities described above were deemed to be exempt from registration under the Securities Act, of 1933, as amended (the Securities Act), in reliance on Section 4(2) of the Securities Act. The recipient of securities in such transaction represented its intention to acquire the securities for investment only and not with a view to or for sale in connection with any distribution thereof and appropriate legends were affixed to the securities issued in such transaction.

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, 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.

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Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not Applicable.

Item 5. Other Information.

None.

Item 6. Exhibits.

Exhibit	Description
4.6*	Warrant to Purchase Common Stock dated March 12, 2015 issued to Danforth Consulting LLC
10.37*	Consulting Agreement, dated March 12, 2015, between the Registrant and Danforth Consulting LLC
31.1*	Certification of the Chief Executive Officer, as required by Section 302 of the Sarbanes-Oxley Act of 2002
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.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 certification attached as Exhibit 32.1 that accompanies this Quarterly Report on Form 10-Q is not deemed filed with the SEC and is not to be incorporated by reference into any filing of Histogenics Corporation under the Securities Act or the Exchange Act, 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.

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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 14, 2015

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

(Principal Executive Officer)

Dated: May 14, 2015

/s/ Stephen J. DiPalma
Stephen J. DiPalma
Interim Chief Financial Officer (Principal

Financial Officer and Principal Accounting Officer)

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