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): June 27, 2017

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 June 27, 2017, Histogenics Corporation ("Histogenics") issued a press release announcing that it has completed 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 and incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) ***Exhibits***

Exhibit No.	Description
99.1	Press Release of Histogenics Corporation dated June 27, 2017.

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: June 27, 2017

HISTOGENICS CORPORATION

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

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press Release of Histogenics Corporation dated June 27, 2017.

Exhibit 99.1

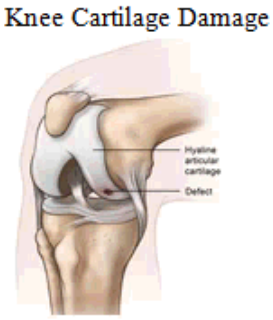
HISTOGENICS COMPLETES ENROLLMENT FOR PHASE 3 CLINICAL TRIAL OF NEOCART® TO TREAT KNEE CARTILAGE DAMAGE

– On Track for Top-Line One Year Superiority Data and Potential BLA Filing in Third Quarter of 2018 –

– Novel Tissue Implant Potentially Accelerates Recovery and Reduces Pain through Proprietary Process that Replicates the Body's Ability to Grow Cartilage as a Juvenile –

WALTHAM, Mass., June 27, 2017 /GLOBE NEWSWIRE/ – Histogenics Corporation (Histogenics) (Nasdaq: HSGX), a regenerative medicine company focused on developing and commercializing products in the musculoskeletal space, today announced the completion of patient enrollment of its NeoCart® Phase 3 clinical trial in accordance with the Special Protocol Assessment (SPA) agreement with the United States Food and Drug Administration (FDA). Histogenics expects to report top-line 1-year superiority data in the third quarter of 2018, followed by a potential Biologics License Application (BLA) filing.

"We are proud to have completed enrollment in the largest prospectively designed, randomized clinical trial evaluating the safety and efficacy of a cellular therapy to treat knee cartilage defects," said Gloria Matthews, Chief Medical Officer of Histogenics. "There is a substantial need for novel treatment options for knee cartilage damage, such as NeoCart, that have the potential to provide effective pain relief and restore function. We would like to thank our committed employees, investigators, coordinators and patients for helping us reach this important milestone and look forward to potentially bringing this therapy to patients as quickly as possible."



Articular cartilage can be damaged by injury or normal wear and tear (http://www.neocartimplant.com/cartilage-injury)

The randomized Phase 3 clinical trial is designed to evaluate the safety and efficacy in 245 patients, of NeoCart compared to microfracture, the current standard of care for the treatment of articular cartilage defects. The primary endpoint of the trial is a dual-threshold responder analysis measuring the improvement in the pain and function of each patient treated with NeoCart compared to those treated with microfracture one year after treatment. The Phase 3 clinical trial design and primary endpoint is based on Histogenics' 30-patient Phase 2 clinical trial that demonstrated highly statistically significant superiority results of NeoCart compared to microfracture at one year.

Embed Video Animation — https://youtu.be/XNnAvWNDhU0

“Our recent market research confirmed that this market is largely underserved due to the lack of rapid, yet durable therapies that treat the underlying problem with one-third of surgeons unsatisfied with the current treatment options. As a result, two-thirds or more of the patients who suffer from knee cartilage injuries remain untreated, due to the variable outcomes and lengthy rehabilitation associated with existing treatments, often leading to debilitating osteoarthritis. Specifically, patients with defects that are smaller than four centimeters in size, which we believe represent the large majority of the market, are less likely to receive surgical treatment in part due to the low satisfaction with and poor outcomes of existing treatments. Against this background, we believe NeoCart could expand the market by meeting the needs of both patients and surgeons with a product that can potentially deliver rapid pain relief and superior one year clinical outcomes utilizing a quick and simple surgical procedure,” stated Adam Gridley, President and Chief Executive Officer of Histogenics.

Mr. Gridley continued, “We are now focused on delivering our one-year superiority data by the end of the third quarter of 2018, submitting our BLA to the FDA shortly thereafter and, if approved, launching NeoCart in the second half of 2019.”

Recent Market Research Conducted by Histogenics

Histogenics recently conducted market research surveys in Japan and the United States to better characterize the target market for NeoCart based on the expected features and benefits of NeoCart, if approved following the Phase 3 clinical trial. Specifically, there were two market research studies recently performed to further define the United States market opportunity for knee cartilage repair. One study was conducted by a third party and the second by Histogenics. In total, almost 100 orthopedic and sports medicine surgeons were interviewed. The findings from both studies were consistent and are summarized below:

- 60% to 80% of patients with symptomatic knee cartilage defects are not treated at all, with a large gap between diagnosed incidence and actual treatment. Of those patients that are treated, most receive debridement or microfracture.
- The average surgeon sees approximately 75 to 100 patients per month with cartilage damage, and performs 15 to 20 surgical procedures per month to treat patients with knee cartilage defects.
- Approximately one third of surgeons are not satisfied with the currently available treatment options for pain and loss of function due to knee cartilage defects.
- Less than one-quarter of surgeons are satisfied with the currently available treatment options for pain and loss of function due to knee cartilage defects.
- The most important factors for surgeons in choosing a course of treatment for patients are: longevity/clinical outcomes, rapid patient recovery, and a quick/easy procedure.
- Almost 90% of the physicians would be extremely likely or likely to use NeoCart, if approved, based on the target product profile, including the data already published by Histogenics.

About NeoCart

NeoCart is a cartilage-like, tissue engineered implant created from a patient’s own cartilage cells. The patient’s cells are multiplied in Histogenics’ laboratory and then infused into a proprietary scaffold to allow

them to organize and function like cartilage cells. 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. NeoCart is currently in a Phase 3 clinical trial that 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 evaluate the superiority of NeoCart against the current standard of care, microfracture, at one year. Histogenics is conducting the Phase 3 clinical trial under an SPA with the FDA and expects to announce top line data from the trial in the third quarter of 2018. NeoCart is not approved for sale in any jurisdiction. For more information, please visit www.neocartimplant.com.

About Histogenics Corporation

Histogenics is a leading regenerative medicine company developing and commercializing novel tissue therapies that may offer more rapid and durable recoveries for patients with pain and loss of function due to musculoskeletal conditions. Histogenics' regenerative medicine platform combines expertise in cell processing, scaffolding, tissue engineering and bioadhesives to create tissue *ex-vivo*. Histogenics' first investigational product candidate, NeoCart is designed to treat cartilage defects in the knee and is currently in Phase 3 clinical development. 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. As a result, NeoCart is the only product in development or on the market with a one-year primary superiority endpoint as compared to the standard of care. There are more than 500,000 or more knee cartilage procedures in the United States each year, with many healthy active adults avoiding treatment as they seek other alternatives. Left untreated, even a small cartilage defect can expand in size and progress to debilitating osteoarthritis, ultimately necessitating a joint replacement procedure. Osteoarthritis is more common in adults over the age of 50, but the condition and precursors of the condition can be observed much earlier, and cartilage damage is believed to be one of the leading contributors of this disease. 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, 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 Histogenics' 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; 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, 2016 and Quarterly Report on Form 10-Q for the quarter ended March 31, 2017, which are on file with the Securities and Exchange Commission (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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Contact:

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