

IntelGenx Technologies Corp.
Form 8-K
December 06, 2017

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

Current Report

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

December 5, 2017

Date of Report (Date of Earliest Event Reported)

IntelGenx Technologies Corp.

(Exact Name of Registrant as Specified in its Charter)

Delaware

(State or other jurisdiction of
incorporation)

000-31187

(Commission File
Number)

870638336

(IRS Employer Identification
No.)

6420 Abrams, Ville St- Laurent, Quebec, Canada

(Address of principal executive offices)

H4S 1Y2

(Zip Code)

Registrant's telephone number, including area code: (514) 331-7440

Check the appropriate box below if the Form 8K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17CFR230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17CFR 240.14a -12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d -2(b))

☐ Pre-commencement communication pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e -4(c))

Item 1.02 Termination of a Material Definitive Agreement.

On December 5, 2017, IntelGenx Corp. (the Company), a wholly owned subsidiary of IntelGenx Technologies Corp., announced it has received notice that RedHill Biopharma Ltd. (NASDAQ: RDHL) (Tel-Aviv Stock Exchange: RDHL) (RedHill) intends to terminate its agreement with the Company for the co-development and commercialization of RIZAPORT®. The termination notice follows receipt of a communication by the U.S. Food and Drug Administration (FDA) indicating that, based on an initial review of the 505(b)(2) New Drug Application (NDA) resubmission for RIZAPORT® 10 mg, the Agency will require additional information before the NDA resubmission is deemed complete and permitted a full review. The questions raised by the FDA, which triggered the current resubmission, primarily related to third party chemistry, manufacturing and controls, and the packaging and labeling of the product. The FDA raised no questions or deficiencies relating to RIZAPORT®'s safety and bio-equivalence data and did not require additional clinical trials.

Item 8.01 Other Events.

On December 5, 2017, the Company issued a press release attached hereto as Exhibit 99.1

The information furnished pursuant to this Item 8.01, including Exhibit 99.1, shall not be deemed filed for purposes of Section 18 of the United States Securities Exchange Act of 1934, as amended (the Exchange Act), or otherwise subject to the liabilities under that Section and shall not be deemed to be incorporated by reference into any filing under the United States Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing

Exhibit Description

99.1 News Release dated December 5, 2017

SIGNATURES

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.

INTELGENX TECHNOLOGIES CORP.

Dated: December 6, 2017

/s/ Horst G. Zerbe
Horst G. Zerbe
President and Chief Executive Officer
