
**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): February 26, 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 February 26, 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 and year ended December 31, 2014. 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’ registration statement on Form S-1 (File No. 333-199202), as amended, which is on file with the SEC and declared effective on December 2, 2014 and available on the SEC’s website at www.sec.gov. Additional information will also be set forth in those sections of Histogenics’ Annual Report on Form 10-K for the year ended December 31, 2014, which will be filed with the SEC in the first quarter of 2015. In addition to the risks described above and in Histogenics’ 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 8.01. Other Events.

On February 26, 2015, Histogenics announced that its 2015 Annual Meeting of Stockholders will be held on Wednesday, June 24, 2015 at the offices of Gunderson Dettmer Stough Villeneuve Franklin & Hachigian, LLP, One Marina Park Drive, Suite 900, Boston, Massachusetts 02210. The meeting will be Histogenics' first annual meeting since becoming a public company in December 2014.

Item 9.01. Financial Statements and Exhibits.

(d) *Exhibits*

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release of Histogenics Corporation dated February 26, 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: February 26, 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 February 26, 2015.

HISTOGENICS CORPORATION ANNOUNCES FOURTH QUARTER AND FULL YEAR 2014 FINANCIAL RESULTS

WALTHAM, Mass., February 26, 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 fourth quarter and full year ended December 31, 2014.

“2014 was a transformative year for Histogenics,” stated Adam Gridley, President and Chief Executive Officer of Histogenics. “We completed our initial public offering in December 2014, including the sale of additional shares pursuant to the underwriters’ overallotment option, pursuant to which we raised approximately \$70.1 million in gross proceeds. We successfully re-initiated our on-going NeoCart Phase 3 clinical trial for knee cartilage injuries and began executing on our manufacturing scale-up and technology transfer plans. We also executed an agreement with Intrexon Corporation to initiate development of potential next-generation universal chondrocyte technologies for our cartilage regeneration platform.”

Financial Results for the Fourth Quarter and Full Year 2014

For the fourth quarter of 2014, Histogenics reported a net profit of \$0.9 million, or \$1.70 per share, which included a one-time \$10.0 million gain on the extinguishment of debt, compared to a net loss of \$(14.2) million, or \$(73.35) per share for the same period in 2013. For the year ended December 31, 2014, Histogenics reported a net loss of \$(22.8) million, or \$(6.85) per share, compared to a net loss of \$(25.7) million, or \$(96.58) per share, for the same period in 2013.

For the fourth quarter of 2014, selling, general and administrative expenses were \$1.9 million, compared to \$1.9 million in the fourth quarter of 2013. Selling, general and administrative expenses were \$6.7 million in the full year 2014, compared to \$4.8 million in 2013. The increases in selling, general and administrative expenses in the full year 2014 were primarily the result of additional resources required to support Histogenics’ initial public offering process as well additional facility and IT related expenses needed to support headcount needs.

For the fourth quarter of 2014, research and development expenses were \$4.6 million, compared to \$3.6 million in the fourth quarter of 2013. Research and development expenses were \$25.9 million in the full year 2014, compared to \$11.9 million in 2013. The increase in research and development expenses in the fourth quarter of 2014 was primarily from the costs of enrollment of patients in Histogenics’ NeoCart® Phase 3 clinical trial. The increases in research and development expenses for the full year 2014 was primarily due to a \$10.0 million up-front, one-time, technology access fee in the form of a convertible promissory note issued to Intrexon Corporation as part of the Exclusive Channel Collaboration with Histogenics, as well as the incremental costs of enrolling patients in Histogenics’ NeoCart® Phase 3 clinical trial.

In December 2014, Histogenics completed its initial offering which resulted in \$65.0 million in gross proceeds. With the inclusion of the underwriter’s overallotment exercise, Histogenics raised approximately \$70.1 million in gross proceeds, for a total of approximately \$62.8 million in net proceeds. The overallotment is not included in cash and cash equivalents as of December 31, 2014 as the proceeds were received in January 2015.

At December 31, 2014, Histogenics had cash, cash equivalents, and marketable securities of \$58.1 million compared to \$8.7 million at December 31, 2013.

2014 Operational Highlights

Histogenics' operational highlights for the year ended December 31, 2014 include:

- Re-initiation of its NeoCart® Phase 3 clinical trial in early 2014, and completion of all site start-up and training activities for approximately 30 investigational sites.
- Initiation of its critical raw material technology transfer project in the spring of 2014, where it will source and supply the critical raw materials used in the manufacture of NeoCart®. Histogenics' has completed its initial engineering runs and initial validation studies for its additional facility in Lexington, Massachusetts, which has been operational since October 2014.
- Execution of an Exclusive Channel Collaboration with Intrexon Corporation in September 2014 to develop next-generation cartilage products, increase Histogenics' future manufacturing capabilities and capacity, and accelerate its platform technology pipeline initiatives.
- Submission of a protocol amendment in November 2014 to its NeoCart® Phase 3 clinical trial to augment addition Health Economics Outcomes Research data, intended to further support its future reimbursement initiatives, including collecting key economic data and outcomes associated with quality of life, productivity and return to work status, and healthcare resource utilization related to direct and indirect costs.
- Histogenics received preliminary feedback and general acceptance of its raw material transition strategy and future commercial readiness upgrades from the U.S. Food and Drug Administration (FDA) in December 2014.

Subsequent Events in 2015

Since January 1, 2015, operational highlights include:

- Finance veteran David Gill joined Histogenics' Board of Directors in February 2015, and will chair Histogenics' Audit Committee of its Board of Directors.

2015 Guidance

"Looking forward, we believe that 2015 will be a pivotal year for Histogenics. Our focus continues to be on completing enrollment of the NeoCart® Phase 3 clinical trial in the second quarter of 2016, along with executing against our longer-term plans for reimbursement and commercial scale-up intended to support NeoCart® upon potential launch following FDA approval, if any," continued Mr. Gridley. "We are also turning our efforts to strategic pipeline opportunities, and our research and development efforts will be focused on generating and publishing additional data demonstrating the utility of our cartilage regeneration platform and our ongoing collaboration with Intrexon."

Histogenics believes its current cash position will fund its operations through the middle of 2017, and expects to have approximately \$33.0 million to \$35.0 million at the end of 2015 based on its current operating plan.

Conference Call Information

Histogenics will host a conference call on Thursday, February 26, 2015 at 8:00 a.m. Eastern Time to discuss Histogenics' financial and operational results for the fourth quarter and full year ended December 31, 2014, and other corporate activities. 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 83728349 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 60 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 under “2015 Financial Guidance” 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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HISTOGENICS CORPORATION
Consolidated Balance Sheet Data
(in thousands)
Unaudited

	December 31,	
	2014	2013
Cash and cash equivalents	\$58,060	\$ 8,734
Total current assets	58,856	10,346
Total assets	65,499	14,796
Total current liabilities	8,251	5,087
Net sales distribution payment liability	—	13,100
Warrant liability	—	636
Other liability	—	13,176
Total liabilities	11,293	33,279
Total stockholders' equity (deficit)	54,206	(75,554)

HISTOGENICS CORPORATION
Consolidated Statements of Operations Data
(in thousands, except share and per share data)
Unaudited

	For the Three Months Ended December 31,		For the Twelve Months Ended December 31,	
	2014	2013	2014	2013
Revenue	\$ —	\$ —	\$ —	\$ 8
Operating expenses:				
Research and development	4,576	3,540	25,856	11,946
Selling, general and administrative	1,903	1,917	6,746	4,847
Impairment of goodwill and intangible assets	60	60	60	60
Total operating expenses	6,539	5,517	32,662	16,853
Loss from operations	(6,539)	(5,517)	(32,662)	(16,845)
Other income (expense):				
Interest expense, net	(132)	—	(151)	—
Other expense, net	19	(23)	13	(52)
Gain on extinguishment of debt	10,007	—	10,007	—
Change in fair value of warrant liability, other liability and net sales distribution payment liability	(2,435)	(8,619)	—	(8,815)
Total other income (expense), net	7,459	(8,642)	9,869	(8,867)
Net loss	\$ 920	\$ (14,159)	\$ (22,793)	\$ (25,712)
Earnings (loss) attributable to common stockholders - basic	\$ 9,622	\$ (42,673)	\$ (10,510)	\$ (56,003)
Earnings (loss) attributable to common stockholders - diluted	\$ 9,586	\$ (42,673)	\$ (10,510)	\$ (56,003)
Earnings (loss) per common share - basic	\$ 2.23	\$ (73.35)	\$ (6.85)	\$ (96.58)
Earnings (loss) per common share - diluted	\$ 1.70	\$ (73.35)	\$ (6.85)	\$ (96.58)
Weighted-average shares used to compute loss per common share - basic	4,309,880	581,770	1,534,108	579,849
Weighted-average shares used to compute loss per common share - diluted	5,602,759	581,770	1,534,108	579,849

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SOURCE: Histogenics Corporation