INTREXON CORP
Form 8-K
October 12, 2018

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

Date of report (Date of earliest event reported): October 5, 2018

INTREXON CORPORATION

(Exact Name of Registrant as Specified in Charter)

Virginia	**001-36042**	**26-0084895**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**
20374 Seneca Meadows Parkway, Germantown, Maryland		**20876**

(Address of Principal Executive Offices) **(Zip Code)**

(301) 556-9900

(Registrant s telephone number, including area code)

Not applicable

(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K 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 (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 (17 CFR 230.405) or Rule 12b-2 of the Exchange Act (17 CFR 240.12b-2).

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.

Entry into Exclusive License Agreement; Forfeiture by Intrexon of Series 1 Preferred Stock

On October 5, 2018, or the Effective Date, Precigen, Inc., or Precigen, a wholly owned subsidiary of Intrexon Corporation, or the Company, entered into an exclusive license agreement, or the License Agreement, with Ziopharm Oncology, Inc., or Ziopharm. The Company is a party to certain provisions of the License Agreement, including with respect to exclusivity, release of claims, and the termination of certain agreements. The terms of the License Agreement: (a) terminate, as of the Effective Date, and replace the terms of that certain Exclusive Channel Partner Agreement by and between the Company and Ziopharm, dated January 6, 2011, as amended by the First Amendment to Exclusive Channel Partner Agreement effective September 13, 2011, the Second Amendment to the Exclusive Channel Partner Agreement effective March 27, 2015, and the Third Amendment to Exclusive Channel Partner Agreement effective June 29, 2016, as assigned by the Company to Precigen; (b) (i) require Precigen to use good faith efforts to obtain consent to the transfer of Ziopharm s right, title and interest under that certain License and Collaboration Agreement effective March 27, 2015 between the Company, Ziopharm and Ares Trading S.A., a subsidiary of the biopharmaceutical business of Merck KGaA, as amended, or the Merck Agreement, and (ii) as between the parties, assign certain rights and obligations under the Merck Agreement to Precigen; and (c) provide for the amendment of that certain License Agreement between the Company, Ziopharm and The University of Texas M.D. Anderson Cancer Center, or MD Anderson, with an effective date of January 13, 2015, or the 2015 MDACC License, assigned by the Company and assumed by Precigen effective as of January 1, 2018, and that certain Research and Development Agreement between the Company, Ziopharm and MD Anderson with an effective date of August 17, 2015, or the MDACC Research Agreement, and any amendments or statements of work thereto.

Pursuant to the terms of the License Agreement, Precigen has granted Ziopharm an exclusive, worldwide, royalty-bearing, sub-licensable license to research, develop and commercialize (i) products utilizing Precigen s RheoSwitch® gene switch, or RTS to express IL-12, or the IL-12 Products, for the treatment of cancer, (ii) chimeric antigen receptor, or CAR, products directed to (A) CD19 for the treatment of cancer, referred to as CD19 Products, and (B) a second target, subject to the rights of Ares Trading, S.A. to pursue such target under the Merck Agreement, and (iii) T-cell receptor, or TCR, products, or TCR Products, designed for neoantigens for the treatment of cancer or the treatment and prevention of human papilloma virus, or HPV, to the extent that the primary reason for such treatment or prevention is to prevent cancer, which is referred to as the HPV Field. Precigen has also granted Ziopharm an exclusive, worldwide, royalty-bearing, sub-licensable license for certain patents relating to the *Sleeping Beauty* technology to research, develop and commercialize TCR Products for both neoantigens and shared antigens for the treatment of cancer and in the HPV Field.

Ziopharm will be solely responsible for all aspects of the research, development and commercialization of the exclusively licensed products for the treatment of cancer. Ziopharm is required to use commercially reasonable efforts to develop and commercialize IL-12 Products and CD19 Products, and after a two-year period, the TCR Products.

Precigen has also granted Ziopharm an exclusive, worldwide, royalty-bearing, sub-licensable license to research, develop and commercialize products utilizing an additional construct that expresses RTS IL-12, or Gorilla IL-12 Products, for the treatment of cancer and in the HPV Field.

Precigen will retain rights to research, develop and commercialize CAR products for all other targets, subject to the rights of Ares Trading, S.A. to pursue such target under the Merck Agreement. In addition, Precigen may research, develop and commercialize products for the treatment of cancer, outside of the products exclusively licensed to Ziopharm.

In consideration of the licenses and other rights granted by Precigen, Ziopharm will pay Precigen an annual license fee of $100,000 and has agreed to reimburse Precigen for certain historical costs of the licensed programs and up to $1.0 million, payable quarterly with respect to historical Gorilla IL-12 Products.

Ziopharm will make milestone payments, payable upon the initiation of later stage clinical trials and upon the approval of exclusively licensed products in various jurisdictions, totaling up to an additional $52.5 million for each of four exclusively licensed products, up to an aggregate of $210 million. In addition, Ziopharm will pay Precigen

tiered royalties ranging from low-single digits to high-single digits on the net sales derived from the sales of any approved IL-12 Products and CAR Products. Ziopharm will also pay Precigen royalties ranging from low-single digits to mid-single digits on the net sales derived from the sales of any approved TCR Products, up to maximum royalty amount of $100.0 million in the aggregate. Ziopharm will also pay Precigen 20% of any sublicensing income received by Ziopharm relating to the licensed products.

Ziopharm is responsible for all development costs associated with each of the licensed products, other than Gorilla IL-12 Products. Ziopharm and Precigen will share the development costs and operating profits for Gorilla IL-12 Products, with Ziopharm responsible for 80% of the development costs and receiving 80% of the operating profits, and Precigen responsible for the remaining 20% of the development costs and receiving 20% of the operating profits, except that Ziopharm will bear all development costs and Precigen will share equally in operating profits for Gorilla IL-12 Products in the HPV Field.

Precigen will pay Ziopharm royalties ranging from low-single digits to mid-single digits on the net sales derived from the sale of Precigen s CAR products, up to $100 million.

In consideration of Ziopharm entering into the License Agreement, the Company has agreed to forfeit and return to Ziopharm all shares of Ziopharm s Series 1 Preferred Stock held by or payable to the Company as of the date of the License Agreement. The shares of Series 1 Preferred Stock were valued at approximately $156.9 million as of September 30, 2018.

Precigen has agreed that, during the term of the License Agreement, it will not use the licensed intellectual property to research, develop or commercialize any exclusive product for the treatment of cancer. In addition, for a three year period following the effective date of the License Agreement, Precigen will not research or develop products utilizing regulatable switches that control expression of IL-12 or TCR products designed for neoantigens, in each case for the treatment or prevention of cancer.

Precigen has agreed to amend the MDACC Research Agreement or otherwise make arrangements in order to ensure that all of its benefits and rights therewith vest in Ziopharm.

As between the parties, Precigen has agreed to perform all of the obligations of Ziopharm under the Merck Agreement, other than an obligation of exclusivity thereunder and Ziopharm will remain responsible for all payments owed to Ares Trading S.A. under the Merck Agreement as a result of Ziopharm s, its affiliates or its sublicensees exploitation of CAR products.

The License Agreement will terminate on a product-by-product and/or country-by-country basis upon the expiration of the later to occur of (i) the expiration of the last to expire patent claim for a licensed product, or (ii) 12 years after the first commercial sale of a licensed product in such country. In addition, Ziopharm may terminate the License Agreement on a country-by-country or program-by-program basis following written notice to Precigen, and either party may terminate the License Agreement following notice of a material breach.

The License Agreement also contains customary representations, warranties and covenants from Ziopharm, the Company and Precigen, as well as customary provisions related to indemnity, confidentiality and other matters.

Termination of 2016 Securities Issuance Agreement

As previously disclosed, on June 29, 2016, the Company entered into a securities issuance agreement, or 2016 Securities Issuance Agreement, with Ziopharm, pursuant to which Ziopharm sold and issued shares of Ziopharm s Series 1 Preferred Stock to the Company and provided the Company with registration rights with respect to any common stock issued upon conversion of the Series 1 Preferred Stock. Pursuant to the License Agreement, the 2016

Securities Issuance Agreement was terminated as of the Effective Date, all of the benefits, rights, obligations and liabilities thereunder immediately ceased and terminated and the Company forfeited and returned to Ziopharm all of the shares of Series 1 Preferred Stock owned by the Company and its affiliates as of the Effective Date.

The foregoing description of the License Agreement is only a summary and is qualified in its entirety by reference to the full text of the License Agreement, a copy of which will be filed as an exhibit to its Quarterly Report on Form 10-Q for the period ended September 30, 2018, with portions of the License Agreement omitted and filed separately with the Securities and Exchange Commission pursuant to a request for confidential treatment.

Item 1.02 Termination of a Material Definitive Agreement.

The information required by this Item 1.02 is included under Item 1.01 of this Current Report on Form 8-K and is incorporated herein by reference.

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.

INTREXON CORPORATION

By: /s/ Donald P. Lehr
Name: Donald P. Lehr
Title: Chief Legal Officer

Date: October 12, 2018