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): September 26, 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 8.01. Other Events.

On September 26, 2018, Histogenics Corporation ("Histogenics") issued a press release announcing that the U.S. Food and Drug Administration (the "FDA") has granted a Type C meeting on October 30, 2018 to discuss the top-line results from the NeoCart Phase 3 clinical trial and Histogenics' planned Biologics License Application submission.

Additionally, Histogenics announced that during the third quarter of 2018, Histogenics has sold an aggregate of 3,550,416 shares of common stock in at-the-market offerings pursuant to Histogenics' equity distribution agreement with Canaccord Genuity Inc. for aggregate net proceeds of $2.72 million after deducting sales agent fees and expenses. Histogenics believes that its existing cash and cash equivalents will be sufficient to fund its projected cash needs late into the fourth quarter of 2018.

A copy of Histogenics' press release is attached hereto as Exhibit 99.1 and is hereby incorporated by reference herein.

Forward-Looking Statements

Various statements in this Current Report on Form 8-K 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 discussions with the FDA regarding the submission of a biologics license application for NeoCart; NeoCart's 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 SEC and available on the SEC's website at www.sec.gov. 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 Current Report on Form 8-K is provided only as of the date of this Current Report on Form 8-K, 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.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release of Histogenics Corporation dated September 26, 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: September 26, 2018

HISTOGENICS CORPORATION

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

HISTOGENICS TO MEET WITH FDA TO DISCUSS NEOCART PHASE 3 CLINICAL TRIAL DATA AND POTENTIAL REGULATORY PATHWAY

WALTHAM, Mass., September 26, 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, today announced that the U.S. Food and Drug Administration (the FDA) has granted a Type C meeting on October 30, 2018 to discuss the top-line results from the NeoCart Phase 3 clinical trial and Histogenics' planned Biologics License Application submission. Histogenics submitted its briefing materials regarding the top-line data of the NeoCart Phase 3 clinical trial to the FDA in mid-September 2018, and has been working closely with the FDA to schedule the meeting. Histogenics expects to provide an update following this meeting in early November 2018, with meeting minutes expected by late November 2018 or early December 2018. During the third quarter of 2018, Histogenics has sold an aggregate of 3,550,416 shares of common stock in at-the-market offerings pursuant to Histogenics' equity distribution agreement with Canaccord Genuity Inc. for aggregate net proceeds of $2.72 million after deducting sales agent fees and expenses. Histogenics believes that its existing cash and cash equivalents will be sufficient to fund its projected cash needs late into the fourth quarter of 2018.

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. 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.

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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 SEC and available on the SEC's website at www.sec.gov. 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.

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