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): August 9, 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 August 9, 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 June 30, 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 and Quarterly Report on Form 10-Q for the quarter ended March 31, 2018, which are 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 June 30, 2018, to be filed with the SEC in the third 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 August 9, 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.

Date: August 9, 2018

HISTOGENICS CORPORATION

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

HISTOGENICS CORPORATION ANNOUNCES SECOND QUARTER 2018 FINANCIAL AND OPERATING RESULTS

– Top-line Superiority Data from NeoCart® Phase 3 Clinical Trial on Track for Third Quarter of 2018 –
– Initiation of Phase 3 Clinical Trial in Japan Expected in Second Half of 2018 –
– Expansion of Management Team in Preparation for Potential Commercialization of NeoCart in 2020 –
– Company to Host Conference Call and Webcast Today at 8:30 a.m. EDT –

WALTHAM, Mass., August 9, 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 operating results for the quarter ended June 30, 2018.

"Our focus in the second quarter of 2018 was on the NeoCart Biologics License Application submission and we remain on track to announce top-line data in the third quarter of 2018. In preparation for this exciting milestone, we enhanced our management team with the addition of Lynne Kelley as Chief Medical Officer. Lynne's experience and capabilities in medical and regulatory affairs and product development will be instrumental as we advance the preparation of the upcoming BLA for NeoCart," said Adam Gridley, President and Chief Executive Officer of Histogenics. "We also made important progress on the international expansion of the NeoCart platform alongside MEDINET, our NeoCart development and commercialization partner in Japan, as they prepare for the initiation of the Phase 3 trial in Japan in the second half of the year."

Second Quarter 2018 and Recent Highlights

- *NeoCart top-line Phase 3 Data Release on Track for Third Quarter of 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, and will follow patients for three years.
- *Expansion and Enhancement of Executive Team:* In July 2018, Histogenics appointed Lynne Kelley as its Chief Medical Officer. In this role, Dr. Kelley will leverage her 20 plus years of executive management and surgical experience in medical affairs, clinical operations, regulatory affairs and product development to establish Histogenics' medical affairs strategy and build a medical affairs team to support the potential launch of NeoCart. Dr. Kelley will also work with the executive team on the preparation of the upcoming Biologics License Application (BLA) for NeoCart and any related discussions with the United States Food and Drug Administration (FDA).
- *Held Inaugural Investor Day:* In June 2018, Histogenics hosted its first investor day in New York City. Members of Histogenics' management team discussed the commercialization plan for NeoCart and provided an overview of its Restorative Cell Technology platform. The team was joined by leading orthopedic surgeons who shared their overall experiences with and provided their clinical perspectives on NeoCart, as well as a NeoCart patient from the Phase 3 clinical trial who provided his thoughts on his recovery, specifically the impact NeoCart has had on his ability to return to work and sports activities. The event also included a discussion on the NeoCart mechanism of action based on work conducted as part of Histogenics' collaboration with Cornell University. A full replay of the webcast is available via the "Investor Relations" page of Histogenics' website, www.histogenics.com, or by clicking here.

Financial Results for the Second Quarter of 2018

Loss from operations was $(7.3) million in the second quarter of 2018, compared to $(6.4) million in the second quarter of 2017. The increase in operating expenses was due to an increase in both research and development expenses and general and administrative expenses.

Research and development expenses were $4.5 million in the second quarter of 2018, compared to $4.2 million in the second quarter of 2017. The increase was primarily due to increases in consulting, salaries and materials in connection with the potential submission of a BLA for NeoCart with the FDA and was partially offset by a reduction in patient 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 second quarter of 2018, compared to $2.2 million in the second quarter of 2017. The increase was primarily due to higher salaries and consulting expenses related to increased activities to support the potential commercialization of NeoCart.

Net loss attributable to common stockholders was $(3.7) million in the second quarter of 2018, or $(0.13) per share, compared to $(5.5) million, or $(0.25) per share, in the second quarter of 2017. The decrease in net loss attributable to common stockholders is primarily due to the conversion of convertible preferred stock issued in connection with the 2016 private placement into common stock and a change in the fair value of the warrant liability which generated a gain in the second quarter of 2018, both of which were partially offset by an increase in operating expenses.

As of June 30, 2018, Histogenics had cash, cash equivalents and marketable securities of $8.8 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, August 9, 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 "6679509" 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 completed enrollment of its NeoCart Phase 3 clinical trial in June 2017 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 June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
Revenue	$ –	$ –	$ –	$ –
Operating expenses:				
Research and development	4,458	4,208	7,744	8,712
General and administrative	2,826	2,166	5,633	4,492
Total operating expenses	7,284	6,374	13,377	13,204
Loss from operations	(7,284)	(6,374)	(13,377)	(13,204)
Other income (expense):				
Interest income (expense), net	32	40	69	75
Other expense, net	(26)	(73)	(50)	(90)
Change in fair value of warrant liability	3,501	(135)	(5,252)	(404)
Total other income (expense), net	3,507	(168)	(5,233)	(419)
Net loss	$ (3,777)	$ (6,542)	$ (18,610)	$ (13,623)
Other comprehensive loss:				
Unrealized gain (loss) from available for sale securities	–	4	–	(2)
Comprehensive loss	$ (3,777)	$ (6,538)	$ (18,610)	$ (13,625)
Net loss attributable to common stockholders – basic and diluted	$ (3,697)	$ (5,454)	$ (18,124)	$ (11,285)
Net loss per common share – basic and diluted:	$ (0.13)	$ (0.25)	$ (0.64)	$ (0.51)
Weighted-average shares used to compute loss per common share – basic and diluted:	28,740,030	22,183,804	28,208,030	22,050,572

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

	June 30, 2018	December 31, 2017
Cash and cash equivalents and marketable securities	$ 8,772	$ 7,981
Prepaid expenses and other current assets	881	194
Property and equipment, net	5,173	2,723
Other assets, net	325	137
Total assets	$ 15,151	$ 11,035
Current liabilities	$ 11,657	$ 3,805
Warrant and other non-current liabilities	26,932	18,498
Total stockholders' equity (deficit)	(23,438)	(11,268)
Total liabilities and stockholders' equity (deficit)	$ 15,151	$ 11,035

Contact:

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SOURCE: Histogenics Corporation