

HISTOGENICS CORP
Form 8-K
November 12, 2015

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 12, 2015

HISTOGENICS CORPORATION

(Exact Name of Registrant as Specified in its Charter)

Delaware
(State or Other Jurisdiction

of Incorporation)

001-36751
(Commission

File Number)
830 Winter Street, 3rd Floor

04-3522315
(I.R.S. Employer

Identification Number)

Edgar Filing: HISTOGENICS CORP - Form 8-K

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 2.02. Results of Operations and Financial Condition.

On November 12, 2015, Histogenics Corporation (the Company or 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, 2015. 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, intent, objective, plan, predict, project, target, likely, should, will, and would, or the negative of these terms or 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 June 30, 2015, which are on file with the SEC and available on the SEC's website at www.sec.gov. Additional factors may also be set forth in those sections of Histogenics quarterly report on Form 10-Q for the quarter ended September 30, 2015, to be filed with the SEC in the fourth quarter of 2015. 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 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 12, 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: November 12, 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 November 12, 2015.