HISTOGENICS CORP
Form 8-K
December 21, 2017

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 20, 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 1.01. Entry Into a Material Definitive Agreement.

On December 20, 2017, Histogenics Corporation (the Company) entered into a License and Commercialization Agreement (the License Agreement), by and between the Company and MEDINET Co., Ltd. (MEDINET) with regards to the commercialization of NeoCart® in Japan. Pursuant to the terms of the License Agreement, MEDINET will pay the Company up to an aggregate of approximately $86.9 million dollars plus royalties, consisting of (i) a non-refundable upfront payment of $10.0 million, (ii) potential regulatory and development milestone payments of up to an aggregate of $10.5 million, (iii) overall sales-dependent milestones of up to an aggregate of $66.4 million and (iv) tiered royalties on net sales of NeoCart in Japan. In return for such consideration, MEDINET will gain exclusive commercialization rights to NeoCart in Japan for the replacement or repair of damaged, worn or defective cartilage in humans and non-human animals.

The License Agreement will remain in effect until the later of (i) expiration of the last-to-expire valid and enforceable patent covering NeoCart in Japan and (ii) ten (10) years from the first commercial sale of NeoCart in Japan. MEDINET has an option to extend the term for five (5) years upon written notice to the Company prior to the end of the initial term. MEDINET has the right to terminate the License Agreement for any or no reason at any time, and Company may terminate the License Agreement in the event MEDINET or one of its affiliates or sublicensees challenges a patent covering NeoCart in Japan. Additionally, either party may terminate the Agreement for an uncured material breach by the other party or upon certain insolvency or bankruptcy proceedings involving the other party. Each party has agreed to indemnify the other party for third party claims arising out of its or its affiliates willful misconduct or negligence, its breaches of representations, warranties, covenants, obligations or agreements contained in the License Agreement, or its exploitation of NeoCart in its respective territory, subject to specified exclusions.

The Company and MEDINET have agreed to enter into supply, quality and pharmacovigilance agreements (the Supply Agreements) as soon as practicable through which MEDINET will purchase its requirements of NeoCart and the related biopsy kit from the Company. Pursuant to the terms of the License Agreement, the Supply Agreements will contain provisions addressing several topics, including those set forth in the License Agreement.

The foregoing description of the License Agreement does not purport to be complete and is qualified in its entirety by License Agreement, which will be filed as an Exhibit to the Company s annual report on Form 10-K for the year ending December 31, 2017. The Company intends to submit a Freedom of Information Act confidential treatment request to the Securities and Exchange Commission pursuant to Rule 24b-2 under the Securities Exchange Act of 1934, as amended, requesting that it be permitted to redact certain portions of the License Agreement. The omitted material will be included in the request for confidential treatment.

Item 8.01. Other Events.

On December 21, 2017, Histogenics issued a press release announcing the execution of the License Agreement. A copy of the press release is filed as Exhibit 99.1 hereto and incorporated by reference herein.

Item 9.01. Financial Statements and Exhibits.

(d) ***Exhibits***

Exhibit No.	Description
99.1	Press release of Histogenics Corporation dated December 21, 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: December 21, 2017

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