
**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): May 9, 2016

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 1.01. Entry Into a Material Definitive Agreement.

On May 10, 2016, Histogenics Corporation (“Histogenics”) amended its license agreement (the “Amendment”) with Purpose Co., Ltd. (“Purpose”). Under the Amendment, Histogenics reassumes sole responsibility for the development and commercialization of all or any portion of the Histogenics product line in Japan. Purpose expands its license to Histogenics to include an exclusive, perpetual (with respect to patent rights, for the full term of each patent licensed) and sublicensable license, under Purpose’s patent rights and technology relating to its tissue processor, in Japan, to make, use, sell, import and otherwise exploit products or services covered by claims of such Purpose patents or Purpose’s technology, only in connection with articular cartilage, ligaments, tendons and meniscus. The Amendment also terminates the license that Purpose held under the original license agreement to develop and commercialize Histogenics’ patents and technology in Japan.

Pursuant to the Amendment, Histogenics is obligated to pay Purpose payments of up to \$10 million in the event certain milestones are satisfied. Histogenics is also required to pay Purpose a royalty payment in the low single digits on the net sales in Japan for Histogenics products that rely on a Purpose patent or incorporate or necessarily rely upon any Purpose technology. Such royalty payment shall be reduced if the applicable Histogenics products do not rely on an outstanding Purpose patent.

The foregoing description of the Amendment does not purport to be a complete statement of the parties’ rights under such agreement and are qualified in their entirety by reference to the full text of such agreement, a copy of such agreement will be filed as an exhibit to Histogenics’ quarterly report on Form 10-Q for the quarter ended June 30, 2016.

On May 10, 2016, Histogenics issued a press release, a copy of which is attached hereto as Exhibit 99.1, announcing entry into the Amendment.

Item 9.01. Financial Statements and Exhibits.

(d) *Exhibits*

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release of Histogenics Corporation dated May 10, 2016.

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: May 10, 2016

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

EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release of Histogenics Corporation dated May 10, 2016.



HISTOGENICS CORPORATION ACQUIRES NEOCART® DEVELOPMENT AND COMMERCIALIZATION RIGHTS FOR JAPANESE MARKET

- Developing Plans to Re-Engage with Japanese Regulatory Authorities and Seek Development and Commercialization Partners in Japan -

WALTHAM, Mass., May 10, 2016 /GLOBE NEWSWIRE/ – Histogenics Corporation (Histogenics) (Nasdaq: HSGX), a regenerative medicine company focused on developing and commercializing products in the musculoskeletal space, announced that it has acquired the development and commercialization rights to NeoCart for the Japanese market from its long-time development partner Purpose Co., Ltd (Purpose). This agreement is the next step in Histogenics’ strong and evolving relationship with Purpose and provides Histogenics the opportunity to capitalize on the recent advancements in regenerative medicine regulatory pathways in Japan.

“We are pleased that we were able to acquire the rights to NeoCart in Japan from Purpose. We believe that, as in the United States, the Japanese market for cartilage repair is in need of a better and more cost-effective alternative that offers patients a more rapid, consistent and durable recovery with a procedure that is quick and easy for physicians,” stated Stephen Kennedy, Chief Technology Officer of Histogenics. “Purpose has been an important development and manufacturing partner to Histogenics since we were founded and we are pleased that our relationship has been strengthened based on Purpose’s innovative, patent-protected tissue engineering processors that enable us to produce cartilage tissue using a combination of cells, biomaterials and engineering,” continued Mr. Kennedy.

Under the terms of the agreement, Histogenics assumes sole responsibility for and rights to the development and commercialization of NeoCart in Japan. The Japanese market for cartilage repair is estimated to represent more than 200,000 procedures annually and is growing due to favorable demographic trends, as well as reforms to the national healthcare system related to regenerative therapies. The Japanese Regenerative Medicine Law was passed in 2014 to potentially expedite the clinical development and commercialization pathways for innovative regenerative cell-based medicines that have demonstrated safety and probable efficacy. Two new products have received full and conditional approval since the law went into effect. In exchange for the transfer of development and commercialization rights, Histogenics will pay a success-based milestone to Purpose upon conditional approval of NeoCart in Japan, as well as commercial milestones and a low single digit royalty on Japanese sales of NeoCart, upon full approval, if any, in Japan.

“With this new agreement in place, we intend to build upon our initial meetings in 2015 with the Japanese Pharmaceuticals and Medical Devices Agency to further define the regulatory pathway for potential conditional approval of NeoCart, based partly on the Phase II data from NeoCart, and our more than 10 years of manufacturing and process development experience supporting the product,” commented Adam Gridley, Chief Executive Officer of Histogenics. “In parallel, we have initiated discussions with development and commercialization partners for the Japanese and pan-Asia markets to better serve this growing and important region for our products. Lastly, we also intend to explore the appropriate regulatory development pathways for our allogeneic induced pluripotent stem cell (iPSC) derived future product candidates being developed with our partner, Intrexon.”

Hiromi Takagi, President of Purpose, Co., Ltd., stated, “Our founder, the late Kazumi Takagi, began this project in order to ‘provide as much relief as possible for the aches, pains, and lack of freedom people might experience as their bodies age and deteriorate,’ and it therefore gives me great joy to know that his vision will take another step toward reality thanks to our new partnership with Histogenics. Assuming NeoCart

receives governmental approval in Japan as well as the US, it is my hope that NeoCart will provide relief and improved quality of life for as many patients as possible.”

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.

About Purpose Co., Ltd.

Purpose offers its products and services in deference to its core motto: “providing clients with safety, security, and comfort in eco-friendly, life-friendly, and human-friendly ways”. Its flagship product, the “tankless water heater” for homes and businesses, has found consumer appeal not only in Japan, but in North America and Oceania as well. Purpose boasts a lineup of goods and services that encompass a wide variety of fields, including electronic control devices, information software, manufacturing equipment, and regenerative medicine supporting equipment. With the help of Dr. Shuichi Mizuno, Assistant Professor of Orthopedic Surgery at Harvard Medical School, Purpose developed the “tissue engineering processor (TEP)” based on the precision machining and electronic control technology it has been developing since the late ‘90s; Purpose’s past and continued provision of this device, as well as the support relating to it, has been a crucial part of its financial and technological support of Histogenics during the initial stages of its endeavors. For more information, please visit www.purpose.co.jp/en/.

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, 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 secure a partner to develop and commercialize NeoCart in Japan; 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, 2015, which is on file with the SEC and available on the SEC’s website at www.sec.gov. Additional factors may be described in those sections of Histogenics’ Quarterly Report on Form 10-Q for the quarter ended March 31, 2016, to be filed with the SEC in the second quarter of 2016. 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.

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SOURCE: Histogenics Corporation