ZIOPHARM ONCOLOGY INC
Form 8-K
October 11, 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

ZIOPHARM Oncology, Inc.

(Exact Name of Registrant as Specified in Charter)

Delaware	**001-33038**	**84-1475642**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

One First Avenue, Parris Building 34, Navy Yard Plaza

Boston, Massachusetts	**02129**
(Address of Principal Executive Offices)	**(Zip Code)**

(617) 259-1970

(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, Ziopharm Oncology, Inc., or the Company, entered into an exclusive license agreement, or the License Agreement, with Precigen, Inc., or Precigen, a wholly owned subsidiary of Intrexon Corporation, or Intrexon. The terms of the License Agreement replace the terms of: (a) that certain Exclusive Channel Partner Agreement by and between the Company and Intrexon, 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 Intrexon to Precigen; (b) certain rights and obligations pursuant to that certain License and Collaboration Agreement effective March 27, 2015 between the Company, Intrexon and ARES TRADING Trading S.A., as assigned by Intrexon to Precigen, or the Merck Collaboration Agreement; and (c) that certain License Agreement between the Company, Intrexon 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 Intrexon and assumed by Precigen effective as of January 1, 2018; and that certain Research and Development Agreement between the Company, Intrexon 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 the Company an exclusive, worldwide, royalty-bearing, sub-licensable license to research, develop and commercialize (i) products utilizing Precigen s RheoSwitch® gene switch, or RTS, for the treatment of cancer, referred to as IL-12 Products, (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 Merck KGaA to pursue such target under the Merck Collaboration Agreement, and (iii) T-cell receptor, or TCR, products designed for neoantigens for the treatment of cancer. Precigen has also granted the Company 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, referred to as TCR Products.

The Company will be solely responsible for all aspects of the research, development and commercialization of the exclusively licensed products for the treatment of cancer. The Company 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 the Company an exclusive, worldwide, royalty-bearing, sub-licensable license to research, develop and commercialize products utilizing an additional construct that expresses RTS IL-12 for the treatment of cancer, referred to as Gorilla IL-12 Products.

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

In consideration of the licenses and other rights granted by Precigen, the Company will pay Precigen an annual license fee of $100 thousand and has agreed to reimburse Precigen for certain historical costs of the licensed programs up to $1.0 million, payable quarterly.

The Company will make milestone payments totaling up to an additional $52.5 million for each exclusively licensed program upon the initiation of later stage clinical trials and upon the approval of exclusively licensed products in various jurisdictions. In addition, the Company will pay Precigen tiered royalties ranging from low-single digit to high-single digit on the net sales derived from the sales of any approved IL-12 Products and CAR Products. The

Company will also pay Precigen royalties ranging from low-single digit to mid-single digit 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. The Company will also pay Precigen 20% of any sublicensing income received by the Company relating to the licensed products.

The Company is responsible for all development costs associated with each of the licensed products, other than Gorilla IL-12 Products. The Company and Precigen will share the development costs and operating profits for Gorilla IL-12 Products, with the Company 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.

Precigen will pay the Company 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 the Company entering into the License Agreement, Intrexon has agreed to forfeit and return to the Company all shares of the Company s Series 1 Preferred Stock held by or payable to Intrexon 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 (3) 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 in order to consent to the assignment by Precigen of its respective future rights arising under the MDACC Research Agreement to the Company. Precigen has also agreed to assign to the Company its rights and obligations under the Cooperative Research and Development Agreement that the parties entered into with the National Cancer Institute, dated October 6, 2016.

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, the Company 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 the Company and Precigen, as well as customary provisions related to indemnity, confidentiality and other matters.

Termination of 2011 Stock Purchase Agreement

As previously disclosed, on January 6, 2011, the Company entered into a stock purchase agreement, or 2011 Stock Purchase Agreement, with Intrexon, pursuant to which Randal J. Kirk, as a designee of Intrexon, was appointed as a director of the Company and nominated for election as a director at the Company s 2011 Annual Meeting of Stockholders. Mr. Kirk was re-elected at the Company s 2011 Annual Meeting of Stockholders, and was subsequently recommended for re-election and re-elected as a director at the Company s subsequent annual meetings, including the Company s recent 2018 Annual Meeting of Stockholders. In connection with the entry into the License Agreement, the Company and Intrexon agreed to terminate the 2011 Stock Purchase Agreement and that all of the benefits, rights, obligations and liabilities thereunder shall immediately cease and terminate. As previously reported, Randal J. Kirk resigned from the Company s board of directors on October 5, 2018.

Termination of 2011 Registration Rights Agreement

As previously disclosed, on January 12, 2011, the Company entered into a registration rights agreement, or 2011 Registration Rights Agreement, with Intrexon. In connection with the entry into the License Agreement, the Company

and Intrexon agreed to terminate the 2011 Registration Rights Agreement and that all of the benefits, rights, obligations and liabilities thereunder shall immediately cease and terminate.

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 Intrexon. In connection with the entry into the License Agreement, the Company

and Intrexon agreed to terminate the 2016 Securities Issuance Agreement and that all of the benefits, rights, obligations and liabilities thereunder shall immediately cease and terminate.

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 Annual Report on Form 10-K for its fiscal year ending December 31, 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.

ZIOPHARM ONCOLOGY, INC.

By: /s/ Robert Hadfield
Name: Robert Hadfield
Title: General Counsel and Secretary

Date: October 11, 2018