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): November 10, 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 November 10, 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 September 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 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; the sufficiency of Histogenics' cash resources and the availability of additional financing on commercially reasonable terms; 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 June 30, 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 September 30, 2016, to be filed with the SEC in the fourth 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 November 10, 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: November 10, 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 November 10, 2016.

HISTOGENICS CORPORATION ANNOUNCES THIRD QUARTER 2016 FINANCIAL AND OPERATING RESULTS

- NeoCart® Phase 3 Clinical Trial More than 75% Enrolled -

- Enrollment On-Track to Complete by End of Second Quarter of 2017 -

- Third Quarter Financing Expected to Fund Company to Phase 3 Data -

- Company to Host Conference Call and Webcast Today at 8:30 a.m. EST -

WALTHAM, Mass., November 10, 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 September 30, 2016.

"We continue to execute on our strategy and operating initiatives in the third quarter of 2016. We have now enrolled more than three-quarters of the 245 patients required to complete our NeoCart Phase 3 clinical trial, and made continued progress on the manufacturing elements of the NeoCart development program. Enrollment is expected to be completed prior to the end of the second quarter of 2017, and we are preparing for the top-line data in the middle of 2018 and a BLA submission shortly thereafter," stated Adam Gridley, President and Chief Executive Officer of Histogenics. "Furthermore, we believe that the financing completed in the third quarter of 2016 was in large part due to our execution over the last year and the recognition of the market opportunity for this important therapy. We believe we are now funded to our expected top-line Phase 3 data read-out in mid-2018," continued Mr. Gridley.

Third Quarter 2016 and Recent Highlights

- *NeoCart Phase 3 Clinical Trial Status:* As of November 9, 2016 Histogenics has enrolled 186 of the 245 patients required under the Special Protocol Assessment (SPA) with the United States Food and Drug Administration (the FDA) in its NeoCart Phase 3 clinical trial. Enrollment trends have remained strong in each of the completed three quarters of 2016 and continue to run ahead of Histogenics' expectations. As a result, Histogenics confirms both its year-end enrollment guidance of 190 to 200 patients and its expectations that patient enrollment will be complete by the end of the second quarter of 2017. As of November 9, 2016, there were 33 sites participating in the clinical trial.
- *Completion of $30 Million Financing:* Histogenics completed a $30 million private placement of common stock, Series A Convertible Preferred Stock and warrants in September 2016. The financing was led by new healthcare-focused, institutional investors and supported by existing Histogenics investors. Histogenics believes the financing will enable it to reach its objective of generating top-line data from the ongoing NeoCart Phase 3 clinical trial in the middle of 2018.
- *Additional Progress on NeoCart Critical Raw Materials:* Having reached agreement with the FDA on internally produced collagen in April 2016, and incorporating this material in the ongoing Phase 3 trial beginning in June 2016, Histogenics reached agreement with the FDA in August 2016 regarding the qualification plan for the NeoCart collagen scaffold to its in-house manufacturing facility in Lexington, Massachusetts. Histogenics is in the process of qualifying those materials to be used upon commercialization of NeoCart, if approved.
- *Additional Discussions with Japanese Regulatory Authority:* During the third quarter of 2016, Histogenics continued its dialog with the Japan Pharmaceuticals and Medical Devices Agency (PMDA) regarding the development of NeoCart for the Japanese market. There were two informal

meetings to discuss the NeoCart Phase 1 and Phase 2 data generated to date, the proposed development program and the required regulatory submission package for potential conditional approval. In the first half of 2017, Histogenics intends to conduct formal meetings with the PMDA to define and agree upon the regulatory pathway and development requirements for the potential conditional approval of NeoCart in Japan. Histogenics intends to leverage the results of these meetings to create value in discussions with potential partners for the Japanese market.

- *Intrexon Collaboration:* Histogenics and Intrexon Corporation continue to generate compelling proof-of-concept data demonstrating our ability to make iPSC derived chondrocytes as measured by the same cartilage biomarkers as NeoCart. The partners are currently working on a strategy to engage with the FDA and other regulatory authorities and anticipate the identification of a development plan in the first half of 2017.
- *Expansion of Scientific Advisory Board:* Histogenics recently expanded its Scientific Advisory Board (SAB) with the addition of Professor Lawrence Bonassar, a leading researcher in the field of cartilage biomechanics and tissue engineering, including the structure-property relationships in cartilage to elucidate mechanisms of disease and inform the design of tissue replacement. Dr. Bonassar is a Professor at Cornell University in the Meinig School of Biomedical Engineering and the Sibley School of Mechanical and Aerospace Engineering. As part of a Sponsored Research Agreement, Dr. Bonassar's lab and Histogenics have successfully demonstrated the biomechanical competence of cartilage tissue engineered using the NeoCart manufacturing technology. The work has resulted in three presentations including one at the Orthopedic Research Society annual meeting in March 2016 and a more recent presentation at the Biomedical Engineering Society Annual Meeting in October 2016.

Financial Results for the Third Quarter of 2016

For the third quarter of 2016, Histogenics reported a loss from operations of $(6.6) million compared to $(8.0) million in the third quarter of 2015. The decrease in operating expenses was driven by reductions in both research and development and general and administrative expenses.

Research and development expenses were $4.9 million in the third quarter of 2016, compared to $5.8 million in the third quarter of 2015. The decrease in expense was primarily due to a reduction in consulting and temporary labor costs, hiring fees, and raw materials and patient recruiting expenses related to the NeoCart Phase 3 clinical trial. This decrease was partially offset by an increase in clinical trial related expenses and facility-related and other expenses in the third quarter of 2016. General and administrative expenses were $1.8 million in the third quarter of 2016, compared to $2.2 million in the third quarter of 2015. The decrease was primarily due to a reduction in hiring fees, facility-related costs and legal and consulting costs which were partially offset by an increase in stock-based compensation expense.

For the third quarter of 2016, Histogenics reported a net loss attributable to common stockholders of $(9.2) million, or $(0.70) per share, compared to $(8.1) million, or $(0.61) per share, in the third quarter of 2015. The increase in net loss attributable to common stockholders is primarily due to accounting charges related to the warrants issued as part of the financing that was completed in September 2016 and was partially offset by the aforementioned reductions in operating expenses.

At September 30, 2016, Histogenics had cash, cash equivalents and marketable securities of $38.0 million, compared to $30.9 million at December 31, 2015. Histogenics believes its current cash position will fund its operations into the middle of 2018.

Conference Call and Webcast Information

Management will host a conference call on Thursday, November 10, 2016 at 8:30 a.m. EST. 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 "73416804" 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

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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.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Revenue	$ —	$ —	$ —	$ —
Operating expenses:				
Research and development	4,880	5,848	16,260	17,470
General and administrative	1,768	2,191	6,141	6,035
Total operating expenses	6,648	8,039	22,401	23,505
Loss from operations	(6,648)	(8,039)	(22,401)	(23,505)
Other (expense) income:				
Interest expense, net	(20)	(23)	(55)	(111)
Other expense, net	(130)	(16)	(298)	(59)
Warrant expense	(3,056)	—	(3,056)	—
Change in fair value of warrant liability	539	—	539	—
Total other expense, net	(2,667)	(39)	(2,870)	(170)
Net loss	$ (9,315)	$ (8,078)	$ (25,271)	$ (23,675)
Loss attributable to common stockholders - basic and diluted	$ (9,234)	$ (8,078)	$ (25,197)	$ (23,675)
Loss per common share - basic and diluted:	$ (0.70)	$ (0.61)	$ (1.90)	$ (1.79)
Weighted-average shares used to compute loss per common share - basic and diluted:	13,297,546	13,238,997	13,279,833	13,218,765

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

	September 30, 2016	December 31, 2015
Cash and cash equivalents	$ 37,994	$ 30,915
Prepaid expenses and other current assets	201	321
Property and equipment, net	4,263	5,213
Other assets, net	337	337
Total assets	$ 42,795	$ 36,786
Current liabilities	$ 7,209	$ 6,359
Warrant and other non-current liabilities	31,550	2,229
Total stockholder's equity	4,036	28,198
Total liabilities and stockholders' equity	$ 42,795	$ 36,786

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SOURCE: Histogenics Corporation