
**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): August 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)

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

On August 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 June 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,” “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 three months ended March 31, 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 June 30, 2015, to be filed with the SEC in the third 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 August 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: August 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 August 12, 2015.



**HISTOGENICS CORPORATION ANNOUNCES SECOND QUARTER 2015
FINANCIAL AND OPERATING RESULTS**

*- Continued Progress on NeoCart® Phase 3 Trial and 2015 Business Objectives -
- Company to Host Conference Call and Webcast Today at 8:30 a.m. EDT -*

WALTHAM, Mass., August 12, 2015 /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 quarter ended June 30, 2015.

“The second quarter was one of transition as we hired several new executives to drive the further development and commercialization of NeoCart,” stated Adam Gridley, President and Chief Executive Officer of Histogenics. “We continued to make steady enrollment progress in our NeoCart trial, and in our collaboration with Intrexon, where our partnership has generated some exciting early technical results. With our new management team and Scientific Advisory Board in place, we’re also turning our efforts to new indications and applications for our regenerative medicine technology platform. Our primary focus for the rest of the year will remain on the enrollment of the NeoCart Phase 3 trial, the technical transfer activities for our manufacturing operations, and on opportunities to advance and expand our pipeline.”

Second Quarter 2015 and Recent Highlights

- Histogenics continued to enroll patients in the NeoCart Phase 3 trial with completion of enrollment targeted by the end of the second quarter of 2016. Several enrollment optimization initiatives in the second quarter were completed, with new investigators joining the trial, expanding eligibility to include Kaiser Permanente patients in California, and the launch of targeted local recruiting campaigns to support the Phase 3 trial investigators.
- Histogenics and Intrexon Corporation (Intrexon), Histogenics’ collaboration partner for potential next generation products, have completed the evaluation of multiple alternatives for development of an allogeneic, one-step treatment for cartilage repair. The partners have elected to pursue an induced pluripotent stem cells (iPSC) approach. The next technical milestone is the demonstration of the capability of an Intrexon developed iPSC-derived cell line in the NeoCart cell and tissue engineering manufacturing process in the first quarter of 2016.
- Histogenics completed the near-term buildout of its management team with the hiring of Jon Lieber and Gloria Matthews as Chief Financial Officer and Chief Medical Officer, respectively. Steve Kennedy was also promoted to Chief Technology Officer to round out the executive management team.
- Histogenics has renewed its focus on its intellectual property estate and product portfolio, and has recently completed several projects to prepare for potential partnerships or collaborations around its broad patent portfolio and historical product candidates, both in the cellular, tissue and biomaterials space of Histogenics’ regenerative medicine platform.
- In June 2015 Histogenics received a notice of allowance from the United States Patent and Trademark Office regarding a method of use for a double-structured tissue implant for treatment of tissue defects. The Company believes this further enhances the depth of protection around the NeoCart proprietary scaffolds.



Financial Results for the Second Quarter 2015

For the second quarter of 2015, Histogenics reported a net loss attributable to common stockholders of \$(7.6) million, or \$(0.58) per share, compared to \$(11.8) million, or \$(19.85) per share, in the second quarter of 2014. The second quarter of 2014 included a \$2.3 million charge related to fair value adjustments to certain liabilities that were either settled or terminated upon the closing of Histogenics' initial public offering in the fourth quarter of 2014. Research and development expenses were \$5.9 million in the second quarter of 2015, compared to \$4.7 million in the second quarter of 2014 reflecting increased activity and enrollment in the NeoCart Phase 3 clinical trial as well as increased investment in various NeoCart development and manufacturing programs. General and administrative expenses were \$1.7 million in the second quarter of 2015, compared to \$1.3 million in the second quarter of 2014 with the increase due to various public company costs such as increased insurance premiums, board fees and stock compensation expense.

At June 30, 2015 Histogenics had cash, cash equivalents and marketable securities of \$45.2 million, compared to \$58.1 million at December 31, 2014. Histogenics' believes its current cash position will fund its operations into 2017.

Conference Call and Webcast Information

Management will host a conference call on Wednesday, August 12, 2015 at 8:30 a.m. EDT. A question-and-answer session will follow Histogenics' remarks. To participate on the live call, please dial (855) 890-8663 (domestic) or (720) 634-2936 (international) and provide the conference ID 85532537 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 30 days following the presentation.

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.

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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 three months ended March 31, 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 June 30, 2015, to be filed with the SEC in the third 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.

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

	<u>Three Months Ended June 30,</u>		<u>Six Months Ended June 30,</u>	
	<u>2015</u>	<u>2014</u>	<u>2015</u>	<u>2014</u>
Operating expenses:				
Research and development	\$ 5,858	\$ 4,669	\$ 11,622	\$ 8,043
General and administrative	1,735	1,341	3,844	3,140
Total operating expenses	<u>7,593</u>	<u>6,010</u>	<u>15,466</u>	<u>11,183</u>
Loss from operations	\$ (7,593)	\$ (6,010)	\$ (15,466)	\$ (11,183)
Other income (expense):				
Interest expense, net	\$ (26)	\$ —	\$ (88)	\$ —
Other income (expense), net	(14)	(3)	(43)	(5)
Change in fair value of warrant liability, other liability and net sales distribution payment liability	<u>—</u>	<u>(2,289)</u>	<u>—</u>	<u>(551)</u>
Total other income (expense), net	<u>(40)</u>	<u>(2,292)</u>	<u>(131)</u>	<u>(556)</u>
Net loss	<u>\$ (7,633)</u>	<u>\$ (8,302)</u>	<u>\$ (15,597)</u>	<u>\$ (11,739)</u>
Loss attributable to common stockholders - basic and diluted	<u>\$ (7,633)</u>	<u>\$ (11,822)</u>	<u>\$ (15,597)</u>	<u>\$ (15,259)</u>
Loss per common share - basic and diluted:	<u>\$ (0.58)</u>	<u>\$ (19.85)</u>	<u>\$ (1.18)</u>	<u>\$ (25.91)</u>
Weighted-average shares used to compute earnings per common share - basic and diluted:	<u>13,215,701</u>	<u>595,552</u>	<u>13,208,483</u>	<u>588,936</u>



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

	<u>June 30,</u> <u>2015</u> <u>(unaudited)</u>	<u>December 31,</u> <u>2014</u>
Cash and cash equivalents	\$ 45,222	\$ 58,060
Prepaid expenses and other current assets	897	796
Property and equipment, net	5,428	4,878
Other assets, net	1,691	1,765
Total assets	<u>\$ 53,238</u>	<u>\$ 65,499</u>
Current liabilities	6,687	8,251
Non-current liabilities	2,686	3,042
Total stockholder's equity	43,865	54,206
Total liabilities and stockholders' equity	<u>\$ 53,238</u>	<u>\$ 65,499</u>

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SOURCE: Histogenics Corporation