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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**  
Washington, D.C. 20549

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**FORM 10-Q**

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(Mark One)

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

For the quarterly period ended June 30, 2015

OR

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

Commission File Number 001-36751

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**Histogenics Corporation**  
(Exact Name of Registrant as Specified in its Charter)

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**Delaware**  
(State or other jurisdiction of  
incorporation or organization)

**830 Winter Street, 3rd Floor**  
**Waltham, Massachusetts**  
(Address of principal executive offices)

**04-3522315**  
(I.R.S. Employer  
Identification No.)

**02451**  
(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)

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

Indicate by check mark whether the registrant has submitted electronically 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  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

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

As of August 10, 2015, there were 13,236,814 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 JUNE 30, 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,” “plan,” “potential,” “predict,” “project,” “will,” “would,” “seek,” “should,” “target,” or the negative version of these words and similar expressions are intended to identify forward-looking statements. These 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 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;
- 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;
- 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, uncertainties and other factors that may cause

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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 27, 2015. 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.

**PART I – FINANCIAL INFORMATION****Item 1. Financial Statements.**

**HISTOGENICS CORPORATION**  
**CONDENSED CONSOLIDATED BALANCE SHEETS**  
**(in thousands, except share and per share data)**

	June 30, 2015 (unaudited)	December 31, 2014
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 45,222	\$ 58,060
Prepaid expenses and other current assets	897	796
Total current assets	46,119	58,856
Property and equipment, net	5,428	4,878
Intangible asset, net	510	510
Noncurrent deferred tax assets, net	1,044	651
Restricted cash	137	604
Total assets	<u>\$ 53,238</u>	<u>\$ 65,499</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 2,337	\$ 4,886
Accrued expenses	2,093	1,683
Current portion of deferred rent	223	219
Current portion of deferred lease incentive	407	407
Current portion of equipment loan	583	405
Deferred tax liabilities, net	1,044	651
Total current liabilities	6,687	8,251
Deferred rent, long-term	413	379
Deferred lease incentive, long-term	1,220	1,318
Equipment loan, long-term	1,053	1,345
Total liabilities	<u>9,373</u>	<u>11,293</u>
Commitments and contingencies (Note 5)		
Stockholders' equity:		
Preferred stock, \$0.01 par value; authorized shares—10,000,000 at June 30, 2015 and December 31, 2014; none issued and outstanding at June 30, 2015 and December 31, 2014	—	—
Common stock, \$0.01 par value; authorized shares—100,000,000 at June 30, 2015 and December 31, 2014; 13,236,814 shares issued and outstanding at June 30, 2015 and 12,755,012 shares issued and outstanding at December 31, 2014	132	127
Additional paid-in capital	192,871	187,620
Accumulated deficit	(149,138)	(133,541)
Total stockholders' equity	<u>43,865</u>	<u>54,206</u>
Total liabilities and stockholders' equity	<u>\$ 53,238</u>	<u>\$ 65,499</u>

*See accompanying notes to unaudited condensed consolidated financial statements.*

**HISTOGENICS CORPORATION**  
**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS**  
**(unaudited)**  
**(in thousands, except share and per share data)**

	<u>Three Months Ended June 30,</u>		<u>Six Months Ended June 30,</u>	
	<u>2015</u>	<u>2014</u>	<u>2015</u>	<u>2014</u>
Operating expenses:				
Research and development	\$ 5,858	\$ 4,669	\$ 11,622	\$ 8,043
General and administrative	1,735	1,341	3,844	3,140
Total operating expenses	<u>7,593</u>	<u>6,010</u>	<u>15,466</u>	<u>11,183</u>
Loss from operations	(7,593)	(6,010)	(15,466)	(11,183)
Other income (expense):				
Interest expense, net	(26)	—	(88)	—
Other income (expense), net	(14)	(3)	(43)	(5)
Change in fair value of warrant liability, other liability and net sales distribution payment liability	—	(2,289)	—	(551)
Total other income (expense), net	<u>(40)</u>	<u>(2,292)</u>	<u>(131)</u>	<u>(556)</u>
Net loss	<u>\$ (7,633)</u>	<u>\$ (8,302)</u>	<u>\$ (15,597)</u>	<u>\$ (11,739)</u>
Loss attributable to common stockholders—basic and diluted	<u>\$ (7,633)</u>	<u>\$ (11,822)</u>	<u>\$ (15,597)</u>	<u>\$ (15,259)</u>
Loss per common share—basic and diluted:	<u>\$ (0.58)</u>	<u>\$ (19.85)</u>	<u>\$ (1.18)</u>	<u>\$ (25.91)</u>
Weighted-average shares used to compute earnings per common share—basic and diluted:	<u>13,215,701</u>	<u>595,552</u>	<u>13,208,483</u>	<u>588,936</u>

*See accompanying notes to unaudited condensed consolidated financial statements.*

**HISTOGENICS CORPORATION**  
**CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS**  
**(unaudited)**  
**(in thousands)**

	<b>Six Months Ended June 30,</b>	
	<b>2015</b>	<b>2014</b>
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>		
Net loss	\$ (15,597)	\$ (11,739)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	768	313
Deferred rent and lease incentive	(60)	(135)
Stock-based compensation	492	188
Warrant expense	15	—
Change in fair value of liabilities	—	551
Amortization of deferred financing costs	—	(118)
Prepaid expenses and other current assets	(101)	144
Other non-current assets	467	(137)
Accounts payable	(2,549)	(173)
Accrued expenses	410	641
Net cash used in operating activities	<u>(16,155)</u>	<u>(10,465)</u>
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>		
Purchases of property and equipment	<u>(1,320)</u>	<u>(193)</u>
Net cash used in investing activities	<u>(1,320)</u>	<u>(193)</u>
<b>CASH FLOWS FROM FINANCING ACTIVITIES</b>		
Proceeds from over allotment, net of issuance costs	4,738	—
Payment on equipment term loan	(114)	—
Issuance of Series A-1 preferred stock, net of cash issuance costs of \$73	—	10,314
Costs associated with Initial Public Offering	—	(639)
Proceeds from the exercise of common stock options	13	25
Net cash provided by financing activities	<u>4,637</u>	<u>9,700</u>
Net decrease in cash and cash equivalents	(12,838)	(958)
Cash and cash equivalents—Beginning of period	58,060	8,734
Cash and cash equivalents—End of period	<u>\$ 45,222</u>	<u>\$ 7,776</u>

*See accompanying notes to unaudited condensed consolidated financial statements.*



**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”) is a Delaware corporation and has its principal operations in Waltham, Massachusetts. The Company is a regenerative medicine company engaged in developing and commercializing products in the musculoskeletal segment of the marketplace. The Company is developing technology and products to treat 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. 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 its products, successfully enrolling patients in its clinical trials in a timely manner, protection of its intellectual property, obtaining FDA approval for its products and maintaining ongoing compliance with government regulations, the 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. The shares began trading on The Nasdaq Global Market on December 3, 2014. 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. 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 authorization 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 June 30, 2015 and 2014. 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, 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.

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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 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 six months ended June 30, 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 and six months ended June 30, 2014.

### Segment and Geographic Information

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

	<u>June 30,</u> <u>2015</u>	<u>December 31,</u> <u>2014</u>
Long-lived assets:		
United States	\$5,418	\$ 4,866
Israel	10	12
Total long-lived assets	<u>\$5,428</u>	<u>\$ 4,878</u>

### 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 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 June 30, 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 June 30, 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.

Transfers are calculated on values as of the transfer date. There were no transfers between Levels 1, 2 and 3 during the six months ended June 30, 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 June 30, 2015.

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### 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	Prices in active markets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
<b>June 30, 2015</b>				
Money market funds	\$43,750	\$ 43,750	\$ —	\$ —
	<u>\$43,750</u>	<u>\$ 43,750</u>	<u>\$ —</u>	<u>\$ —</u>
<b>December 31, 2014</b>				
Money market funds	\$49,750	\$ 49,750	\$ —	\$ —
	<u>\$49,750</u>	<u>\$ 49,750</u>	<u>\$ —</u>	<u>\$ —</u>

### Intangible Asset

As of June 30, 2015 and December 31, 2014, the Company's intangible asset consists of acquired in-process research and development ("IPR&D").

For the six months ended June 30, 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 June 30, 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
	<u>\$630</u>	<u>\$ (120)</u>	<u>\$ 510</u>	<u>\$630</u>	<u>\$ (120)</u>	<u>\$ 510</u>

### 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 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 issued awards with market conditions during the three months ended March 31, 2015. There were no awards with market conditions granted during the three months ended June 30, 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.

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### Recent Accounting Pronouncements

In May 2014, the FASB issued Accounting Standards Update No. 2014-09 (ASU 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 and six month periods ended June 30, 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 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):

	<u>Three Months Ended June 30,</u>		<u>Six Months Ended June 30,</u>	
	<u>2015</u>	<u>2014</u>	<u>2015</u>	<u>2014</u>
Convertible redeemable preferred stock and dividends	—	4,560,185	—	4,560,185
Restricted stock and options to purchase common stock	925,004	467,157	925,004	467,157
Warrants exercisable into common stock	170,102	162,037	170,102	162,037

The Company also had certain warrants and other liabilities outstanding as of June 30, 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 six months ended June 30, 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 June 30, 2014, the Company has excluded these instruments from the table above and the calculation of diluted net income per share for that period. There were no such instruments outstanding during the three months and six months ended June 30, 2015.

### 4. PROPERTY AND EQUIPMENT

Property and equipment consisted of the following:

	<u>June 30,</u>	<u>December 31,</u>
	<u>2015</u>	<u>2014</u>
Office equipment	\$ 504	\$ 467
Laboratory equipment	4,062	2,978
Leasehold improvements	7,682	7,503
Construction in progress	227	270
Software	96	35
Total property and equipment	12,571	11,253
Less: accumulated depreciation	\$ (7,143)	\$ (6,375)
Property and equipment, net	<u>\$ 5,428</u>	<u>\$ 4,878</u>

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Depreciation expense related to property and equipment amounted to \$397 and \$160 for the three months ended June 30, 2015 and 2014, respectively, and \$768 and \$313 for the six months ended June 30, 2015 and 2014, 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 facilities in Woburn, Massachusetts and Israel.

Rent expense under operating lease agreements amounted to approximately \$300 and \$182 for the three months ended June 30, 2015 and 2014, respectively, and \$591 and \$333 for the six months ended June 30, 2015 and 2014, respectively. In addition, the Company maintained a stand-by letter of credit in connection with the Lexington facility lease of \$137 at June 30, 2015 and December 31, 2014. This amount is 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 June 30, 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
- 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 June 30, 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.

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.

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### *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.

### *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 June 30, 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 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 made a payment of \$250 to reimburse Purpose for development costs on a next generation tissue processor.

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.

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### **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, a payment of \$227 made in June 2015, and the remaining \$190 to be paid upon the Company's acceptance of the delivery of the system, which is expected in 2016.

## **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.

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 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 of \$117 was estimated using the Black-Scholes option pricing model and 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 June 30, 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 Line of Credit Warrant**

On July 9, 2014, the Company entered into a loan and security agreement with Silicon Valley Bank, which provides for a line of credit to purchase equipment. The amount of the line of credit is up to an aggregate of \$1,750 with an annual interest rate of 2.75% plus the greater of 3.25% and the prime rate at the date of each draw, 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.

In connection with entering into the loan and security agreement, 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 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.

## **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 six months ended June 30, 2015 is summarized as follows:

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	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	508,822			
Exercised	(16,802)			
Cancelled	(111,303)			
Outstanding at June 30, 2015	<u>918,400</u>	<u>\$ 7.74</u>	<u>9.1</u>	<u>\$ (1,232)</u>
Vested and expected to vest at June 30, 2015	<u>854,801</u>	<u>\$ 7.65</u>	<u>9.1</u>	<u>\$ (1,013)</u>
Exercisable at June 30, 2015	<u>249,538</u>	<u>\$ 3.95</u>	<u>8.0</u>	<u>\$ 625</u>

As of June 30, 2015, the unrecognized compensation cost related to outstanding options was \$3,672 and is expected to be recognized as expense over approximately 2.67 years. As of June 30, 2015, the weighted average grant date fair value of vested options was \$3.37 and the weighted average grant date fair value of shares outstanding was \$5.12.

The weighted average grant date fair value per share of employee option grants within the period was \$3.88 and \$6.50 for the three months ended June 30, 2015 and 2014, respectively, and \$5.48 and \$6.50 for the six months ended June 30, 2015 and 2014, respectively.

Restricted stock awards under the 2012 Plan and 2013 Plan for the six months ended June 30, 2015 are summarized as follows:

	Number of Shares	Weighted-Average Grant Date Fair Value
Unvested at December 31, 2014	8,493	\$ 1.04
Vesting of restricted stock	(1,889)	
Unvested at June 30, 2015	<u>6,604</u>	<u>\$ 1.00</u>

As of June 30, 2015, the unrecognized compensation cost related to restricted stock awards was \$6 and is expected to be recognized as expense over approximately 1.61 years.

### Stock-Based Compensation Expense

The Company granted stock options to employees for the three months ended June 30, 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 \$257 and \$112 for the three months ended June 30, 2015 and 2014, respectively, and \$492 and \$188 for the six months ended June 30, 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:

	<u>Three Months Ended June 30,</u>		<u>Six Months Ended June 30,</u>	
	<u>2015</u>	<u>2014</u>	<u>2015</u>	<u>2014</u>
Research and development	\$ 93	\$ 31	\$ 193	\$ 58
General and administrative	164	81	299	130
Total stock-based compensation expense	<u>\$ 257</u>	<u>\$ 112</u>	<u>\$ 492</u>	<u>\$ 188</u>

Stock-based compensation by award type is as follows:

	<u>Three Months Ended June 30,</u>		<u>Six Months Ended June 30,</u>	
	<u>2015</u>	<u>2014</u>	<u>2015</u>	<u>2014</u>
Stock options	\$ 256	\$ 111	\$ 490	\$ 186
Restricted stock	1	1	2	2
Total stock-based compensation expense	<u>\$ 257</u>	<u>\$ 112</u>	<u>\$ 492</u>	<u>\$ 188</u>

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:

	<u>Three Months Ended June 30,</u>		<u>Six Months Ended June 30,</u>	
	<u>2015</u>	<u>2014</u>	<u>2015</u>	<u>2014</u>
Risk-free interest rate	1.77%	1.85%	1.64%	1.21%
Expected volatility	59.6%	104.6%	64.3%	92.0%
Expected term (in years)	5.77	6.08	6.01	5.54
Expected dividend yield	0.0%	0.0%	0.0%	0.0%

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

	<u>Three months ended June 30,</u>		<u>Six months ended June 30,</u>	
	<u>2015</u>	<u>2014</u>	<u>2015</u>	<u>2014</u>
Risk-free interest rate	2.64%	0.88%	1.60%	0.68%
Expected volatility	69.6%	104.4%	64.6%	107.9%
Expected term (in years)	7.73	2.97	4.98	2.44
Expected dividend yield	0.0%	0.0%	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 \$1,044 and a current deferred tax liability of \$1,044 as of June 30, 2015.

## 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

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 245 patient Phase 3 clinical trial under a Special Protocol Assessment with the U.S. Food and Drug Administration (FDA). We expect to complete enrollment in the second quarter of 2016. NeoCart, an innovative tissue implant that utilizes various aspects of our regenerative medicine platform, is 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 or in other jurisdictions.

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.

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 \$149.1 million as of June 30, 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;
- manufacture preclinical and clinical trial materials;
- maintain, expand and protect our intellectual property portfolio;

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

### **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

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offset future taxable income and tax, respectively. In general, an “ownership change” as defined by Section 382 of the Code results from a transaction or series of transactions over a three-year period resulting in an ownership change of more than 50 percentage points of the outstanding stock of a company by certain stockholders. We have completed a study to assess whether an ownership change has occurred or whether there have been multiple ownership changes since our formation. The results of this study indicated we experienced ownership changes, as defined by Section 382 of the Code, in each of 2006, 2011, 2012 and 2013. We have not recorded NOLs that as a result of these restrictions will expire unused. Accordingly, we have recorded NOL carryforwards net of these limitations, which are \$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 June 30, 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 June 30, 2015 and 2014**

The following table summarizes the results of our operations for the three month periods ended June 30, 2015 and 2014:

	<u>Three Months Ended June 30,</u>		<u>Change</u>	
	<u>2015</u>	<u>2014</u>	<u>\$</u>	<u>%</u>
Research and development expenses	\$ 5,858	\$ 4,669	\$1,189	25%
General and administrative expenses	1,735	1,341	394	29%
Other income (expense), net	(40)	(2,292)	2,252	-98%

**Research and Development Expenses.** Research and development expenses were \$5.9 million for the three month period ended June 30, 2015 as compared to \$4.7 million for the three month period ended June 30, 2014. The increase in expense of \$1.2 million was primarily due to approximately \$0.6 million of incremental costs related to patient enrollment in the NeoCart Phase 3 clinical trial, approximately \$0.2 million related to the Lexington facility, approximately \$0.2 million of increased consulting costs, and approximately \$0.2 million related to an increase in personnel-related costs.

**General and Administrative Expenses.** General and administrative expenses were \$1.7 million for the three month period ended June 30, 2015 as compared to \$1.3 million for the three month period ended June 30, 2014. The increase in expense of \$0.4 million was primarily due to approximately \$0.2 million of increased Directors and Officers (“D&O”) insurance costs, approximately \$0.1 million related to Board of Directors fees and expenses, approximately \$0.1 million of increased stock compensation expense and warrant expense, and an approximately \$0.1 million increase in other expenses including SEC related fees and depreciation expense. These increases were partially offset by a reduction of approximately \$0.1 million in professional service charges including legal and audit fees.

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**Other Income (Expense), Net.** Net other expense was \$40,000 for the three month period ended June 30, 2015 as compared to net other expense of \$2.3 million for the three month period ended June 30, 2014. The \$2.2 million change 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.

### **Six Month Periods Ended June 30, 2015 and 2014**

The following table summarizes the results of our operations for the six month periods ended June 30, 2015 and 2014:

	<u>Six Months Ended June 30,</u>		<u>Change</u>	
	<u>2015</u>	<u>2014</u>	<u>\$</u>	<u>%</u>
Research and development expenses	\$ 11,622	\$ 8,043	\$3,579	44%
General and administrative expenses	3,844	3,140	704	22%
Other income (expense), net	(131)	(556)	425	-76%

**Research and Development Expenses.** Research and development expenses were \$11.6 million for the six month period ended June 30, 2015 as compared to \$8.0 million for the six month period ended June 30, 2014. The increase in expense of \$3.6 million was primarily due to approximately \$1.1 million of incremental costs related to patient enrollment in the NeoCart Phase 3 clinical trial, approximately \$1.1 million of increased consulting services, approximately \$0.7 million related to an increase in personnel-related costs, approximately \$0.3 million related to depreciation expense, approximately \$0.2 million in increased stock compensation expense, approximately \$0.1 million related to material and supplies charges, and approximately \$0.1 million related to the Lexington facility.

**General and Administrative Expenses.** General and administrative expenses were \$3.8 million for the six month period ended June 30, 2015 as compared to \$3.1 million for the six month period ended June 30, 2014. The increase in expense of \$0.7 million was primarily due to approximately \$0.3 million of increased D&O insurance costs, approximately \$0.3 million of facility and office expenses such as utilities and real estate taxes, approximately \$0.2 million related to Board of Directors fees and expenses, approximately \$0.2 million related to depreciation expense, approximately \$0.1 million related to the stock compensation expense and warrant expense due to new option grants, and approximately \$0.1 million increase in other expenses including SEC related fees. These increases were partially offset by a reduction in professional service charges of \$0.5 million, primarily related to legal and audit fees incurred in 2014 during the preparation and execution of our IPO that did not recur in 2015.

**Other Income (Expense), Net.** Net other expense was \$0.1 million for the six month period ended June 30, 2015 as compared to net other expense of \$0.5 million for the six month period ended June 30, 2014. The \$0.4 million change 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.

### **Liquidity and Capital Resources**

We have incurred losses and negative cash flows from operations resulting in an accumulated deficit at June 30, 2015 of \$149.1 million. We anticipate that we will continue to incur net losses for the next several years.

Through June 30, 2015, we have funded our consolidated operations primarily through the funds raised in 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. 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 June 30, 2015, we had cash and cash equivalents of \$45.2 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 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.

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

	<u>Six Months Ended June 30,</u>		<u>Change</u>	
	<u>2015</u>	<u>2014</u>	<u>\$</u>	<u>%</u>
Net cash used in operating activities	\$ (16,155)	\$ (10,465)	\$ (5,690)	54%
Net cash used in investing activities	(1,320)	(193)	(1,127)	584%
Net cash provided by financing activities	4,637	9,700	(5,063)	100%
Net decrease in cash and cash equivalents	<u>(12,838)</u>	<u>(958)</u>	(11,880)	1240%

### ***Operating Activities***

Cash used in operating activities increased \$5.7 million to \$16.2 million for the six month period ended June 30, 2015 from \$10.5 million for the six month period ended June 30, 2014. During the six month period ended June 30, 2015, the net cash used for operating activities of \$16.2 million consisted primarily of our net loss of \$15.6 million, a \$1.8 million net change in operating assets and liabilities and a \$60,000 charge for deferred rent and lease incentive, partially offset by stock-based compensation expense of \$0.5 million and depreciation expense of \$0.8 million. During the six months ended June 30, 2014, the net cash used for operating activities of \$10.5 million consisted primarily of our net loss of \$11.7 million partially offset by a change in the fair value of certain liabilities of \$0.6 million and a change in accrued expenses of \$0.6 million mainly related to a technology transfer agreement entered into in April 2014.

### ***Investing Activities***

Cash used in investing activities increased \$1.1 million to \$1.3 million for the six month period ended June 30, 2015 from \$0.2 million for the six month period ended June 30, 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 decreased \$5.0 million to \$4.7 million for the six month period ended June 30, 2015 from cash provided of \$9.7 million for the six month period ended June 30, 2014. During the six month period ended June 30, 2015, we received net proceeds of \$4.7 million from the partial exercise of the underwriters' overallocation option. During the six months ended June 30, 2014, we closed the sale of our Series A-1 Preferred Stock for \$10.3 million in net proceeds and had an exercise of stock options for \$25,000 which were partially offset by the costs we incurred related to the IPO of \$0.6 million.

### ***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 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 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, which may never occur, 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.

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

If we cannot expand our operations or otherwise capitalize on our business opportunities because we lack sufficient capital, our business, financial condition and results of operations could be materially adversely affected.

## **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. 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 July 2014, we received funding of \$1.75 million to purchase certain equipment, which is being repaid in 36 monthly installments of principal and interest. The annual interest rate is 6.00%. In accordance with the terms of the equipment line of credit, in July 2014 we issued a warrant to Silicon Valley Bank 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 June 30, 2015, \$1.64 million of borrowings were outstanding under the line of credit and we were in compliance with all required covenants.

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**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 June 30, 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 June 30, 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.



## 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.**

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.

**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.

Dated: August 12, 2015

Histogenics Corporation

/s/ Adam Gridley

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

Dated: August 12, 2015

/s/ Jonathan Lieber

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

**EXHIBIT INDEX**

<u>Exhibit</u>	<u>Description</u>
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

## CERTIFICATION

I, Adam Gridley, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Histogenics Corporation;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a. designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b. [Paragraph omitted in accordance with SEC Release Nos. 33-8238; 34-47986; IC-26068; June 5, 2003];
  - c. evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d. disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a. all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b. any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 12, 2015

/s/ Adam Gridley

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

## CERTIFICATION

I, Jonathan Lieber, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Histogenics Corporation;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a. designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b. [Paragraph omitted in accordance with SEC Release Nos. 33-8238; 34-47986; IC-26068; June 5, 2003];
  - c. evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d. disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a. all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b. any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 12, 2015

/s/ Jonathan Lieber

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

## Certification

## Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

## (Subsections (a) and (b) of Section 1350, Chapter 63 of Title 18, United States Code)

Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (subsections (a) and (b) of section 1350, chapter 63 of title 18, United States Code), each of the undersigned officers of Histogenics Corporation (the Company), does hereby certify, to the best of such officer's knowledge, that:

The Quarterly Report on Form 10-Q for the quarter ended June 30, 2015 (the Form 10-Q) of the Company fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, and the information contained in the Form 10-Q fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: August 12, 2015

/s/ Adam Gridley

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

Date: August 12, 2015

/s/ Jonathan Lieber

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

A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request. This certification "accompanies" the Form 10-Q to which it relates, is not deemed filed with the SEC and is not to be incorporated by reference into any filing of the Company 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 the Form 10-Q), irrespective of any general incorporation language contained in such filing.