

HISTOGENICS CORP  
Form 8-K  
December 21, 2018

**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): December 21, 2018 (December 19, 2018)

**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**

**Waltham, Massachusetts 02451**

**(781) 547-7900**

**04-3522315**

(I.R.S. Employer Identification  
Number)

Edgar Filing: HISTOGENICS CORP - Form 8-K

(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 1.01 Entry into a Material Definitive Agreement.**

The disclosure set forth in Item 5.02(c) below is incorporated herein by reference.

**Item 1.02 Termination of a Material Definitive Agreement.**

On December 21, 2018, Histogenics Corporation (the Company) and Intrexon Corporation (Intrexon) entered into a mutual termination and release agreement (the Mutual Termination Agreement) pursuant to which the Company and Intrexon mutually agreed to terminate the Exclusive Channel Collaboration entered into between the Company and Intrexon in September 2014 (the ECC).

Pursuant to the ECC, the Company was responsible for the research and development costs incurred by Intrexon associated with the development of product candidates under the collaboration. As of September 30, 2018, the Company had accrued approximately \$3.0 million of research and development expenses under the ECC (the Accrued Expenses).

In connection with the Mutual Termination Agreement, in lieu of payment of the Accrued Expenses, the Company agreed to pay Intrexon an aggregate of up to \$1.5 million, with \$0.375 million paid at the time of entering into the Mutual Termination Agreement and \$1.125 million payable within one year following the Company's submission of a Biologics License Application (BLA) to U.S. Food and Drug Administration (the FDA) for NeoCart.

This summary of the Mutual Termination Agreement is qualified in its entirety by reference to the full text of the Mutual Termination Agreement, which is included as Exhibit 10.1 hereto and incorporated herein by reference.

**Item 3.01 Notice of Delisting or Failure to Satisfy a Continued Listing Rule or Standard; Transfer of Listing.**

On December 19, 2018, the Company received a letter (the Notice) from the Listing Qualifications staff (the Staff) of The Nasdaq Stock Market LLC (Nasdaq) notifying the Company that for the last 30 consecutive business days prior to the date of the Notice, the market value of the Company's listed securities was less than \$35 million, which does not meet the requirement for continued listing on The Nasdaq Capital Market, as required by Nasdaq Listing Rule 5550(b)(2) (the Market Value Rule). In accordance with Nasdaq Listing Rule 5810(c)(3)(C), Nasdaq has provided the Company with 180 calendar days, or until June 17, 2019, to regain compliance with the Market Value Rule. If the Company regains compliance with the Market Value Rule, Nasdaq will provide written confirmation to the Company and close the matter.

The Notice does not result in the delisting of the Company's common stock from The Nasdaq Capital Market. To regain compliance with the Market Value Rule, the market value of the Company's listed securities must meet or exceed \$35 million for a minimum of ten consecutive business days during the 180-day grace period ending on or before June 17, 2019. The Company could also regain compliance with Nasdaq's alternative continued listing requirements by having stockholders' equity of \$2.5 million or more, or net income from continuing operations of \$500,000 in the most recently completed fiscal year.

In the event that the Company does not regain compliance with the Market Value Rule within this 180-day period, the Company may be eligible to seek an additional compliance period of 180 calendar days if it meets the continued listing requirement for market value of publicly held shares and all other initial

listing standards for the Nasdaq Capital Market, and provides written notice to Nasdaq of its intent to cure the deficiency during this second compliance period.

As previously disclosed by the Company, on October 17, 2018, the Staff notified the Company that the bid price of its listed security had closed at less than \$1 per share over the previous 30 consecutive business days, and, as a result, did not comply with Nasdaq Listing Rule 5550(a)(2) (the Bid Price Rule). In accordance with Nasdaq Listing Rule 5810(c)(3)(A), the Company was provided 180 calendar days, or until April 15, 2019 to regain compliance with the Bid Price Rule. Further information is available in the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission (the SEC) on October 18, 2018.

**Item 5.02 Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.**

**(b) *Resignation of Executive Officer***

On December 19, 2018, Jonathan Lieber notified the Company of his resignation as the Company's Chief Financial Officer and Treasurer and all other corporate positions with the Company and its subsidiaries effective as of December 21, 2018. Mr. Lieber resigned to pursue other business opportunities as a consultant with Danforth Advisors, LLC (Danforth) and not due to any disagreement with the Company's operations, financials, policies or procedures. As described below under Item 5.02(c), Mr. Lieber will continue as the Company's interim chief financial officer pursuant to a consulting agreement between the Company and Danforth.

**(c) *Appointment of Certain Officers***

On December 21, 2018, the Company entered into a consulting agreement (the Consulting Agreement) with Danforth pursuant to which Danforth will provide finance, accounting and administrative functions, including interim chief financial officer services to be provided by Mr. Lieber, to the Company. The Company will pay Danforth an agreed upon hourly rate for such services and will reimburse Danforth for expenses. The Consulting Agreement has an initial term of one year and may be extended by mutual agreement of the parties. The Consulting Agreement may be terminated by the Company or Danforth with cause, upon 30 days written notice and without cause, upon 60 days written notice.

The Board of Directors (the Board) has appointed Mr. Lieber, Managing Director of Danforth, as Interim Chief Financial Officer, effective December 21, 2018 immediately upon the resignation of Mr. Lieber from his role as full-time Chief Financial Officer of the Company.

Mr. Lieber, age 49, has served as the Company's Chief Financial Officer since July 2015. Prior to joining the Company, Mr. Lieber was Senior Vice President and Chief Financial Officer of Metamark Genetics, Inc., a privately held, urology-focused, molecular diagnostics company, from January 2014 to June 2015. From September 2012 to September 2013, Mr. Lieber served as the Chief Financial Officer and Treasurer of Repligen Corporation, a manufacturer and supplier of high-value consumables to the life sciences industry. From June 2009 to May 2012, Mr. Lieber served as Chief Financial Officer and Treasurer of Xcellerex, Inc., a privately-held company engaged in the manufacture and sale of capital equipment and related consumables to the biopharmaceutical industry. Mr. Lieber received an M.B.A. in finance from the Stern School of Business of New York University and a B.S. in business administration from Boston University. Mr. Lieber currently holds 5,000 shares of the Company's common stock and vested options to purchase up to 176,457 shares of the Company's common stock, which are exercisable through June 30, 2018.



Other than as described above there are no related party transactions between the Company and Mr. Lieber and Mr. Lieber is neither related to, nor does he have any relationship with, any existing member of the Board or any executive officer of the Company.

This summary of the Consulting Agreement is qualified in its entirety by reference to the full text of the Consulting Agreement, which is included as Exhibit 10.2 hereto and incorporated herein by reference.

#### **Item 8.01 Other Events.**

On December 20, 2018, the Company had a telephonic meeting with senior members of the FDA. Based on the feedback received from the FDA, while the NeoCart Phase 3 clinical trial resulted in certain compelling data, the FDA indicated that an additional clinical trial would need to be completed before it would accept a submission of a BLA for NeoCart. The FDA indicated receptivity to novel clinical trial methodologies and regenerative medicine advanced therapy designations in order to support additional data for a future potential submission. However, considering the time and funding required to conduct such a trial, the Company expects to discontinue the development of NeoCart and does not plan to submit a BLA.

The Company has not yet received an official FDA notification of the determination made by the FDA and discussed at the December 20, 2018 meeting and the information in this Current Report on Form 8-K may be altered or supplemented by the information contained in the official documentation.

The Board has initiated a process to evaluate strategic alternatives to maximize value for all stakeholders. This process, which will be conducted with the assistance of financial and legal advisors, will consider the full range of potential strategic alternatives, which includes, but is not limited to, acquisitions, business combinations, joint ventures, public and private capital raises, recapitalization, and sale transaction options, including a sale of assets or intellectual property. Since these efforts may not be successful and in light of its limited cash reserves the Company is considering all possible alternatives, including restructuring activities, a wind-down of operations, or seeking chapter 11 bankruptcy protection to complete or execute a restructuring transaction or liquidation. The Company intends to implement a restructuring plan to reduce costs.

The Company has retained Canaccord Genuity LLC as financial advisor to assist in the review and will engage such other advisors and consult with existing advisors as appropriate.

The Company has determined not to proceed at this time with its earlier plans to conduct a stockholder meeting to increase its authorized shares and a reverse split, for which it had filed a preliminary proxy statement with the SEC on October 18, 2018.

A copy of the Company's press release dated December 21, 2018 announcing the results of its December 20, 2018 discussions with the FDA and its plans to evaluate strategic alternatives is attached hereto as Exhibit 99.1 and is hereby incorporated by reference herein.

#### **Supplemental Risk Factor**

In connection with entering into the disclosure set forth above, the Company is also updating the risk factors, and subsequent filings, included in its Annual Report on Form 10-K for the year ended December 31, 2017 and Quarterly Report on Form 10-Q for the quarter ended September 30, 2018, as follows:



***There is no certainty that the Company will be able to execute on any strategic alternatives to maximize stakeholder value. If the Company is unable to identify and execute such strategic alternatives, it may be forced to cease operations and liquidate.***

Based on the results of the Company's Phase 3 clinical study of NeoCart and feedback from the FDA regarding a potential BLA submission, the Company began a comprehensive review of strategic alternatives to maximize stakeholder value. The Company will utilize its previously formed special committee of independent directors (the

Special Committee) to evaluate potential strategic alternatives in an effort to maximize value for stakeholders. The Board and the Special Committee have retained Canaccord Genuity LLC to advise and assist the Company in this review, along with legal advisors. The strategic alternatives that the Company is exploring, may include some or all of the following: license, divestiture, or monetization of current assets; license or acquisition of additional assets; merger, joint venture, partnership, or other business combination with another entity, public or private. There can be no assurance that this process will result in a transaction, or that if a transaction does occur, that it will successfully enhance stakeholder value. The Company's expected cash position, net of all liabilities, limits the Company's attractiveness to potential merger candidates and the value that the Company may receive in such merger, joint venture, partnership or other business combination scenarios may be less than the current market value of the Company. If the Company is unable to identify and execute on a strategic alternative, it may be forced to wind down and liquidate its assets.

#### **Item 9.01. Financial Statements and Exhibits.**

##### **(d) Exhibits**

<b>Exhibit No.</b>	<b>Description</b>
10.1	<u>Mutual Termination and Release Agreement dated December 21, 2018, between Histogenics Corporation and Intrexon Corporation.</u>
10.2+	<u>Consulting Agreement, effective December 21, 2018, between the Company and Danforth Advisors, LLC</u>
99.1	<u>Press Release of Histogenics Corporation dated December 21, 2018.</u>

+ Indicates management contract or compensatory plan.

#### **Forward-Looking Statements**

Various statements in this Current Report on Form 8-K are forward-looking statements under the securities laws. Words such as, but not limited to, anticipate, believe, can, could, expect, estimate, design, goal, intend, 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: statements regarding the future business operations of the Company; completing a restructuring plan and the associated costs and charges related thereto; the prospect for the successful sale of the Company or of any of the Company's assets; the possibility of a liquidating distribution to Company stockholders; the ability of the Company to pay its creditors and successfully complete an orderly wind



down; the ability to liquidate the Company's assets outside of a court-supervised proceeding; the ability of the Company to restructure; 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 the Company's Annual Report on Form 10-K for the year ended December 31, 2017 and Quarterly Report on Form 10-Q for the quarter ended September 30, 2018, which are on file with the SEC and available on the SEC's website at [www.sec.gov](http://www.sec.gov). In addition to the risks

described above and in the Company's 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 the Company's results.

There can be no assurance that the actual results or developments anticipated by the Company will be realized or, even if substantially realized, that they will have the expected consequences to, or effects on, the Company. 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 the Company or any person acting on its behalf are expressly qualified in their entirety by the cautionary statements contained or referred to herein. The Company cautions investors not to rely too heavily on the forward-looking statements the Company makes or that are made on its behalf. The information in this Current Report on Form 8-K is provided only as of the date of this Current Report on Form 8-K, and the Company 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.

**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: December 21, 2018

By: /s/ Adam Gridley  
Adam Gridley

President and Chief Executive Officer