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 10, 2018

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 10, 2018, 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, 2018. 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 generating the data from the clinical trial; the ability to obtain and maintain regulatory approval of NeoCart or any product candidates, and the labeling for any approved products; NeoCart's regulation as a Regenerative Medical Product in Japan; the market size and potential patient population in Japan; 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; 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, 2017, which is on file with the 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, 2018, to be filed with the SEC in the second quarter of 2018. 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 10, 2018.

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 10, 2018

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

HISTOGENICS CORPORATION ANNOUNCES FIRST QUARTER 2018 FINANCIAL AND OPERATING RESULTS

– Top-line Superiority Data from NeoCart® Phase 3 Clinical Trial and Potential Biologics License Application Submission on Track for Third Quarter of 2018 –
– Initiation of Phase 3 Clinical Trial in Japan Expected in Second Half of 2018 –
– Company to Host Conference Call and Webcast Today at 8:30 a.m. EDT –

WALTHAM, Mass., May 10, 2018 /GLOBE NEWSWIRE/ – Histogenics Corporation (Histogenics) (Nasdaq: HSGX), a leader in the development of restorative cell therapies (RCTs) that may offer rapid-onset pain relief and restored function, announced its financial and operational results for the quarter ended March 31, 2018.

"The preparation for top-line data and the NeoCart Biologics License Application for the U.S. Food and Drug Administration remained a key focus for Histogenics in the first quarter of 2018, and we are on track to achieve these important milestones in the third quarter," said Adam Gridley, President and Chief Executive Officer of Histogenics. "We are also actively supporting MEDINET, our NeoCart development and commercialization partner in Japan, as they prepare for the initiation of the planned confirmatory trial in Japan in the second half of 2018. We also continue to work with our surgeon investigators on our commercialization plans in both the U.S. and Japanese markets, and are pursuing additional NeoCart licensing and partnership opportunities in other major international markets. Our objective is to make NeoCart available to as many patients as possible with a goal of maximizing the clinical and commercial value of this innovative, restorative cell therapy that treats pain at the source," continued Mr. Gridley.

First Quarter 2018 and Recent Highlights

- *Release of NeoCart top-line Phase 3 Data and Submission of Biologics License Application on Track for Third Quarter 2018:* Histogenics expects to report top-line data from its 249-patient Phase 3 randomized, controlled clinical trial of NeoCart in the third quarter of 2018. The trial is designed to show superiority of NeoCart at one year after treatment as compared to microfracture, the current standard of care. The trial will follow patients for three years and is being conducted under a Special Protocol Assessment with the United States Food and Drug Administration.
- *Development of Additional NeoCart Biomechanical Data to Support Potential Commercialization:* As part of their Sponsored Research Agreement, Histogenics and Cornell University (Cornell) continue to build upon the robust body of evidence related to the biomechanical properties of NeoCart, with additional data that were presented at the Orthopaedic Research Society Annual Meeting in March 2018. The body of data is intended to provide additional mechanism of action and physical competence information to regulatory agencies and clinicians regarding the potential performance advantages of NeoCart when compared to other treatment alternatives. Furthermore, Histogenics and Cornell are working together in related areas including the novel testing and three-dimensional printing of cartilage tissue. Histogenics believes this work may have significant utility in identifying and supporting additional future product opportunities including the automation of certain aspects of the NeoCart manufacturing process.

- *Expansion and Enhancement of Board of Directors:* In April 2018, Susan Washer, President and Chief Executive Officer of Applied Genetic Technologies (AGTC) joined Histogenics' Board of Directors. Ms. Washer has served as CEO of AGTC, a company developing genetic therapies to treat patients with rare inherited conditions, since 2002. She also serves on the boards of Biotechnology Innovation Organization and the Alliance for Regenerative Medicine.
- *Receipt of MEDINET Licensing Agreement Proceeds and Completion of Financing:* Histogenics received a $10 million up-front payment from MEDINET Co., Ltd. (MEDINET) pursuant to the terms of the license agreement with MEDINET for the development and commercialization of NeoCart in Japan. In addition, Histogenics successfully completed a registered direct offering of common stock in January 2018 that raised proceeds of $5.7 million, after deducting underwriter's discounts and commissions, and expenses related to the offering.

Financial Results for the First Quarter of 2018

Loss from operations was $(6.1) million in the first quarter of 2018, compared to $(6.8) million in the first quarter of 2017. The decrease in operating expenses was driven by a reduction in research and development expenses which was partially offset by an increase in general and administrative expenses.

Research and development expenses were $3.3 million in the first quarter of 2018, compared to $4.5 million in the first quarter of 2017. The decrease was primarily due to a reduction in costs related to the NeoCart Phase 3 clinical trial, for which enrollment was completed in June 2017. General and administrative expenses were $2.8 million in the first quarter of 2018, compared to $2.3 million in the first quarter of 2017. The increase was primarily due to increases in salaries and consulting expenses related to increased activities to support the potential commercialization of NeoCart.

Net loss attributable to common stockholders was $(14.4) million in the first quarter of 2018, or $(0.52) per share, compared to $(5.8) million, or $(0.27) per share, in the first quarter of 2017. The increase in net loss attributable to common stockholders is primarily due to the conversion of convertible preferred stock into common stock and an increase in expense related to the fair value of the warrant liability which was partially offset by lower operating expenses.

As of March 31, 2018, Histogenics had cash, cash equivalents and marketable securities of $15.5 million, compared to $8.0 million at December 31, 2017. Histogenics believes its current cash position will be sufficient to fund its operations into the fourth quarter of 2018.

Conference Call and Webcast Information

Histogenics management will host a conference call on Thursday, May 10, 2018 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 "8376199" five to ten minutes before the start of the call.

To access a live audio webcast of the presentation on the "Investor Relations" page of the Histogenics website, please click here. A replay of the webcast will be archived on Histogenics' website for approximately 45 days following the presentation.

About Histogenics Corporation

Histogenics (Nasdaq: HSGX) is a leader in the development of restorative cell therapies that may offer rapid-onset pain relief and restored function. Histogenics' lead investigational product, NeoCart, is designed to rebuild a patient's own knee cartilage to treat pain at the source and potentially prevent a patient's progression to osteoarthritis. NeoCart is one of the most rigorously studied restorative cell therapies for orthopedic use. Histogenics recently completed enrollment of its NeoCart Phase 3 clinical trial and expects to report top-line, one-year superiority data in the third quarter of 2018. NeoCart is designed to perform like articular hyaline cartilage at the time of treatment, and as a result, may provide patients with more rapid pain relief and accelerated recovery as compared to the current standard of care. Histogenics' technology platform has the potential to be used for a broad range of additional restorative cell therapy indications. For more information on Histogenics and NeoCart, please visit www.histogenics.com.

Forward-Looking Statements

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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,	
	2018	2017
Revenue	$ —	$ —
Operating expenses:		
Research and development	3,286	4,504
General and administrative	2,807	2,326
Total operating expenses	6,093	6,830
Loss from operations	(6,093)	(6,830)
Other income (expense):		
Interest income, net	37	35
Other (expense), net	(24)	(17)
Change in fair value of warrant liability	(8,753)	(269)
Total other (expense), net	(8,740)	(251)
Net Loss	$ (14,833)	$ (7,081)
Other comprehensive loss:		
Unrealized loss from available for sale securities	—	(6)
Comprehensive Loss	$ (14,833)	$ (7,087)
Net loss attributable to common stockholders – basic and diluted	$ (14,370)	$ (5,832)
Net loss per common share – basic and diluted	$ (0.52)	$ (0.27)
Weighted-average shares used to compute loss per common share – basic and diluted:	27,670,118	21,914,001

HISTOGENICS CORPORATION
CONDENSED CONSOLIDATED BALANCE SHEETS
(Unaudited)
(in thousands)

	March 31, 2018	December 31, 2017
Cash and cash equivalents and marketable securities	$ 15,507	$ 7,981
Prepaid expenses and other current assets	858	194
Property and equipment, net	4,448	2,723
Other assets, net	512	137
Total assets	$ 21,325	$ 11,035
Current liabilities	$ 8,420	$ 3,805
Warrant and other non-current liabilities	32,975	18,498
Total stockholders' equity	(20,070)	(11,268)
Total liabilities and stockholders' equity	$ 21,325	$ 11,035

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SOURCE: Histogenics Corporation