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): November 9, 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 November 9, 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 September 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 biologics license application with the U.S. Food and Drug Administration; 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 June 30, 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 September 30, 2017, to be filed with the SEC in the fourth 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 November 9, 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: November 9, 2017

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

HISTOGENICS CORPORATION ANNOUNCES THIRD QUARTER 2017 FINANCIAL AND OPERATING RESULTS

– Top-line, 1-year Superiority Data for NeoCart® Phase 3 Clinical Trial and Potential Biologics License Application Filing Remain on Track for Third Quarter of 2018 –
– Company to Host Conference Call and Webcast Thursday, November 9, 2017 at 8:30 a.m. ET –

WALTHAM, Mass., November 9, 2017 /GLOBE NEWSWIRE/ – Histogenics Corporation (Histogenics) (Nasdaq: HSGX), a leader in the development of restorative cell therapies that may offer rapid-onset pain relief and restored function, announced financial and operational results for the quarter ended September 30, 2017.

"With enrollment in the NeoCart Phase 3 clinical trial complete, we are focused on preparing for the top- line, superiority data and potential BLA filing for NeoCart in the third quarter of 2018. In the third quarter of 2017, we enhanced Histogenics' operational capabilities and expanded our portfolio of data supporting the unique mechanism of action of NeoCart," stated Adam Gridley, President and Chief Executive Officer of Histogenics. "We believe that the data published in the *Journal of Biomechanics* in October 2017 provide additional evidence that Histogenics' proprietary cell therapy platform produces cartilage that may accelerate recovery time and reduce pain. These data support the potential of NeoCart to replace microfracture as the standard of care for the treatment of knee cartilage defects, as well as the future development of additional product candidates from the NeoCart product platform. Histogenics' priorities are now focused on preparing for our upcoming Biologics License Application (BLA) submission, further defining our commercial strategies for our launch of NeoCart, and our ongoing partnering activities for NeoCart in Japan and Asia,"

Recent Highlights

- *Peer Reviewed Publication Further Strengthens NeoCart Data Portfolio.* In October 2017, Histogenics announced the publication of a study, "*In Vitro Culture Increases Mechanical Stability of Human Tissue Engineered Cartilage Constructs by Prevention of Microscale Scaffold Buckling*" in the online version of the peer-reviewed *Journal of Biomechanics*. The study analyzes the compressive properties of engineered cartilage tissue grown with chondrocytes seeded in a porous scaffold. Histogenics intends to include the results of this study to provide additional data to the U.S. Food and Drug Administration (FDA) as part of a potential BLA for NeoCart, subject to a successful outcome in the ongoing NeoCart Phase 3 clinical trial.
- *Enhancement of Executive Team in Advance of Potential Approval and Commercialization of NeoCart.* In October 2017, Histogenics promoted Stephen Kennedy from Chief Technology Officer to Executive Vice President & Chief Operating Officer. The promotion is consistent with Mr. Kennedy's focus on the manufacturing scale-up of NeoCart to supply the U.S. market, if approved. Mr. Kennedy has more than 30 years of executive product development, manufacturing, technology assessment and commercialization experience at leading biotechnology companies, which includes extensive experience overseeing product technologies from development through commercial launch.

Financial Results for the Third Quarter of 2017

Loss from operations was $(5.7) million in the third quarter of 2017, compared to $(6.6) million in the third quarter of 2016. The decrease in operating expenses was primarily driven by a reduction in research and development expenses that was offset by an increase in general and administrative expenses.

Research and development expenses were $3.5 million in the third quarter of 2017, compared to $4.9 million in the third quarter of 2016. The decrease was primarily due to reductions in collaboration, consulting and temporary labor expenses and clinical trial-related costs. General and administrative expenses were $2.2 million in the third quarter of 2017, compared to $1.8 million in the third quarter of 2016. The increase was primarily due to activities related to a potential BLA submission and commercialization of NeoCart, if approved.

Net loss attributable to common stockholders was $(5.1) million in the third quarter of 2017, or $(0.23) per share, compared to $(9.2) million, or $(0.70) per share, in the third quarter of 2016. The decrease in net loss attributable to common stockholders is primarily due to lower operating expenses in the third quarter of 2017, $3.1 million in expenses related to the private placement completed in the third quarter of 2016 and an increase in weighted average shares outstanding, also resulting from the 2016 private placement.

As of September 30, 2017, Histogenics had cash, cash equivalents and marketable securities of $12.6 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, November 9, 2017 at 8:30 a.m. ET. 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: 89009539 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, or by clicking 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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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 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; 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 June 30, 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 September 30, 2017, to be filed with the SEC in the fourth 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.

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HISTOGENICS CORPORATION
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited)
(in thousands, except share and per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Revenue	$ —	$ —	$ —	$ —
Operating expenses:				
Research and development	3,488	4,880	12,200	16,260
General and administrative	2,225	1,768	6,717	6,141
Total operating expenses	5,713	6,648	18,917	22,401
Loss from operations	(5,713)	(6,648)	(18,917)	(22,401)
Other income (expense):				
Interest income (expense), net	39	(20)	114	(55)
Other expense, net	(52)	(130)	(142)	(298)
Warrant expense	—	(3,056)	—	(3,056)
Change in fair value of warrant liability	(269)	539	(673)	539
Total other (expense), net	(282)	(2,667)	(701)	(2,870)
Net loss	$ (5,995)	$ (9,315)	$ (19,618)	$ (25,271)
Other comprehensive loss:				
Unrealized gain from available for sale securities	1	—	—	—
Comprehensive Loss	$ (5,994)	$ (9,315)	$ (19,618)	$ (25,271)
Net Loss attributable to common stockholders - basic and diluted	$ (5,080)	$ (9,234)	$ (16,380)	$ (25,197)
Net Loss per common share - basic and diluted:	$ (0.23)	$ (0.70)	$ (0.74)	$ (1.90)
Weighted-average shares used to compute loss per common share - basic and diluted:	22,552,341	13,297,546	22,219,666	13,279,833

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

	September 30, 2017	December 31, 2016
Cash and cash equivalents and marketable securities	$ 12,619	$ 31,908
Prepaid expenses and other current assets	258	173
Property and equipment, net	2,814	3,860
Other assets, net	137	137
Total assets	$ 15,828	$ 36,078
Current liabilities	$ 2,914	$ 5,171
Warrant and other non-current liabilities	17,727	17,340
Total stockholders' equity (deficit)	(4,813)	13,567
Total liabilities and stockholders' equity (deficit)	$ 15,828	$ 36,078

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SOURCE: Histogenics Corporation