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 12, 2015

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 12, 2015, Histogenics Corporation (the "Company" or "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, 2015. 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 the Company's 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 needs for additional financing; 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, 2014 and Quarterly Report on Form 10-Q for the quarter ended June 30, 2015, 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, 2015, to be filed with the SEC in the fourth quarter of 2015. 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 12, 2015.

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 12, 2015

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 12, 2015.

HISTOGENICS CORPORATION ANNOUNCES THIRD QUARTER 2015 FINANCIAL AND OPERATING RESULTS

- Completion of Enrollment of NeoCart® Phase 3 Trial Now Expected in Second Quarter of 2017 -
- Company to Host Conference Call and Webcast Today at 8:30 a.m. EST -

WALTHAM, Mass., November 12, 2015 /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, 2015.

"With our new team fully in-place, we are working aggressively to enroll our NeoCart Phase 3 clinical trial, complete the technical transfer activities for our manufacturing operations, continue to support our collaboration with Intrexon, and explore opportunities to enhance and expand our pipeline," stated Adam Gridley, President and Chief Executive Officer of Histogenics. "We are disappointed that the trial will take longer to enroll than initially expected, but are encouraged by what we see and hear from our investigators regarding their patients that receive NeoCart in the trial and we will be carefully managing our operations to achieve our enrollment goals."

Third Quarter 2015 and Recent Highlights

- Histogenics has enrolled a total of 103 patients in its NeoCart Phase 3 trial and now expects to complete enrollment by the end of the second quarter of 2017. Histogenics completed in the second and third quarters several enrollment optimization initiatives, which included a change in patient recruiting efforts as well as changes to the site initiation process. These efforts are beginning to positively impact enrollment. In addition, Histogenics continues to change the mix of sites with a goal of increasing the rate of enrollment. In the third quarter, Histogenics closed several more low-performing clinical sites than originally anticipated and now has 32 sites in this trial. Histogenics' new clinical leadership has already identified additional investigative sites to bring the total to the 40 permitted sites in the first quarter of 2016.
- Histogenics recently completed the last performance qualification manufacturing run for collagen, which is a key raw material needed for the manufacture of NeoCart. In the coming months, Histogenics intends to complete the manufacturing transition of the remaining raw materials, including the scaffold component and surgical adhesive for NeoCart, pending approval by the United States Food and Drug Administration.
- Histogenics and Intrexon Corporation (Intrexon), Histogenics' collaboration partner for potential next generation products, are pursuing an induced pluripotent stem cells (iPSC) approach, and continue to make excellent progress on a multi-step process development plan for an iPSC chondrocyte program. The partners have multiple scientific pathways ongoing with plans for a pilot manufacturing run in the first quarter of 2016 using Intrexon's cell line in the NeoCart cell and tissue engineering manufacturing process.
- In October 2015, Histogenics received a United States Patent regarding a method of preparing an implant for cartilage repair. Histogenics believes this patent further enhances the protection around Histogenics' NeoCart proprietary collagen scaffolds.
- In September and October 2015, Histogenics hosted its first Scientific Advisory Board meetings focused on its tissue engineering and biomaterials capabilities, and on its future stem cell and regenerative medicine platform opportunities. Feedback from the members of the Scientific Advisory Board was universally positive regarding the quality of the data generated to date from the laboratory work as well as the clinical trials, and Histogenics looks forward to exploring further opportunities to expand its future pipeline.

- Histogenics has initiated discussions around various business development opportunities including collaborations around the commercial rights to NeoCart outside of the United States, including recent discussions with our licensing partner in Japan with regards to an accelerated regulatory process in that market.

"We have now identified and consented almost half of the patients in the NeoCart Phase 3 clinical trial and believe that we are beginning to see the early results from the changes we made to our clinical strategy in the second and third quarters of 2015," stated Dr. Gloria Matthews, Histogenics' Chief Medical Officer. "We believe the positive momentum that we have recently seen is a result of our new approach that focuses on replacing certain existing sites with higher-enrolling sites; focused, local patient recruiting done in conjunction with the investigators; and a practice management mindset in close cooperation with study coordinators," concluded Dr. Matthews.

Financial Results for the Third Quarter of 2015

For the third quarter of 2015, Histogenics reported a net loss attributable to common stockholders of $(8.1) million, or $(0.61) per share, compared to $(12.0) million, or $(19.38) per share, in the third quarter of 2014. The third quarter of 2014 included a $3.0 million gain related to fair value adjustments to certain liabilities that were either settled or terminated upon the closing of Histogenics' initial public offering in the fourth quarter of 2014.

Research and development expenses were $5.8 million in the third quarter of 2015, compared to $13.2 million in the third quarter of 2014. The decrease in expense was primarily due to the expensing of license rights valued at $10.0 million and acquired as part of Histogenics' exclusive channel collaboration with Intrexon Corporation in 2014 and was partially offset by higher costs related to the NeoCart Phase 3 clinical trial and related development and manufacturing activities. General and administrative expenses were $2.2 million in the third quarter of 2015, compared to $1.7 million in the third quarter of 2014. The increase was due to various public company costs such as increased insurance premiums, board fees and stock compensation expense.

At September 30, 2015 Histogenics had cash, cash equivalents and marketable securities of $37.7 million, compared to $58.1 million at December 31, 2014. Histogenics' believes its current cash position will fund its operations into 2017.

Conference Call and Webcast Information

Management will host a conference call on Thursday, November 12, 2015 at 8:30 a.m. EST. A question-and-answer session will follow Histogenics' remarks. To participate on the live call, please dial (855) 890-8663 (domestic) or (720) 634-2936 (international) and provide the conference ID "60793192" 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 30 days following the presentation.

About Histogenics Corporation

Histogenics is a regenerative medicine company focused on 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 that can be utilized individually or in concert to treat musculoskeletal-related conditions. Histogenics' first investigational product candidate, NeoCart, leverages its platform to provide an innovative treatment in the orthopedic space, specifically cartilage damage in the knee.

Forward-Looking Statements

Various statements in this release, including, but not limited to, the guidance provided above, 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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and Histogenics undertakes no obligation, and specifically declines any obligation, to update or revise publicly any forward-looking statements, whether as a result of new information, future events or otherwise.

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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,	
	2015	2014	2015	2014
Operating expenses:				
Research and development	$ 5,848	$ 13,237	$ 17,470	$ 21,280
General and administrative	2,191	1,703	6,035	4,843
Total operating expenses	8,039	14,940	23,505	26,123
Loss from operations	$ (8,039)	$ (14,940)	$ (23,505)	$ (26,123)
Other income (expense):				
Interest expense, net	$ (23)	$ (19)	$ (111)	$ (19)
Other income (expense), net	(16)	(1)	(59)	(6)
Change in fair value of warrant liability, other liability and net sales distribution payment liability	—	2,986	—	2,435
Total other income (expense), net	(39)	2,966	(170)	2,410
Net loss	$ (8,078)	$ (11,974)	$ (23,675)	$ (23,713)
Loss attributable to common stockholders - basic and diluted	$ (8,078)	$ (11,974)	$ (23,675)	$ (27,233)
Loss per common share - basic and diluted:	$ (0.61)	$ (19.38)	$ (1.79)	$ (45.49)
Weighted-average shares used to compute earnings per common share - basic and diluted:	13,238,997	617,860	13,218,765	598,684

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

	September 30, 2015 (unaudited)	December 31, 2014
Cash and cash equivalents	$ 37,723	$ 58,060
Prepaid expenses and other current assets	365	796
Property and equipment, net	5,513	4,878
Other assets, net	1,700	1,765
Total assets	$ 45,301	$ 65,499
Current liabilities	6,690	8,251
Non-current liabilities	2,435	3,042
Total stockholder's equity	36,176	54,206
Total liabilities and stockholders' equity	$ 45,301	$ 65,499

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SOURCE: Histogenics Corporation