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 10, 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 August 10, 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 June 30, 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 releasing the top-line data for the NeoCart Phase 3 clinical trial and timing of filing a BLA; the ability to obtain and maintain regulatory approval of NeoCart or any product candidates, and the labeling for any approved products; Histogenics' ability to secure a development and commercialization partner for NeoCart 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; 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 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 and Quarterly Report on Form 10-Q for the quarter ended March 31, 2017, 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, 2017, to be filed with the SEC in the third 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 August 10, 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: August 10, 2017

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

HISTOGENICS CORPORATION ANNOUNCES SECOND QUARTER 2017 FINANCIAL AND OPERATING RESULTS

— Completed Enrollment in NeoCart® Phase 3 Clinical Trial —
— Top-line Data and Potential BLA Filing Expected in Third Quarter of 2018 —
— Defined Regulatory Pathway with Japan Pharmaceuticals and Medical Devices Agency —
— Market Research in U.S. and Japan Points to Potential Large Markets with Significant Unmet Need —

WALTHAM, Mass., August 10, 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 June 30, 2017.

"We achieved a significant milestone in the second quarter of 2017 when we completed enrollment of the NeoCart Phase 3 clinical trial with a record 17 patients in the month of June and 30 patients for the quarter. Furthermore, we continue to receive positive feedback from our surgeons regarding the ease of the NeoCart procedure and the potential early pain and functional relief," stated Adam Gridley, President and Chief Executive Officer of Histogenics. "The small lesion microfracture market continues to be underserved and our recent market research in Japan and the United States indicates a product like NeoCart, if approved, could have a meaningful impact in the market as both physicians and patients are seeking novel alternatives to treat cartilage defects. We look forward to the results from our Phase 3 study in the third quarter of 2018, and believe our robust dual threshold responder protocol, along with our one-year endpoint, may provide clear evidence of the potential for NeoCart to replace microfracture as the standard of care for these small lesions."

Second Quarter 2017 and Recent Highlights

- *NeoCart Phase 3 Clinical Trial Enrollment Complete:* As of June 30, 2017, Histogenics enrolled a total of 249 patients, including 30 patients in the second quarter of 2017 and 17 patients in the month of June 2017. The Phase 3 clinical trial is being conducted under a Special Protocol Assessment (SPA) with the United States Food and Drug Administration (FDA) and Histogenics expects to report top-line data from the trial in the third quarter of 2018 and file a Biologics License Application (BLA) with the FDA in the same quarter, with potential commercialization, if approved, in the second half of 2019.
- *Identification of Japanese Regulatory Approval Pathway for NeoCart:* Histogenics reached agreement with the Japan Pharmaceuticals and Medical Devices Agency (PMDA) regarding the required regulatory pathway for NeoCart in Japan. Due to the quality, breadth and depth of the NeoCart data package, the PMDA agreed that the only 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 trial and the one-year U.S. Phase 3 clinical trial data for NeoCart would be appropriate for submission to and potential approval by the PMDA. The PMDA also agreed with Histogenics' proposal to manufacture NeoCart implants for the Japanese clinical trial at its facility in Waltham, Massachusetts. Histogenics continues to explore partnership opportunities with biotechnology and pharmaceutical companies to complete the limited clinical development required to gain full marketing authorization and commercialize NeoCart in Japan.

- *U.S. and Japan NeoCart Market Potential:* Histogenics recently conducted primary market research in both the U.S. and Japan with almost 200 orthopedic and sports medicine surgeons across both markets. The findings provide support for Histogenics' assumptions regarding the size of each market and confirm the need in both markets for a novel cartilage repair therapy that will serve as an alternative to microfracture by potentially offering patients a more rapid recovery from pain and return to function as well as a durable treatment response. The results also showed a strong willingness to use a new therapeutic alternative with the characteristics of NeoCart, based on the data from Histogenics completed and ongoing clinical trials. In the U.S., Histogenics is targeting the 150,000 to 200,000 patients receiving microfracture each year, out of the estimated 600,000 procedures annually to treat cartilage defects. Similarly, in Japan there are an estimated 200,000 procedures annually for patients suffering from pain associated with cartilage defects in the knee.
- *Development of NeoCart Clinical Data and Related Publications:* Histogenics continues to work with its university research collaborators on research and development activities. In the second quarter of 2017, data from a collagen and chondrocyte 3-D bioprinting study were published. Histogenics believes that these data can be used to support both process optimization for NeoCart and the NeoCart BLA filing, as well as for the future development of additional product candidates based on the NeoCart platform. Histogenics has also continued its work with Intrexon Corporation (Intrexon) to develop next-generation allogeneic products to treat cartilage defects. The companies have generated exciting proof-of-concept data by combining Intrexon's induced Pluripotent Stem Cell (iPSC) technology and Histogenics' NeoCart platform to manufacture next generation, NeoCart implants using iPSC-derived chondrocytes. These implants exhibited similar critical biomarkers of cartilage production and biomechanical data of both native cartilage and the current generation of NeoCart implants. The companies seek to publish the data in 2018.
- *Enhancement of Executive Team:* In the second quarter of 2017, Histogenics appointed Donald Haut, Ph.D. as Chief Business Officer. Dr. Haut has primary responsibility for Histogenics' commercial licensing discussions in Japan and other regions outside of the United States, commercial and product development strategies and all alliance management and business development activities. Dr. Haut has extensive experience in corporate strategy, business development and licensing, and sales and marketing.

Financial Results for the Second Quarter of 2017

Loss from operations was $(6.4) million in the second quarter of 2017, compared to $(8.0) million in the second quarter of 2016. The decrease in operating expenses was primarily driven by a reduction in research and development expenses.

Research and development expenses were $4.2 million in the second quarter of 2017, compared to $5.8 million in the second quarter of 2016. The decrease was primarily due to reductions in collaboration, consulting and temporary labor costs as well as salary and patient recruitment costs and was partially offset by a small increase in sponsored research expenses with institutions, including Cornell University and

Brigham and Women's Hospital. General and administrative expenses were $2.2 million in the second quarter of 2017, compared to $2.2 million in the second quarter of 2016. An increase in facility related costs was offset by a decrease in stock-based compensation expense.

Net loss attributable to common stockholders was $(5.5) million in the second quarter of 2017, or $(0.25) per share, compared to $(8.0) million, or $(0.61) per share, in the second 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 June 30, 2017, Histogenics had cash, cash equivalents and marketable securities of $18.5 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, August 10, 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 "37210066" 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. The Company recently completed enrollment of its NeoCart Phase 3 clinical trial and expects to report top-line data in the third quarter of 2018. 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

Various statements in this release 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 releasing the top-line data for the NeoCart Phase 3 clinical trial and timing of filing a BLA; the ability to obtain and maintain regulatory approval of NeoCart or any product candidates, and the labeling for any approved products; Histogenics’ ability to secure a development and commercialization partner for NeoCart 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; 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 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 and Quarterly Report on Form 10-Q for the quarter ended March 31, 2017, which are on file with the Securities and Exchange Commission (the “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, 2017, to be filed with the SEC in the third 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 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.

* * * *

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,	
	2017	2016	2017	2016
Revenue	$ —	$ —	$ —	$ —
Operating expenses:				
Research and development	4,208	5,794	8,712	11,380
General and administrative	2,166	2,161	4,492	4,373
Total operating expenses	6,374	7,955	13,204	15,753
Loss from operations	(6,374)	(7,955)	(13,204)	(15,753)
Other income (expense):				
Interest income (expense), net	40	(17)	75	(36)
Other expense, net	(73)	(66)	(90)	(167)
Change in fair value of warrant liability	(135)	—	(404)	—
Total other (expense), net	(168)	(83)	(419)	(203)
Net loss	$ (6,542)	$ (8,038)	$ (13,623)	$ (15,956)
Other comprehensive loss:				
Unrealized gain (loss) from available for sale securities	4	—	(2)	—
Comprehensive Loss	$ (6,538)	$ (8,038)	$ (13,625)	$ (15,956)
Net Loss attributable to common stockholders - basic and diluted	$ (5,454)	$ (8,038)	$ (11,285)	$ (15,956)
Net Loss per common share - basic and diluted:	$ (0.25)	$ (0.61)	$ (0.51)	$ (1.20)
Weighted-average shares used to compute loss per common share - basic and diluted:	22,183,804	13,270,433	22,050,572	13,270,531

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

	June 30, 2017	December 31, 2016
Cash and cash equivalents and marketable securities	$18,540	$ 31,908
Prepaid expenses and other current assets	304	173
Property and equipment, net	3,146	3,860
Other assets, net	137	137
Total assets	$22,127	$ 36,078
Current liabilities	$ 3,827	$ 5,171
Warrant and other non-current liabilities	17,494	17,340
Total stockholder's equity	806	13,567
Total liabilities and stockholders' equity	$22,127	$ 36,078

Contact:

Investor Relations
Tel: +1 (781) 547-7909
InvestorRelations@histogenics.com

SOURCE: Histogenics Corporation