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 8, 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 November 8, 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 September 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: expectations regarding the timing and success of ongoing discussions with the FDA regarding the potential submission of a BLA for NeoCart; Histogenics' potential as a treatment for knee cartilage damage; the timing, associated expenses and ability to obtain and maintain regulatory approval of NeoCart or any product candidates, and the labeling for any approved products; the market size and potential patient population in markets where Histogenics' and its partners expect to compete; updated or refined data based on Histogenics' continuing review and quality control analysis of clinical data; the scope, progress, timing, 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 its technology transfer and manufacturing location transition; Histogenics' expectations regarding its expenses and revenue; Histogenics' ability to obtain additional debt or equity capital; 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 June 30, 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 September 30, 2018, to be filed with the SEC in the fourth 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. Histogenics has not yet received the official FDA meeting minutes from the Type C meeting held on October 30, 2018 and the information in the release and stated on the conference call may be altered or supplemented by the information contained in the official meeting minutes or any subsequent meetings that may be held with the FDA.

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 8, 2018.

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: November 8, 2018

HISTOGENICS CORPORATION

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

Exhibit 99.1

HISTOGENICS CORPORATION ANNOUNCES THIRD QUARTER 2018 FINANCIAL AND OPERATING RESULTS

– Histogenics and FDA Continue Discussions on NeoCart® Phase 3 Data and Potential BLA Submission –

– October 2018 Financing Expected to Provide Funding Into Middle of 2019 –

– Histogenics to Host Conference Call and Webcast Today at 8:30 a.m. ET –

WALTHAM, Mass., November 8, 2018 /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 its financial and operating results for the quarter ended September 30, 2018.

"We continue to focus on advancing NeoCart towards the potential submission of a Biologics License Application by the end of the first quarter of 2019 and have an extensive dialogue with the FDA covering all aspects of the NeoCart development program, including the clinical data and related statistics from the NeoCart Phase 3 clinical trial," said Adam Gridley, President and Chief Executive Officer of Histogenics. "We believe, based on our continued analysis of the totality of the data, that NeoCart, if approved, may offer patients a treatment alternative that provides a more rapid recovery from pain and return to daily activity than other options to treat damaged knee cartilage. We are also working closely with MEDINET, our development and commercialization partner in Japan, toward the goal of initiating the Japanese Phase 3 clinical trial of NeoCart in 2019."

Third Quarter 2018 and Recent Highlights

- *Meeting Held with FDA to Discuss Potential NeoCart Regulatory Submission:* Histogenics recently met with the United States Food and Drug Administration (FDA) to discuss the NeoCart Phase 3 clinical trial data and the potential for the submission of a Biologics License Application (BLA) for NeoCart. The FDA and Histogenics continue to discuss the clinical data generated to date, the potential need for any additional supplemental clinical data, including longer-term data from the ongoing Phase 3 trial or additional studies, and possible alternative regulatory pathways for acceptance of the BLA. The FDA has not made a final decision regarding a potential BLA submission and based on expected feedback from the FDA, Histogenics intends to provide a further update on these negotiations by the end of November 2018.
- *NeoCart Top-Line Phase 3 Data Announced in Third Quarter of 2018:* Histogenics reported top-line data from the NeoCart Phase 3 clinical trial in September 2018. This trial is believed to be the largest and first prospectively designed, randomized clinical trial in North America evaluating the safety and efficacy of a restorative cell therapy to treat knee cartilage damage. It is also believed to be the only trial with a dual threshold responder analysis endpoint. While the Phase 3 clinical trial did not meet its primary endpoint of a statistically significant improvement in pain and function in the dual threshold responder analysis one year after treatment as compared to microfracture, patients treated with NeoCart saw statistically significant and clinically meaningful improvements in their pain and function levels using a variety of clinically validated scales. In addition, NeoCart demonstrated

superiority on the responder analysis endpoint at six months, and in different subgroups at one year such as patients with lesions greater than 2 cm or with higher body mass index. Both NeoCart and microfracture were well tolerated and exhibited strong safety profiles.

- *Completion of $17.0 Million Financing:* In October 2018, Histogenics completed an underwritten public offering of common stock and warrants that generated $17.0 million in gross proceeds and approximately $15.4 million in net proceeds after deducting underwriting discounts and commissions, and estimated offering expenses payable by Histogenics. These amounts do not include the proceeds, if any, that Histogenics may receive in connection with any exercise of the warrants issued in the offering. The financing was led by healthcare-focused, institutional investors and supported by existing Histogenics investors. Histogenics believes the financing will be sufficient to fund its projected cash needs into the middle of 2019.
- *Development and Presentation of Additional NeoCart Biomechanical Data to Support Potential Commercialization:* As part of their Sponsored Research Agreement, Histogenics and Cornell University continue to generate additional biomechanical data to support the potential commercialization of NeoCart, if approved. The most recent data were presented at the Biomedical Engineering Society Annual Meeting in October 2018. These data build upon earlier studies and further demonstrate the importance of the presence of extracellular matrix, or tissue, in making biomechanically competent cartilage. Histogenics believe the data may be important to both regulatory agencies and clinicians regarding the potential performance advantages of NeoCart when compared to other treatment alternatives.

Financial Results for the Third Quarter of 2018

Histogenics' loss from operations was $(7.0) million in the third quarter of 2018, compared to $(5.7) million in the third quarter of 2017. The increase in loss from operations was due to higher operating expenses in the third quarter of 2018 relative to the third quarter of 2017.

Research and development expenses were $4.6 million in the third quarter of 2018, compared to $3.5 million in the third quarter of 2017. The increase was primarily due to increases in consulting and compensation related expenses in connection with the preparation and evaluation of the data from the NeoCart Phase 3 clinical trial and the potential submission of a BLA for NeoCart with the FDA. General and administrative expenses were $2.4 million in the third quarter of 2018, compared to $2.2 million in the third 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.

As of September 30, 2018, Histogenics had cash, cash equivalents and marketable securities of $5.2 million, compared to $8.0 million at December 31, 2017. In October 2018, Histogenics received net proceeds of approximately $15.9 million through an underwritten public offering of common stock and warrants and sales through its at-the-market offering facility. Histogenics believes its current cash position will be sufficient to fund its operations into the middle of 2019.

Conference Call and Webcast Information

Histogenics management will host a conference call on Thursday, November 8, 2018 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 "5491168" 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 may prevent a patient's progression to osteoarthritis. NeoCart is one of the most rigorously studied restorative cell therapies for orthopedic use. 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

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.

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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 June 30, 2018, which are on file with 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 September 30, 2018, expected to be filed with the SEC in the fourth 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. Histogenics has not yet received the official FDA meeting minutes from the Type C meeting held on October 30, 2018 and the information in this release may be altered or supplemented by the information contained in the official meeting minutes or any subsequent meetings that may be held with the FDA.

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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,	
	2018	2017	2018	2017
Revenue	$ —	$ —	$ —	$ —
Operating expenses:				
Research and development	4,563	3,488	12,307	12,200
General and administrative	2,426	2,225	8,059	6,717
Total operating expenses	6,989	5,713	20,366	18,917
Loss from operations	(6,989)	(5,713)	(20,366)	(18,917)
Other income (expense):				
Interest income, net	19	39	88	114
Other expense, net	(21)	(52)	(71)	(142)
Change in fair value of warrant liability	17,776	(269)	12,524	(673)
Total other income (expense), net	17,774	(282)	12,541	(701)
Net income (loss)	$ 10,785	$ (5,995)	$ (7,825)	$ (19,618)
Other comprehensive income (loss):				
Unrealized gain from available for sale securities	—	1	—	—
Comprehensive income (loss)	$ 10,785	$ (5,994)	$ (7,825)	$ (19,618)
Net income (loss) attributable to common stockholders				
Basic	$ 10,650	$ (5,080)	$ (7,657)	$ (16,380)
Diluted	$ (7,126)	$ (5,080)	$ (20,181)	$ (16,380)
Net income (loss) per common share				
Basic	$ 0.36	$ (0.23)	$ (0.27)	$ (0.74)
Diluted	$ (0.24)	$ (0.23)	$ (0.68)	$ (0.74)
Weighted-average shares used to compute income (loss) per common share				
Basic	29,737,632	22,552,341	28,723,500	22,219,666
Diluted	29,737,632	22,552,341	29,515,700	22,219,666

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

	September 30, 2018	December 31, 2017
Cash and cash equivalents and marketable securities	$ 5,192	$ 7,981
Prepaid expenses and other current assets	825	194
Property and equipment, net	4,352	2,723
Other assets, net	512	137
Total assets	$ 10,881	$ 11,035
Current liabilities	$ 8,943	$ 3,805
Warrant and other non-current liabilities	11,614	18,498
Total stockholders' (deficit)	(9,676)	(11,268)
Total liabilities and stockholders' (deficit)	$ 10,881	$ 11,035

Contact:

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SOURCE: Histogenics Corporation