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 11, 2017

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))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 2.02. Results of Operations and Financial Condition.

On May 11, 2017, 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, 2017. 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; 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; 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; the early stage of development of the technologies on which Histogenics' channel partnering agreement with Intrexon Corporation is based; the additional expenses that Histogenics will incur 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, 2016, which is on file with the U.S. Securities and Exchange Commission ("SEC") and available on the SEC's website at www.sec.gov. Additional factors may be set forth in those sections of Histogenics' Quarterly Report on Form 10-Q for the quarter ended March 31, 2017, to be filed with the SEC in the second quarter of 2017. 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 May 11, 2017.

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: May 11, 2017

By: /s/ Adam Gridley

Adam Gridley
President and Chief Executive Officer

HISTOGENICS CORPORATION ANNOUNCES FIRST QUARTER 2017 FINANCIAL AND OPERATING RESULTS

– NeoCart® Phase 3 Clinical Trial Enrollment Near Completion –
– NeoCart Approval Pathway in Japan Defined After Successful Conclusion of Discussions with the Japan Pharmaceuticals and Medical Devices Agency –
– Publication of Additional Data to Support Potential Approval and Commercialization of NeoCart –
– Company to Host Conference Call and Webcast Today at 8:30 a.m. EDT –

WALTHAM, Mass., May 11, 2017 /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, 2017.

"In the first quarter of 2017, we continued to execute on our important near- and long-term business objectives. Importantly, we enrolled an additional 23 patients in the NeoCart Phase 3 clinical trial, and completed a series of productive formal meetings with the PMDA in Japan where we determined a near-term regulatory pathway for NeoCart to gain full Marketing Authorization in the Japanese market," stated Adam Gridley, President and Chief Executive Officer of Histogenics. "We are pleased to report continued strength in our enrollment of the clinical trial, which is expected to conclude this quarter. We also continue to build on our strong portfolio of bench and clinical data with several new publications on the clinical and biomechanical performance of NeoCart. This contributes to our goal of a rapid BLA filing in the second half of 2018, and helps prepare us for the potential commercialization of NeoCart in 2019, pending positive results from the NeoCart Phase 3 clinical trial and FDA approval," continued Mr. Gridley.

First Quarter 2017 and Recent Highlights

- *Enrollment Stage of NeoCart Phase 3 Clinical Trial Nearing Completion:* As of May 10, 2017, Histogenics has enrolled 230 of the 245 patients required under the Special Protocol Assessment (SPA) with the United States Food and Drug Administration in the NeoCart Phase 3 clinical trial. The 15 patients required to complete enrollment are currently in various stages of the screening process and Histogenics confirms its expectation that patient enrollment in the Phase 3 clinical trial will be complete by the end of the second quarter of 2017, with an announcement in early July 2017.
- *Discussions with Japanese Regulatory Authorities and Identification of NeoCart Development Pathway in Japan:* In the first quarter of 2017, Histogenics reached agreement with the Japan Pharmaceuticals and Medical Devices Agency (PMDA) regarding the required regulatory pathway for NeoCart to gain full Marketing Authorization in Japan. Based on the strength of the NeoCart clinical and non-clinical data package and the long history of current good manufacturing practices for NeoCart, the PMDA agreed that the additional clinical data required for full Marketing Authorization would be a small 30-patient, one-year confirmatory clinical trial in Japanese patients that compares NeoCart to microfracture. The data from this small trial, along with the one-year U.S. Phase 3 clinical trial data for NeoCart would be appropriate for submission to and potential approval by the PMDA.
- *Japanese Market Research and Commercialization Plans:* The Japanese market represents a significant opportunity with an estimated 200,000 patients in Japan suffering from pain associated with cartilage defects in the knee and limited options to treat the defect or related pain. Histogenics is exploring partnership opportunities to complete the limited clinical development required to gain authorization and commercialize NeoCart in Japan. Histogenics conducted market research with over 80 orthopedic surgeons in Japan that revealed that pain and loss of function due to cartilage defects were seen in approximately 40% of their total knee trauma cases. Furthermore, the defect is often not

treated in over 60% of those patients and there is a belief by those surgeons that more than 60% of those patients who are not treated will likely progress to Osteoarthritis. The feedback received by these physicians indicate that a treatment such as NeoCart may be helpful to their practice and would be used to treat cartilage defects.

- *Development of NeoCart Clinical Data and Related Publications:* In the first quarter of 2017, long-term data from the combined Phase 1 and 2 NeoCart clinical trials were published in the American Journal of Sports Medicine. Patients receiving NeoCart implants in the two trials demonstrated statistically significant improvements when compared to baseline on virtually all of the pain and functional endpoints as early as three to six months, with sustained outcomes through five years from the date of implant. Furthermore, the magnetic resonance imaging data from the trials indicated NeoCart repair tissue is durable and evolves over time.

Financial Results for the First Quarter of 2017

Loss from operations was $(6.8) million in the first quarter of 2017, compared to $(7.8) million in the first quarter of 2016. The decrease in operating expenses was driven by a reduction in research and development expense and partially offset by a small increase in general and administrative expenses.

Research and development expenses were $4.5 million in the first quarter of 2017, compared to $5.6 million in the first quarter of 2016. The decrease was primarily due to a reduction in consulting and temporary labor costs and patient recruiting expenses related to the NeoCart Phase 3 clinical trial. This decrease was partially offset by an increase in hiring fees in the first quarter of 2017. General and administrative expenses were $2.3 million in the first quarter of 2017, compared to $2.2 million in the first quarter of 2016. The increase was primarily due to increases in stock-based compensation and repairs and maintenance expense that were partially offset by a reduction in hiring fees and consulting costs.

Net loss attributable to common stockholders was $(5.8) million in first quarter of 2017, or $(0.27) per share, compared to $(7.9) million, or $(0.60) per share, in the first quarter of 2016. The decrease in net loss attributable to common stockholders is primarily due to lower operating expenses and the allocation of a portion of the net loss to the Series A Preferred Stock.

As of March 31, 2017, Histogenics had cash, cash equivalents and marketable securities of $24.4 million, compared to $31.9 million at December 31, 2016. Histogenics believes its current cash position will be sufficient to fund its operations into the middle of 2018.

Conference Call and Webcast Information

Histogenics' management will host a conference call on Thursday, May 11, 2017 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 "97247103" 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 novel tissue therapies that may offer more rapid and durable recoveries for patients with pain and loss of function due to

musculoskeletal conditions. Histogenics' regenerative medicine platform combines expertise in cell processing, scaffolding, tissue engineering and bioadhesives to create tissue *ex-vivo*. Histogenics' first investigational product candidate, NeoCart is designed to treat cartilage defects in the knee and is currently in Phase 3 clinical development. 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. As a result, NeoCart is the only product in development or on the market with a one-year primary superiority endpoint as compared to the standard of care. There are more than 500,000 or more knee cartilage procedures in the United States each year, with many healthy active adults avoiding treatment as they seek other alternatives. Left untreated, even a small cartilage defect can expand in size and progress to debilitating osteoarthritis, ultimately necessitating a joint replacement procedure. Osteoarthritis is more common in adults over the age of 50, but the condition and precursors of the condition can be observed much earlier, and cartilage damage is believed to be one of the leading contributors of this disease. For more information, please visit www.histogenics.com.

Forward-Looking Statements

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or that are made on its behalf. The information in this release is provided only as of the date of this release, 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 March 31,	
	2017	2016
Revenue	$ –	$ –
Operating expenses:		
Research and development	4,504	5,586
General and administrative	2,326	2,212
Total operating expenses	6,830	7,798
Loss from operations	(6,830)	(7,798)
Other income (expense):		
Interest income (expense), net	35	(19)
Other expense, net	(17)	(101)
Change in fair value of warrant liability	(269)	–
Total other (expense), net	(251)	(120)
Net Loss	$ (7,081)	$ (7,918)
Other comprehensive loss:		
Unrealized loss from available for sale securities	(6)	–
Comprehensive Loss	$ (7,087)	$ (7,918)
Loss attributable to common stockholders – basic and diluted	$ (5,832)	$ (7,918)
Loss per common share – basic and diluted	$ (0.27)	$ (0.60)
Weighted-average shares used to compute loss per common share – basic and diluted:	21,914,001	13,269,021

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

	March 31, 2017	December 31, 2016
Cash and cash equivalents and marketable securities	$ 24,374	$ 31,908
Prepaid expenses and other current assets	296	173
Property and equipment, net	3,503	3,860
Other assets, net	137	137
Total assets	$ 28,310	$ 36,078
Current liabilities	$ 3,895	$ 5,171
Warrant and other non-current liabilities	17,443	17,340
Total stockholder's equity	6,972	13,567
Total liabilities and stockholders' equity	$ 28,310	$ 36,078

Contact:

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SOURCE: Histogenics Corporation