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 29, 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.

A copy of Histogenics Corporation's press release dated November 29, 2018 is attached hereto as Exhibit 99.1 and is hereby incorporated by reference herein.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release of Histogenics Corporation dated November 29, 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 29, 2018

HISTOGENICS CORPORATION

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

HISTOGENICS AND FDA CONTINUE TO DISCUSS NEOCART® PHASE 3 CLINICAL TRIAL DATA AND POTENTIAL REGULATORY PATHWAY

WALTHAM, Mass., November 29, 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 provided an update on the NeoCart regulatory pathway based on its ongoing dialogue with the U.S. Food and Drug Administration (the FDA). Since the initial Type C meeting in October 2018, Histogenics and the FDA have continued their discussions on the clinical data generated to date, the potential need for any additional supplemental clinical data (which may include longer-term data from the ongoing Phase 3 trial or additional studies) and potential alternative regulatory pathways for the NeoCart Biologics License Application (BLA). The FDA has not yet made a final decision regarding a potential BLA submission. Histogenics intends to provide a further update by the end of 2018 or early 2019 based on additional feedback from the FDA, once available.

"We very much appreciate the FDA's consideration and active review of our request to evaluate the existing Phase 3 clinical data for a potential NeoCart BLA submission. We continue to work very closely with the FDA to review the data from the NeoCart development program. Our discussions have covered many areas including the clinical data, patient population and related statistics from the NeoCart Phase 3 clinical trial, potential alternative pathways for the BLA as well as the current treatment paradigms for knee cartilage defects in relation to the design of the NeoCart Phase 3 clinical trial," said Adam Gridley, President and Chief Executive Officer of Histogenics. "We continue to believe, based on the totality of the data, that NeoCart, if the BLA were accepted and approved by the FDA, may offer patients a treatment alternative that provides a more rapid recovery from pain and return to daily activity than other currently available options to treat damaged knee cartilage."

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.

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: expectations regarding the timing and success of ongoing discussions with the FDA regarding the potential submission or acceptance of a BLA 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 September 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. Histogenics has not yet received the official FDA meeting minutes from the Type C meeting and the information in this Press 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.

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.

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