# 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): December 21, 2015**

# 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))

**Item 8.01. Other Events.**

On December 21, 2015, Histogenics Corporation ("Histogenics") issued a press release regarding the announcement of a protocol amendment to its Phase 3 clinical trial of NeoCart®, an investigational cartilage replacement for damage in the knee. The U.S. Food and Drug Administration has agreed to the amendment under the existing Special Protocol Agreement (SPA) between it and Histogenics.

The press release is attached as Exhibit 99.1 to this Current Report on Form 8-K.

**Item 9.01. Financial Statements and Exhibits.**

(d) ***Exhibits***

| Exhibit No. | Description |
|---|---|
| 99.1 | Press Release of Histogenics Corporation dated December 21, 2015. |

**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.

**HISTOGENICS CORPORATION**

Date: December 21, 2015

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

## EXHIBIT INDEX

| Exhibit No. | Description |
|---|---|
| 99.1 | Press Release of Histogenics Corporation dated December 21, 2015. |

**Exhibit 99.1**

**HISTOGENICS CORPORATION ANNOUNCES AMENDMENT TO NEOCART® PHASE 3 CLINICAL TRIAL ENROLLMENT CRITERIA**

*- Company and FDA Agree on Changes to Study Protocol Allowing for Modification of Patient Inclusion/Exclusion Criteria -*

**WALTHAM, Mass., December 21, 2015 /GLOBE NEWSWIRE/** – Histogenics Corporation (Histogenics) (Nasdaq: HSGX), a regenerative medicine company focused on developing and commercializing products in the musculoskeletal space, announced that the United States Food and Drug Administration (FDA) has accepted the Company's amendment filed in November 2015 to the NeoCart Phase 3 clinical trial protocol to expand the eligible patient population. The approved protocol amendment was submitted, and the clinical trial is being conducted under, a Special Protocol Assessment (SPA) with the FDA.

**"**We are pleased that the FDA agreed with our proposed changes to the study protocol, and believe this may enhance our ability to attract qualified patient candidates while maintaining the integrity of the clinical evaluation of NeoCart, our product candidate for knee cartilage repair," stated Dr. Gloria Matthews, Chief Medical Officer of Histogenics. "We continue to be pleased with the recent momentum we have seen in trial enrollment and we remain on track to complete enrollment by the end of the second quarter of 2017," concluded Dr. Matthews.

**Revisions to the NeoCart Phase 3 clinical trial protocol include:**

- Patients with trochlear lesions will now be included in the trial.
- The upper age limit of patients eligible to participate in the trial will be increased from 55 years to 59 years.
- The time between a prior procedure, such as ligament reconstruction and meniscal tears, and a patient's participation in the study will be reduced from six months prior to arthroscopy, which is the final step prior to enrollment, to three months prior to arthroscopy.
- Patients with asymptomatic lesions in non-study locations that are larger than the study lesion will no longer be excluded from the trial.

**About Histogenics Corporation**

Histogenics is a regenerative medicine company focused on developing and commercializing products in the musculoskeletal segment of the marketplace. Histogenics' regenerative medicine platform combines expertise in cell processing, scaffolding, tissue engineering, bioadhesives and growth factors to provide solutions that can be utilized individually or in concert to treat musculoskeletal-related conditions. Histogenics' first investigational product candidate, NeoCart, leverages its platform to provide an innovative treatment in the orthopedic space, specifically cartilage damage in the knee.

**Forward-Looking Statements**

Various statements in this release, including, but not limited to, the guidance provided above, 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 the Company's forward-looking statements include, among others: the timing and success of Histogenics' NeoCart Phase 3 clinical trial, including, without limitation, possible delays in enrolling the NeoCart Phase 3 clinical 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; the sufficiency of Histogenics' cash resources and needs for additional financing; Histogenics' ability to attract or retain key personnel; the technologies on which Histogenics' channel partnering agreement with Intrexon Corporation is based are currently in preclinical and clinical stages of development; Histogenics will incur additional expenses in connection with its exclusive channel collaboration agreement with Intrexon Corporation 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, 2014 and Quarterly Report on Form 10-Q for the quarter ended September 30, 2015, 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 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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SOURCE: Histogenics Corporation