# 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): March 16, 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))

**Item 2.02. Results of Operations and Financial Condition.**

On March 16, 2017, Histogenics Corporation ("Histogenics") issued a press release and is holding a conference call regarding its results of operations and financial condition for the full year and quarter ended December 31, 2016. 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," "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 Corporation 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 September 30, 2016, which are on file with the U.S. Securities and Exchange Commission ("SEC") and available on the SEC's website at www.sec.gov. Additional factors may be set forth in those sections of Histogenics' Annual Report on Form 10-K for the year ended December 31, 2016, to be filed with the SEC in the first quarter of 2017. 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 March 16, 2017. |

**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: March 16, 2017

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

## EXHIBIT INDEX

| Exhibit No. | Description |
| --- | --- |
| 99.1 | Press release of Histogenics Corporation dated March 16, 2017. |

**HISTOGENICS CORPORATION ANNOUNCES FINANCIAL AND OPERATING RESULTS FOR THE FOURTH QUARTER AND YEAR ENDED DECEMBER 31, 2016**

*– NeoCart® Phase 3 Clinical Trial Enrollment on Track for Completion by End of Second Quarter of 2017 –*
*– Strong Performance in all Areas of the Business in 2016 –*
*– Financing Completed in the Third Quarter of 2016 Expected to Fund Company to Phase 3 Data –*
*– Company to Host Conference Call and Webcast Today at 8:30 a.m. EDT –*

**WALTHAM, Mass., March 16, 2017 /GLOBE NEWSWIRE/** – Histogenics Corporation (Histogenics) (Nasdaq: HSGX), a regenerative medicine company focused on developing and commercializing products in the musculoskeletal space, announced its financial and operational results for the year ended December 31, 2016.

"We made significant progress in all areas of our business in 2016. We enrolled 82 patients in the NeoCart Phase 3 clinical trial to bring total enrollment to 196 patients at the end of 2016, consistent with the high end of our previously raised enrollment guidance. In addition, we made substantial progress on the transition of NeoCart raw materials from third party suppliers to our in-house manufacturing, completed a successful $30 million capital raise, published compelling, long-term NeoCart data from our completed Phase 1 and 2 clinical trials and generated encouraging data as part of our collaborations with Cornell University and Intrexon Corporation," stated Adam Gridley, President and Chief Executive Officer of Histogenics. "We remain focused on our priority activities with the anticipated completion of enrollment in the NeoCart Phase 3 trial by end of the second quarter of 2017, which leads to expected top-line data in the middle of 2018 and are rapidly turning our attention to the BLA submission based on those anticipated results," continued Mr. Gridley.

**2016 and Recent Highlights**

- *Continued Strength in NeoCart Phase 3 Clinical Trial Enrollment:* As of March 14, 2017, Histogenics has enrolled 214 of the 245 patients required under the Special Protocol Assessment (SPA) with the United States Food and Drug Administration (FDA) in the NeoCart Phase 3 clinical trial. Total enrollment at the end of 2016 was approximately 70% higher than year-end 2015. In addition, enrollment has remained strong in the first quarter of 2017 with contributions from both existing and new clinical sites, including additional sites in Canada. Histogenics received approval from Health Canada to expand the ongoing NeoCart Phase 3 clinical trial to investigative sites in Canada and added four clinical sites that were selected based on their patient demographics and their potential ability to provide additional patients into the trial. Histogenics confirms its expectation that patient enrollment in the Phase 3 clinical trial will be complete by the end of the second quarter of 2017.
- *Significant Progress on NeoCart Critical Raw Materials:* Histogenics reached agreement with the FDA on the transition plan for internally produced collagen in April 2016, and incorporated this material into the ongoing Phase 3 trial in June 2016. In August 2016, Histogenics reached agreement with the FDA on the transition and qualification plan for the NeoCart collagen scaffold. Histogenics is in the process of qualifying the scaffold for use upon commercialization of NeoCart, if approved.
- *Completion of $30 Million Financing:* Histogenics completed a $30 million private placement of common stock, Series A Convertible Preferred Stock and warrants in September 2016. The financing was led by new healthcare-focused, institutional investors and supported by existing Histogenics investors. Histogenics currently anticipates that its existing cash will enable it to reach its objective of generating top-line data from the ongoing NeoCart Phase 3 clinical trial in the middle of 2018.

- *Discussions with Japanese Regulatory Authorities:* Histogenics continues to maintain an active dialog with the Japan Pharmaceuticals and Medical Devices Agency (PMDA) regarding the development of NeoCart for the Japanese market using the new Japanese Regenerative Medicine Laws passed in 2014. Histogenics has had a series of productive meetings to discuss the NeoCart Phase 1 and Phase 2 data generated to date, the proposed confirmatory clinical development program in Japan and the required regulatory submission package for potential conditional approval.
- *Development of NeoCart Clinical Data and Related Publications:* Long-term data from the combined Phase 1 and 2 NeoCart clinical trials was recently published in the American Journal of Sports Medicine. The magnetic resonance imaging data from the trials indicated NeoCart repair tissue is durable and evolves over time. In addition, patients receiving NeoCart implants in the two trials demonstrated statistically significant improvements when compared to baseline on virtually all of the pain and functional endpoints. These improvements were reported by patients as early as 3 to 6 months, with sustained outcomes through 5 years from the date of implant.
- *Development of NeoCart Pre-Clinical Data and Related Publications:* Together with its partners, Cornell University (Cornell), Intrexon Corporation (Intrexon), and Brigham and Women's Hospital, Histogenics expanded and strengthened the NeoCart platform technology to support the potential commercialization of NeoCart, if approved. Histogenics and Cornell generated biomechanical and structural data under a Sponsored Research Agreement that was initially presented at the Orthopaedic Research Society annual meeting in March 2016 and at the Biomedical Engineering Society Annual Meeting in October 2016. These data, which were also recently published in the Journal of Orthopaedic Research, demonstrate that Histogenics' tissue engineered cartilage constructs exhibit mechanical properties approaching native human cartilage as early as three weeks in culture. In conjunction with Histogenics collaboration with Cornell, Professor Lawrence Bonassar, a leading researcher in the field of cartilage biomechanics and tissue engineering, joined the Histogenics Scientific Advisory Board in October 2016. Histogenics and Intrexon advanced their effort to develop a second generation NeoCart by producing compelling, proof-of-concept data showing NeoCart implants based on iPSC derived chondrocytes exhibited similar properties to current generation, autologous NeoCart tissue implants.

**2017 Corporate Objectives**

- *Complete NeoCart Clinical Enrollment and Manufacturing Transition:* In addition to completing enrollment in the Phase 3 clinical trial by the end of the second quarter 2017, Histogenics intends to complete the raw materials engineering runs in 2017, including generating the data for the collagen scaffold and proprietary adhesive. These materials contain Histogenics produced collagen, which is currently being used in the Phase 3 clinical trial.
- *Generate and Publish Additional Data to Support NeoCart Commercialization:* Histogenics intends to work with its investigators and collaborators to generate and publish additional, meaningful data to support the NeoCart technology platform including, five-year data from the completed Phase 2 clinical trial and additional mechanical data generated under the SPA with Cornell.
- *Complete Meetings with Japanese Regulatory Authority to Define Requirements for Approval of NeoCart in Japan:* Histogenics intends to conduct and complete formal meetings with the PMDA to agree upon the development and regulatory pathway for the potential conditional approval of NeoCart

in Japan. Histogenics intends to leverage the results of these meetings to create value and advance discussions with potential partners for the Japan/Asia market with a goal of completing by the end of the year, a collaboration to manufacture and commercialize NeoCart, if approved.

**Financial Results for the Year Ended December 31, 2016**

Histogenics' loss from operations was $(30.3) million for the year ended December 31, 2016, compared to $(31.8) million for the year ended December 31, 2015. The decrease in operating expenses was driven by a reduction in research and development expense and partially offset by a small increase in general and administrative expenses.

Research and development expenses were $21.6 million for the year ended December 31, 2016, compared to $23.2 million for the year ended December 31, 2015. The decrease in expense was primarily due to a reduction in consulting, raw materials and patient recruiting expenses and was partially offset by an increase in clinical trial related expenses due to higher patient enrollment in the NeoCart Phase 3 clinical trial in 2016. General and administrative expenses were $8.5 million for the year ended December 31, 2016, compared to $8.3 million for the year ended December 31, 2015. The increase was primarily due to higher personnel and related costs as well as an increase in facility-related costs and was partially offset by a decrease in professional fees and consulting expense.

Basic net loss attributable to common stockholders was $(13.9) million for the year ended December 31, 2016, or $(0.97) per share, compared to $(32.0) million, or $(2.42) per share, for the year ended December 31, 2015. The decrease in basic net loss attributable to common stockholders is primarily due to the change in fair value of the warrants issued as part of the financing that was completed in September 2016 and reductions in operating expenses offset by increased expenses related to the financing. Diluted net loss attributable to common stockholders was $(31.4) million for the year ended December 31, 2016, or $(2.18) per share, compared to $(32.0) million, or $(2.42) per share, for the year ended December 31, 2015. Diluted net loss attributable to common stockholders excludes the gain on fair value of warrant liability. The remaining difference between 2016 and 2015 is primarily due to increased expenses related to the financing, offset by a reduction in operating expense.

At December 31, 2016, Histogenics had cash, cash equivalents and marketable securities of $31.9 million, compared to $30.9 million at December 31, 2015. Histogenics expects total operating expenses of between $25 and $27 million for the year ended December 31, 2017 and believes its current cash position will be sufficient to fund its operations into the middle of 2018.

**Conference Call and Webcast Information**

Histogenics management will host a conference call on Thursday, March 16, 2017 at 8:30 a.m. EDT. A question-and-answer session will follow Histogenics' remarks. To participate on the live call, please dial (877) 930-8064 (domestic) or (253) 336-8040 (international) and provide the conference ID "56826793" five to ten minutes before the start of the call.

A live audio webcast of the presentation will be available via the "Investor Relations" page of the Histogenics website, www.histogenics.com. A replay of the webcast will be archived on Histogenics' website for approximately 45 days following the presentation.

**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 Corporation 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 September 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' Annual Report on Form 10-K for the year ended December 31, 2016, to be filed with the SEC in the first quarter of 2017. 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.

* * * *

**HISTOGENICS CORPORATION**
**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS**
**(Unaudited)**
**(in thousands, except share and per share data)**

| | Three Months Ended December 31, | | Year Ended December 31, | |
|---|---|---|---|---|
| | 2016 | 2015 | 2016 | 2015 |
| Revenue | $ — | $ — | $ — | $ — |
| Operating expenses: | | | | |
| Research and development | 5,317 | 5,773 | 21,577 | 23,243 |
| General and administrative | 2,389 | 2,231 | 8,530 | 8,266 |
| Impairment of intangible asset | 200 | 310 | 200 | 310 |
| Total operating expenses | 7,906 | 8,314 | 30,307 | 31,819 |
| Loss from operations | (7,906) | (8,314) | (30,307) | (31,819) |
| Other income (expense): | | | | |
| Interest expense, net | (5) | (22) | (60) | (133) |
| Other income (expense), net | 50 | (13) | (248) | (72) |
| Warrant expense | (44) | — | (3,100) | — |
| Change in fair value of warrant liability | 16,968 | — | 17,507 | — |
| Total other income (expense), net | 16,969 | (35) | 14,099 | (205) |
| Net Income (loss) | $ 9,063 | $ (8,349) | $ (16,208) | $ (32,024) |
| Net Income (loss) attributable to common stockholders | | | | |
| Basic: | $ 5,844 | $ (8,349) | $ (13,863) | $ (32,024) |
| Diluted: | $ (11,125) | $ (8,349) | $ (31,370) | $ (32,024) |
| Net Income (loss) per common share: | | | | |
| Basic: | $ 0.34 | $ (0.63) | $ (0.97) | $ (2.42) |
| Diluted: | $ (0.63) | $ (0.63) | $ (2.18) | $ (2.42) |
| Weighted-average shares used to compute earnings (loss) per common share: | | | | |
| Basic: | 17,143,121 | 13,266,866 | 14,256,954 | 13,231,126 |
| Diluted: | 17,508,120 | 13,266,866 | 14,389,192 | 13,231,126 |

**HISTOGENICS CORPORATION**
**CONDENSED CONSOLIDATED BALANCE SHEETS**
**(Unaudited)**
**(in thousands, except share and per share data)**

| | December 31, 2016 | December 31, 2015 |
|---|---|---|
| Cash and cash equivalents | $ 31,908 | $ 30,915 |
| Prepaid expenses and other current assets | 173 | 321 |
| Property and equipment, net | 3,860 | 5,213 |
| Other assets, net | 137 | 337 |
| Total assets | $ 36,078 | $ 36,786 |
| Current liabilities | $ 5,171 | $ 6,359 |
| Warrant and other non-current liabilities | 17,340 | 2,229 |
| Total stockholder's equity | 13,567 | 28,198 |
| Total liabilities and stockholders' equity | $ 36,078 | $ 36,786 |

**Contact:**

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

SOURCE: Histogenics Corporation