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): March 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 March 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 full year and quarter ended December 31, 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 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, 2014 and Quarterly Report on Form 10-Q for the quarter ended September 30, 2015, which are on file with the SEC and available on the SEC's website at www.sec.gov. Additional information will also be set forth in those sections of Histogenics' Annual Report on Form 10-K for the year ended December 31, 2015, which will be filed with the SEC in the first 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 March 10, 2016.

SIGNATURE

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 hereunto duly authorized.

HISTOGENICS CORPORATION

Date: March 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 March 10, 2016.

HISTOGENICS CORPORATION ANNOUNCES FINANCIAL AND OPERATING RESULTS FOR THE FOURTH QUARTER AND YEAR ENDED DECEMBER 31, 2015

- NeoCart® Phase 3 Clinical Trial More Than 50% Enrolled and on Track for Full Enrollment by End of Second Quarter of 2017 -
- Company to Host Conference Call and Webcast Today at 8:30 a.m. EST -

WALTHAM, Mass., March 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 year ended December 31, 2015.

"2015 was a year of transition for Histogenics. We made significant progress toward our long-term business objectives by strengthening our management team with several key hires, changing and augmenting our approach to recruiting the NeoCart Phase 3 clinical trial and continuing to advance both the technical transfer activities for our manufacturing operations and our collaboration with Intrexon," stated Adam Gridley, President and Chief Executive Officer of Histogenics. "We believe that the recruiting and investigator changes we put in place for the NeoCart Phase 3 clinical trial are having a positive impact on our enrollment rates and remain confident that we will complete enrollment by the end of the second quarter of 2017."

2015 and Recent Highlights

- *NeoCart Phase 3 Clinical Trial Status:* As of March 9, 2016 Histogenics has enrolled a total of 132 patients in its NeoCart Phase 3 clinical trial, with recent enrollment trends running slightly ahead of previous guidance. As a result, Histogenics remains confident that enrollment is on-track and that it will complete the Phase 3 clinical trial by the end of the second quarter of 2017. In the second and third quarters of 2015, Histogenics made several changes to its approach to enrolling the Phase 3 clinical trial, including changing the mix of sites participating in the trial as well as changing the tactics used to recruit patients into the trial. There are 33 sites participating in the clinical trial as of March 9, 2016 and Histogenics has plans to bring the total to the 40 sites allowed under the Special Protocol Assessment (SPA) with the United States Food and Drug Administration (FDA) for the clinical trial in the coming months.
- *NeoCart Phase 3 Clinical Trial Amendment:* In December 2015, the FDA accepted Histogenics' amendment to the Phase 3 clinical trial protocol to change certain inclusion/exclusion criteria. Changes to the enrollment criteria include, among other things, accepting patients with trochlear lesions into the clinical trial which may expand the eligible patient population without impacting the robust design of the clinical trial. The amendment was rolled out to the sites in the first quarter of 2016 and appears to be having an impact on enrollment trends. The protocol amendment was submitted, and the clinical trial is being conducted under, the SPA.
- *Manufacturing Transition.* Histogenics continued to work internally and with the FDA to complete the transition and regulatory approval of the production of certain raw materials for NeoCart from third party suppliers to its in-house manufacturing facility. In December 2014, Histogenics received affirmative feedback from the FDA on the path forward for this transition. During the year ended December 31, 2015 Histogenics completed the qualification runs for collagen, a key raw material needed for the manufacture of NeoCart, the NeoCart scaffold and adhesive. Histogenics continues working to complete the manufacturing transition of the remaining raw materials, including the scaffold component and surgical adhesive for NeoCart.

- *Intrexon Collaboration.* Histogenics and Intrexon Corporation (Intrexon), Histogenics' collaboration partner for potential next generation products, significantly advanced their collaboration in the fourth quarter of 2015. The partners are pursuing an induced pluripotent stem cells (iPSC) approach, and continue to make significant progress on a multi-step process development plan for an iPSC chondrocyte program. Histogenics is currently evaluating the laboratory scale manufacture of second-generation NeoCarts using the iPSC chondrocytes supplied by Intrexon. Initial results are promising, and the iPSC NeoCarts produced exhibit critical biomarkers of cartilage production. The partners are developing regulatory strategies and data packages to engage with the FDA regarding the next appropriate clinical development steps.
- *Management Team and Board of Directors.* Histogenics strengthened its Board of Directors and management team with the addition of David Gill, President and Chief Financial Officer of EndoChoice, Inc. in February 2015, the promotion of Steve Kennedy to Chief Technology Officer in July 2015 and the hiring of Jon Lieber, Gloria Matthews and Amnon Eylath as Chief Financial Officer, Chief Medical Officer and Vice President of Quality Operations, respectively, in the second half of 2015. With these additions, Histogenics now has a team in place with deep experience to ensure the execution of its operational and strategic plans.
- *Scientific Advisory Board.* Histogenics established a new Scientific Advisory Board (SAB) comprised of internationally renowned scientists and researchers. The SAB's mission is to provide strategic scientific and technical oversight as Histogenics brings NeoCart through its Phase 3 clinical trial, leverages its biomaterials manufacturing experience, and advances its product pipeline. The SAB held its first meetings in the fall of 2015.

2016 Corporate Objectives

- *NeoCart Clinical Development.* Histogenics expects to have 180 to 200 patients enrolled in the NeoCart Phase 3 clinical trial by the end of 2016. In addition to continued Phase 3 clinical trial enrollment, Histogenics expects scientific publications relating to NeoCart in 2016 including five-year data and MRI data from the completed Phase 2 clinical trial, and initial bench and preclinical data related to the Intrexon collaboration.
- *NeoCart Manufacturing Transition.* Histogenics intends to work with the FDA to complete the manufacturing transition of collagen and the collagen scaffold and include these materials in the ongoing NeoCart Phase 3 clinical trial.
- *Intrexon Collaboration.* Histogenics will continue to work on the manufacture of and complete the proof-of-concept testing on a NeoCart implant using Intrexon's iPSC technology. Subject to generating positive data from these activities, Histogenics plans to provide a strategy for the potential development of a one-step, next generation NeoCart.

"The changes we made in 2015 to our clinical trial strategy and management team provide a solid foundation for us to complete our NeoCart Phase 3 clinical trial, and we are now focused on execution of our objectives for 2016," stated Mr. Gridley. "We are pleased with the enrollment rates we have seen over the last few months in the NeoCart Phase 3 clinical trial as well as with the progress we have made on the other aspects of the NeoCart development program. We look forward to a successful year in 2016," concluded Mr. Gridley.

Financial Results for the Year Ended December 31, 2015

For the year ended December 31, 2015, Histogenics reported a net loss attributable to common stockholders of $(32.0) million, or $(2.42) per share, compared to $(10.5) million, or $(6.85) per share, for the year ended December 31, 2014. The year ended December 31, 2014 included a $10.0 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 $23.2 million for the year ended December 31, 2015, compared to $26.0 million for the year ended December 31, 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 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 $8.3 million for the year ended December 31, 2015, compared to $6.6 million for the year ended December 31, 2014. The increase was due to various public company costs such as increased insurance premiums, board fees and stock compensation expense.

At December 31, 2015 Histogenics had cash, cash equivalents and marketable securities of $30.9 million, compared to $58.5 million at December 31, 2014. Histogenics' believes its current cash position will fund its operations through the first quarter of 2017.

Conference Call and Webcast Information

Management will host a conference call on Thursday, March 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 "60614260" 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 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 2016 corporate objectives, the financial guidance regarding how long the 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)

	Three Months Ended December 31,		Year Ended December 31,	
	2015	2014	2015	2014
Operating expenses:				
Research and development	$ 5,773	$ 4,654	$ 23,243	$ 26,037
General and administrative	2,231	1,825	8,266	6,565
Impairment of intangible asset	310	60	310	60
Total operating expenses	8,314	6,539	31,819	32,662
Loss from operations	$ (8,314)	$ (6,539)	$ (31,819)	$ (32,662)
Other income (expense):				
Interest expense, net	$ (22)	$ (132)	$ (133)	$ (151)
Other income (expense), net	(13)	19	(72)	13
Change in fair value of warrant liability, other liability and net sales distribution payment liability	—	7,572	—	10,007
Total other income (expense), net	(35)	7,459	(205)	9,869
Net Earnings (Loss)	$ (8,349)	$ 920	$ (32,024)	$ (22,793)
Earnings (Loss) attributable to common stockholders – basic	$ (8,349)	$ 9,629	$ (32,024)	$ (10,510)
Earnings (Loss) attributable to common stockholders – diluted	$ (8,349)	$ 9,676	$ (32,024)	$ (10,510)
Earnings (Loss) per common share – basic:	$ (0.63)	$ 2.23	$ (2.42)	$ (6.85)
Earnings (Loss) per common share – diluted:	$ (0.63)	$ 1.70	$ (2.42)	$ (6.85)
Weighted-average shares used to compute earnings per common share – basic:	13,266,866	4,309,880	13,231,126	1,534,108
Weighted-average shares used to compute earnings per common share – diluted	13,266,866	5,691,162	13,231,126	1,534,108

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

	December 31, 2015	December 31, 2014
Cash and cash equivalents	$ 30,915	$ 58,527
Prepaid expenses and other current assets	321	796
Property and equipment, net	5,213	4,878
Other assets, net	337	1,298
Total assets	$ 36,786	$ 65,499
Current liabilities	$ 6,359	$ 7,600
Non-current liabilities	2,229	3,693
Total stockholder's equity	28,198	54,206
Total liabilities and stockholders' equity	$ 36,786	$ 65,499

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SOURCE: Histogenics Corporation