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): August 11, 2016

HISTOGENICS CORPORATION
(Exact Name of Registrant as Specified in its Charter)

Delaware	**001-36751**	**04-3522315**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(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))

Item 2.02. Results of Operations and Financial Condition.

On August 11, 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 June 30, 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 sufficiency of Histogenics' cash resources and the availability of additional financing on commercially reasonable terms; 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; 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 and Quarterly Report on Form 10-Q for the quarter ended March 31, 2016, which are 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 June 30, 2016, to be filed with the SEC in the third 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***

Exhibit No.	Description
99.1	Press release of Histogenics Corporation dated August 11, 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: August 11, 2016

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

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press release of Histogenics Corporation dated August 11, 2016.

HISTOGENICS CORPORATION ANNOUNCES SECOND QUARTER 2016 FINANCIAL AND OPERATING RESULTS

- NeoCart® Phase 3 Clinical Trial Remains on Track for Enrollment Completion by End of Second Quarter of 2017 -
- Increasing Year-End 2016 Enrollment Guidance to 190 to 200 patients -
- Company to Host Conference Call and Webcast Today at 8:30 a.m. EDT -

WALTHAM, Mass., August 11, 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 June 30, 2016.

"We are very pleased with the progress we have made during the first half of 2016. Our underlying business fundamentals continue to strengthen, with enrollment ahead of plan and our continued transition to fully integrated manufacturing in support of our anticipated BLA filing with the FDA," stated Adam Gridley, President and Chief Executive Officer of Histogenics. "With our recent operational success, we continue to narrow our focus on upcoming near-term milestones, including enrollment progress, an interim analysis in early 2017 and continued progress on our pipeline activities in Japan and with our partner Intrexon. We will also continue to explore potential commercial partnering alternatives for NeoCart that may enable us to further expand this important therapy outside of the U.S.," continued Mr. Gridley.

Second Quarter 2016 and Recent Highlights

- *NeoCart Phase 3 Clinical Trial Status:* As of August 10, 2016 Histogenics has enrolled 167 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. Following a strong start to the year, recent increasing enrollment trends continue to run ahead of Histogenics' expectations. As a result, Histogenics is narrowing its year-end enrollment guidance by increasing the low end of the range from 180 to 190 patients. In addition, Histogenics confirms its expectations that patient enrollment will be complete by the end of the second quarter of 2017. There are 35 sites participating in the clinical trial as of August 10, 2016.
- *NeoCart Product Rights for Japanese Market:* Histogenics acquired the NeoCart development and commercialization rights for the Japanese market from its long-time, development partner Purpose Co., Ltd (Purpose). Histogenics intends to capitalize on the recent advancements in regenerative medicine regulatory pathways in Japan and its robust Phase 1 and 2 data packages. Additionally, Histogenics is re-engaging with Japanese regulatory authorities with the next informal and formal meetings targeted for the second half of 2016. In parallel, Histogenics is engaging with development and commercialization partners in Japan and elsewhere in Asia with a goal of securing commercial partners after receiving clarity on the path to commercialization from the Japanese regulatory authorities.
- *Histogenics Raw Materials Approved by FDA and Incorporated into 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 is another milestone in a project that was initiated in 2013 with several goals, including improving the quality of critical raw materials, lowering

the future cost of goods sold and ensuring ample supply to support both the ongoing clinical trial and the potential future commercial launch of NeoCart. In 2015, Histogenics completed the qualification runs for its collagen, a key raw material needed for the manufacture of NeoCart with submission of the supporting data to the FDA in March of 2016. In April 2016, the FDA approved the use of the internally produced collagen and Histogenics began using this material in the ongoing Phase 3 trial in June 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. The partners held a meeting of medical, regulatory and scientific experts to both evaluate the analytical and comparability data generated since the beginning of 2016 and determine the most efficient development plan and regulatory pathway. The partners are currently using feedback from the meeting to determine the need for any additional work prior to engaging with the FDA and other regulatory authorities and anticipate the identification of a development plan prior to the end of 2016.

"We have now enrolled approximately two-thirds of the 245 patients required to complete the NeoCart Phase 3 clinical trial under the SPA. Based on the recent positive enrollment trend, we are increasing the bottom range of our enrollment guidance to 190 patients for revised guidance of 190 to 200 patients enrolled in the trial by the end of 2016," stated Mr. Gridley.

Financial Results for the Second Quarter of 2016

For the second quarter of 2016, Histogenics reported a net loss attributable to common stockholders of $(8.0) million, or $(0.61) per share, compared to $(7.6) million, or $(0.58) per share, in the second quarter of 2015.

Research and development expenses were $5.8 million in the second quarter of 2016, compared to $5.9 million in the second quarter of 2015. The decrease in expense was primarily due to raw materials purchases in the second quarter of 2015 to support the NeoCart Phase 3 clinical trial combined with a reduction in consulting expense in the second quarter of 2016. This decrease was partially offset by an increase in headcount and clinical trial related expenses in the second quarter of 2016. General and administrative expenses were $2.2 million in the second quarter of 2016, compared to $1.7 million in the second quarter of 2015. The increase was primarily due to higher salaries, facility-related and legal costs which were partially offset by a reduction in consulting expense.

At June 30, 2016, Histogenics had cash, cash equivalents and marketable securities of $15.9 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, August 11, 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 "32244215" 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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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.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
Revenue	$ —	$ —	$ —	$ —
Operating expenses:				
Research and development	5,794	5,858	11,380	11,622
General and administrative	2,161	1,735	4,373	3,844
Total operating expenses	7,955	7,593	15,753	15,466
Loss from operations	(7,955)	(7,593)	(15,753)	(15,466)
Other expense:				
Interest expense, net	(17)	(26)	(36)	(88)
Other expense, net	(66)	(14)	(167)	(43)
Total other expense, net	(83)	(40)	(203)	(131)
Net loss	$ (8,038)	$ (7,633)	$ (15,956)	$ (15,597)
Loss attributable to common stockholders - basic and diluted	$ (8,038)	$ (7,633)	$ (15,956)	$ (15,597)
Loss per common share - basic and diluted:	$ (0.61)	$ (0.58)	$ (1.20)	$ (1.18)
Weighted-average shares used to compute loss per common share - basic and diluted:	13,270,433	13,215,701	13,270,531	13,208,483

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

	June 30, 2016	December 31, 2015
Cash and cash equivalents	$15,926	$ 30,915
Prepaid expenses and other current assets	350	321
Property and equipment, net	4,665	5,213
Other assets, net	337	337
Total assets	$21,278	$ 36,786
Current liabilities	$ 6,721	$ 6,359
Non-current liabilities	1,668	2,229
Total stockholder's equity	12,889	28,198
Total liabilities and stockholders' equity	$21,278	$ 36,786

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SOURCE: Histogenics Corporation