
**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): October 24, 2016

HISTOGENICS CORPORATION
(Exact Name of Registrant as Specified in its Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-36751
(Commission
File Number)

04-3522315
(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 7.01. Regulation FD Disclosure.

On October 24, 2016, Histogenics Corporation (“Histogenics”) issued a press release announcing that it had enrolled 183, or approximately three quarters, of the 245 patients required to complete enrollment of its Phase 3 clinical trial of NeoCart®, an investigational product designed to repair and replace damaged cartilage, initially in the knee.

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

The information disclosed in this Item 7.01, including the press release attached hereto as Exhibit 99.1, is being furnished and 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 under 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 filing.

Item 9.01. Financial Statements and Exhibits.

(d) *Exhibits*

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release of Histogenics Corporation dated October 24, 2016.

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: October 24, 2016

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

EXHIBIT INDEX

Exhibit No.

Description

99.1 Press Release of Histogenics Corporation dated October 24, 2016.



HISTOGENICS CORPORATION PROVIDES NEOCART® PHASE 3 CLINICAL TRIAL ENROLLMENT UPDATE

- 75% of Patients Enrolled in NeoCart Phase 3 Clinical Trial -

WALTHAM, Mass., October 24, 2016 /GLOBE NEWSWIRE/ – Histogenics Corporation (Histogenics) (Nasdaq: HSGX), a regenerative medicine company focused on developing and commercializing products in the musculoskeletal space, announced that as of October 24, 2016 it had enrolled 183, or approximately three-quarters, of the 245 patients required to complete enrollment of its ongoing NeoCart Phase 3 clinical trial. This trial is being conducted under a Special Protocol Assessment (SPA) with the United States Food and Drug Administration (FDA).

“The enrollment strategies we implemented last year continue to result in increased patient enrollment in our ongoing NeoCart Phase 3 clinical trial. With enrollment approximately 75% complete and tracking ahead of our expectations, we are now counting down the number of patients required to complete enrollment and turning our focus to the generation and availability of the one-year superiority data and a BLA submission to the FDA shortly thereafter,” stated Adam Gridley, Chief Executive Officer of Histogenics. “Having recently completed a financing aimed at funding Histogenics through our top-line data read-out in mid-2018, we believe we are well positioned to execute on our operating plans to bring this important therapy to market, if approved,” continued Mr. Gridley.

The Phase 3 clinical trial is designed to evaluate the safety and efficacy of NeoCart as a first-line therapy for full thickness knee cartilage defects in skeletally mature adults ages 18 to 59 and to show superiority of NeoCart against the current standard of care, microfracture. NeoCart is a tissue-engineered cartilage implant created from a patient’s own cells. The patient’s cells are multiplied in Histogenics’ laboratory and then infused into a proprietary scaffold to allow them to function like native cartilage. Before NeoCart is shipped to the surgeon for implantation, the cell and scaffold construct undergoes a bioengineering process that is designed to mimic a joint so that the implant, upon placement in the knee with a proprietary bioadhesive, is primed to begin functioning like healthy cartilage. Histogenics believes that these attributes may offer patients a more rapid recovery and a more durable treatment option, if approved, than other products and procedures, either on the market or in development.

About Histogenics Corporation

Histogenics is a leading regenerative medicine company 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 to treat musculoskeletal-related conditions. Histogenics’ first investigational product candidate, NeoCart, is currently in Phase 3 clinical development. NeoCart is an autologous cell therapy designed to treat cartilage defects in the knee using the patient’s own cells. Knee cartilage defects represent a significant opportunity in the United States, with an estimated 500,000 or more applicable procedures each year. NeoCart is designed to exhibit characteristics of articular, hyaline cartilage prior to and upon implantation into the knee and therefore does not rely on the body to make new cartilage, characteristics not exhibited in other current treatment options. For more information, 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: the timing and success of Histogenics’ NeoCart Phase 3 clinical trial; 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; 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; the early stage of development of the technologies on which Histogenics’ channel partnering agreement with Intrexon is based; the additional expenses that Histogenics will incur 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, 2015 and Quarterly Report on Form 10-Q for the quarter ended June 30, 2016 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, 2016, to be filed with the SEC in the fourth quarter of 2016. 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.

* * * * *

Contact:

Investor Relations
Tel: +1 (781) 547-7909
InvestorRelations@histogenics.com

SOURCE: Histogenics Corporation