
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, DC 20549

FORM 8-K

**Current Report Pursuant
to Section 13 or 15(d) of the
Securities Exchange Act of 1934**

Date of Report (Date of earliest event Reported): May 12, 2016

HISTOGENICS CORPORATION

(Exact Name of Registrant as Specified in its Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-36751
(Commission
File Number)

04-3522315
(I.R.S. Employer
Identification Number)

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

(Addresses, including zip code, and telephone numbers, including area code, of principal executive offices)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
 - Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
 - Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
 - Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
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Item 2.02. Results of Operations and Financial Condition.

On May 12, 2016, Histogenics Corporation (“Histogenics”) issued a press release and is holding a conference call regarding its results of operations and financial condition for the quarter ended March 31, 2016. The press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated by reference herein.

Various statements to be made during the conference call are “forward-looking statements” under the securities laws. Words such as, but not limited to, “anticipate,” “believe,” “can,” “could,” “expect,” “estimate,” “design,” “goal,” “intend,” “may,” “might,” “objective,” “plan,” “predict,” “project,” “target,” “likely,” “should,” “will,” and “would,” or the negative of these terms and similar expressions or words, identify forward-looking statements. Forward-looking statements are based upon current expectations that involve risks, changes in circumstances, assumptions and uncertainties.

Important factors that could cause actual results to differ materially from those reflected in Histogenics forward-looking statements include, among others: the timing and success of Histogenics’ NeoCart Phase 3 clinical trial, including, without limitation, possible delays in enrolling the NeoCart Phase 3 clinical trial; the ability to obtain and maintain regulatory approval of NeoCart or any product candidates, and the labeling for any approved products; the scope, progress, expansion, and costs of developing and commercializing Histogenics’ product candidates; the ability to obtain and maintain regulatory approval regarding the comparability of critical NeoCart raw materials following our technology transfer and manufacturing location transition; the size and growth of the potential markets for Histogenics’ product candidates and the ability to serve those markets; Histogenics’ expectations regarding its expenses and revenue; the sufficiency of Histogenics’ cash resources and the availability of additional financing on commercially reasonable terms; Histogenics’ ability to attract or retain key personnel; the technologies on which Histogenics’ channel partnering agreement with Intrexon Corporation is based are currently in preclinical and clinical stages of development; Histogenics will incur additional expenses in connection with its exclusive channel collaboration agreement with Intrexon Corporation and other factors that are described in the “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” sections of Histogenics’ Annual Report on Form 10-K for the year ended December 31, 2015, which is on file with the SEC and available on the SEC’s website at www.sec.gov. Additional factors may also be set forth in those sections of Histogenics’ quarterly report on Form 10-Q for the quarter ended March 31, 2016, to be filed with the SEC in the second quarter of 2016. In addition to the risks described above and in Histogenics’ Annual Report on Form 10-K and Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and other filings with the SEC, other unknown or unpredictable factors also could affect Histogenics’ results.

There can be no assurance that the actual results or developments anticipated by Histogenics will be realized or, even if substantially realized, that they will have the expected consequences to, or effects on, Histogenics. Therefore, no assurance can be given that the outcomes stated in such forward-looking statements and estimates will be achieved.

All written and verbal forward-looking statements attributable to Histogenics or any person acting on its behalf are expressly qualified in their entirety by the cautionary statements contained or referred to herein. Histogenics cautions investors not to rely too heavily on the forward-looking statements Histogenics makes or that are made on its behalf. The information conveyed on the conference call will be provided only as of the date of the call, and Histogenics undertakes no obligation, and specifically declines any obligation, to update or revise publicly any forward-looking statements made during the call after the date thereof, whether as a result of new information, future events or otherwise.

The information in Item 2.02 of this Current Report on Form 8-K and the Exhibit attached hereto shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”) or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release of Histogenics Corporation dated May 12, 2016.

SIGNATURE

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

HISTOGENICS CORPORATION

Date: May 12, 2016

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

EXHIBIT INDEX

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**HISTOGENICS CORPORATION ANNOUNCES FIRST QUARTER 2016
FINANCIAL AND OPERATING RESULTS**

- *NeoCart® Phase 3 Clinical Trial Remains on Track for Enrollment
Completion by End of Second Quarter of 2017 -
- Company to Host Conference Call and Webcast Today at 8:30 a.m. EDT -*

WALTHAM, Mass., May 12, 2016 /GLOBE NEWSWIRE/ – Histogenics Corporation (Histogenics) (Nasdaq: HSGX), a regenerative medicine company focused on developing and commercializing products in the musculoskeletal space, announced its financial and operational results for the quarter ended March 31, 2016.

“We made significant progress on a number of important business objectives in the first quarter of 2016. Most importantly, we continued the positive enrollment trends we have seen over the last several months in the NeoCart Phase 3 clinical trial and remain confident that we are on track to complete patient enrollment by the end of the second quarter of 2017,” stated Adam Gridley, President and Chief Executive Officer of Histogenics. “In addition, we completed an important operational milestone for the in-house transfer of critical raw materials for NeoCart and received approval from the FDA to begin using internally produced collagen in the ongoing NeoCart Phase 3 clinical trial. Operationally, the Company is in its strongest position in many years and we believe the completion of enrollment is in sight. We now have expanded rights in Japan, and continued positive feedback from our investigators and the regulatory agencies,” continued Mr. Gridley.

First Quarter 2016 and Recent Highlights

- *NeoCart Phase 3 Clinical Trial Status:* As of May 11, 2016 Histogenics has enrolled 147 of the 245 patients required under the Special Protocol Assessment (SPA) with the United States Food and Drug Administration (FDA) in its NeoCart Phase 3 clinical trial. Recent enrollment trends are continuing to run ahead of the Company’s expectations, with a record 12 patients enrolled in March 2016. As a result, Histogenics remains confident that patient enrollment is on-track and will be complete by the end of the second quarter of 2017. There are 34 sites participating in the clinical trial as of May 11, 2016 and Histogenics continues to identify additional sites for qualification as allowed under the SPA with the FDA.
- *NeoCart Product Rights for Japanese Market:* Histogenics recently reached agreement with its long-time development partner Purpose Co., Ltd (Purpose) to acquire the NeoCart development and commercialization rights for the Japanese market. The amended agreement provides Histogenics the opportunity to capitalize on the recent advancements in regenerative medicine regulatory pathways in Japan, and Histogenics intends to re-engage with Japanese regulatory authorities and seek development and commercialization partners in Japan and elsewhere in Asia.
- *Histogenics Raw Materials Approved by FDA for Use in NeoCart Phase 3 Trial:* Histogenics reached agreement with the FDA in April 2016 regarding the development and transition of the production of certain critical raw materials for NeoCart from third party suppliers to its in-house manufacturing facility in Lexington, Massachusetts. This project was initiated in 2013 in order to control the manufacture and quality systems of Histogenics’ critical raw materials, lower the future cost of goods sold and ensure production capacities for the potential future commercial launch of NeoCart. Following a type C meeting with the FDA in December 2014, Histogenics completed the qualification

runs for its collagen, a key raw material needed for the manufacture of NeoCart, the NeoCart scaffold and adhesive in 2015. In March 2016, Histogenics submitted the supporting data from the qualification runs with its request to the FDA to begin using the internally produced collagen in the current NeoCart Phase 3 clinical trial. Histogenics plans to begin to use the internally produced collagen in the Phase 3 clinical trial in the second quarter of 2016.

- *Intrexon Collaboration:* Histogenics and Intrexon Corporation (Intrexon), Histogenics' collaboration partner for potential next generation products, continued to advance their collaboration for the development of an iPSC chondrocyte program. Histogenics continues to evaluate second-generation NeoCart implants produced at laboratory scale in the last two quarters using the iPSC-derived chondrocytes supplied by Intrexon. The partners generated a significant amount of analytical and comparability data since the beginning of 2016 and have plans to convene a panel of regulatory experts in the second quarter of 2016 to analyze the data and finalize our development and regulatory strategy for the purpose of engaging with the FDA and other regulatory authorities to determine potential future clinical development plans.
- *NeoCart Data Presentations:* In the first quarter of 2016, Histogenics participated in a presentation of non-clinical data at the Orthopaedic Research Society Annual Meeting that were generated as a part of its sponsored research collaboration with Cornell University. The data demonstrated support for the importance of the combination of cells, engineering and scaffold to produce mechanically competent cartilage tissue implants prior to implantation. The results suggest that the maturation of tissue-engineered cartilage implants, such as NeoCart, leads to improved mechanical properties prior to implantation which may be beneficial in the early response and repair of focal cartilage lesions. Histogenics continues to work with its lead clinical investigators on the publication of the five-year data from the NeoCart Phase 2 clinical trial and expects the data to be published in the next few months.

“In early 2016, we have continued to execute by maintaining our recent enrollment momentum in the Phase 3 clinical trial, strengthening the NeoCart development program by working with our partners at Intrexon and Cornell University to generate valuable data, and acquiring the NeoCart product rights for the Japanese market. Our objectives remain focused on the near-term milestones that we believe will create the most value for our shareholders including completing the patient enrollment of the Phase 3 clinical trial and the manufacturing transition of critical raw materials, and potentially exploring commercial partnering alternatives for NeoCart,” stated Mr. Gridley.

Financial Results for the First Quarter of 2016

For the first quarter of 2016, Histogenics reported a net loss attributable to common stockholders of \$(7.9) million, or \$(0.60) per share, compared to \$(8.0) million, or \$(0.60) per share, in the first quarter of 2015.

Research and development expenses were \$5.6 million in the first quarter of 2016, compared to \$5.8 million in the first quarter of 2015. The decrease in expense was primarily due to raw materials purchased in 2015 for the NeoCart Phase 3 clinical trial and a reduction in consulting expense in the first quarter of 2016, which were partially offset by increased headcount and clinical trial related activities in the first quarter of 2016. General and administrative expenses were \$2.2 million in the first quarter of 2016, compared to \$2.1 million in the first quarter of 2015. The increase was due to increased recruiting fees and stock compensation expense, which were partially offset by decreased insurance premiums.



At March 31, 2016 Histogenics had cash, cash equivalents and marketable securities of \$22.9 million, compared to \$30.9 million at December 31, 2015. Histogenics' believes its current cash position will fund its operations into the first quarter of 2017.

Conference Call and Webcast Information

Management will host a conference call on Thursday, May 12, 2016 at 8:30 a.m. EDT. A question-and-answer session will follow Histogenics' remarks. To participate on the live call, please dial (877) 930-8064 (domestic) or (253) 336-8040 (international) and provide the conference ID "88447041" five to ten minutes before the start of the call.

A live audio webcast of the presentation will be available via the "Investor Relations" page of the Histogenics website, www.histogenics.com. A replay of the webcast will be archived on Histogenics' website for approximately 45 days following the presentation.

About Histogenics Corporation

Histogenics is a leading regenerative medicine company developing and commercializing products in the musculoskeletal segment of the marketplace. Histogenics' regenerative medicine platform combines expertise in cell processing, scaffolding, tissue engineering, bioadhesives and growth factors to provide solutions to treat musculoskeletal-related conditions. Histogenics' first investigational product candidate, NeoCart, is currently in Phase 3 clinical development. NeoCart is an autologous cell therapy designed to treat cartilage defects in the knee using the patient's own cells. Knee cartilage defects represent a significant opportunity in the United States, with an estimated 500,000 or more applicable procedures each year. NeoCart is designed to exhibit characteristics of articular, hyaline cartilage prior to and upon implantation into the knee and therefore does not rely on the body to make new cartilage, characteristics not exhibited in other current treatment options. For more information, please visit www.histogenics.com.

Forward-Looking Statements

Various statements in this release, including, but not limited to, the market in Japan for the sale of NeoCart and Histogenics' ability to find a partner for such market, financial guidance regarding how long Histogenics' current cash position will fund operations and comments about the clinical development of NeoCart, the transition of Histogenics' manufacturing capabilities and Histogenics' collaboration with Intrexon are "forward-looking statements" under the securities laws. Words such as, but not limited to, "anticipate," "believe," "can," "could," "expect," "estimate," "design," "goal," "intend," "may," "might," "objective," "plan," "predict," "project," "target," "likely," "should," "will," and "would," or the negative of these terms and similar expressions or words, identify forward-looking statements. Forward-looking statements are based upon current expectations that involve risks, changes in circumstances, assumptions and uncertainties.

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

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



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

	<u>March 31,</u> <u>2016</u>	<u>December 31,</u> <u>2015</u>
Cash and cash equivalents	\$ 22,897	\$ 30,915
Prepaid expenses and other current assets	466	321
Property and equipment, net	4,815	5,213
Other assets, net	337	337
Total assets	<u>\$ 28,515</u>	<u>\$ 36,786</u>
Current liabilities	\$ 5,975	\$ 6,359
Non-current liabilities	1,948	2,229
Total stockholder's equity	20,592	28,198
Total liabilities and stockholders' equity	<u>\$ 28,515</u>	<u>\$ 36,786</u>

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SOURCE: Histogenics Corporation