

ZIOPHARM ONCOLOGY INC
Form 8-K
April 02, 2015

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): **March 27, 2015**

ZIOPHARM Oncology, Inc.

(Exact Name of Registrant as Specified in Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-33038
(Commission File Number)

84-1475672
(IRS Employer

Identification No.)

One First Avenue, Parris Building 34, Navy Yard Plaza

Boston, Massachusetts
(Address of Principal Executive Offices)

(617) 259-1970

02129
(Zip Code)

(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)).

Item 1.01 Entry into a Material Definitive Agreement

Ares Trading License and Collaboration Agreement

On March 27, 2015, ZIOPHARM Oncology, Inc., or the Company, and Intrexon Corporation, or Intrexon, entered into a worldwide License and Collaboration Agreement, or the Ares Trading Agreement, with ARES Trading S.A., or Ares Trading, a company within the pharmaceutical business of Merck KGaA, Darmstadt, Germany, through which the parties established a collaboration for the research and development and commercialization of Products (as defined below) for the prophylactic, therapeutic, palliative or diagnostic use for cancer in humans, which we refer to as the Field.

The Ares Trading Agreement provides for the establishment of committees composed of Ares Trading and Intrexon representatives that will govern activities in, among others, the areas of project establishment, research plans and intellectual property.

The Ares Trading Agreement grants Ares Trading an exclusive, worldwide, royalty-bearing, sub-licensable license under the Company's and Intrexon's patents, know-how and proprietary platform of research tools and technology necessary for the Company and Intrexon to perform their tasks directed towards the design, identification, culturing, and/or production of genetically modified cells to (a) generate and test Chimeric Antigen Receptor T-Cell Products (as defined in the Ares Trading Agreement) solely for the development, regulatory approval and commercialization of Products containing such Chimeric Antigen Receptor T-Cell Products pursuant to the licenses granted in clauses (b) and (c) of this paragraph; (b) develop and commercialize Products in the Field, worldwide, provided that such Products are not Out-of-Scope Products (as defined below) where Ares Trading has not exercised its Option (as defined below); and (c) commercialize the chimeric antigen receptor for Products.

Exclusivity

During the term of the Ares Trading Agreement, subject to the change in control provisions described below, neither the Company nor Intrexon may, directly or indirectly, clinically develop or commercialize any chimeric antigen receptor or Chimeric Antigen Receptor T-Cell Products in the Field other than pursuant to the Ares Trading Agreement, or grant any third party the right to research, develop or commercialize any chimeric antigen receptor or Chimeric Antigen Receptor T-Cell Products in the Field, other than pursuant to the Ares Trading Agreement, or, in the case of Intrexon, pursuant to its rights of independent development as described below. In addition, neither the Company nor Intrexon may, directly or indirectly, clinically develop or commercialize any chimeric antigen receptor or Chimeric Antigen Receptor T-Cell Products in the Field against a Target in animal health.

If Ares Trading fails to exercise its Option with respect to an Out-of-Scope Target as described below, Ares Trading may not directly or indirectly, clinically develop or commercialize any Chimeric Antigen Receptor T-Cell Product against such Out-of-Scope Target under the Ares Trading Agreement.

Consideration and Royalties

Ares Trading will pay an upfront fee of \$115.0 million to Intrexon as consideration for entry into the Ares Trading Agreement. Intrexon will pay 50% of the fee to the Company in accordance with the ECP Amendment, discussed below. Ares Trading will, pursuant to the terms of the Ares Trading Agreement, pay Intrexon certain fees for the research and development activities related to the Products.

Subject to certain expense allocations, Ares Trading will pay Intrexon royalties ranging from the lower-single digits to the lower-double digits of the net sales derived from the sale of Products developed under the Ares Trading Agreement, on a Product-by-Product and a country-by-country basis, which royalties are subject to increase under the Option, as described below. Royalty amounts are subject to adjustment, and the royalty term will terminate, based

upon certain conditions as further described in the Ares Trading Agreement. In accordance with the ECP Amendment, Intrexon will pay to the Company 50% of all royalties that it receives under the Ares Trading Agreement.

The Agreement initially covers two Targets (as defined below) for which Ares Trading must pay a cash fee. Ares Trading may elect additional Targets by paying Intrexon a cash fee.

Milestones

Ares Trading has to make certain payments to Intrexon upon Ares Trading's achievement of designated milestones. Intrexon will pay 50% of all milestones that it receives under the Ares Trading Agreement to the Company under the ECP Amendment. These payments are payable in cash and are generally due within 30 days of the achievement of the relevant milestone.

Development and commercial milestones. Development milestone payments (not to exceed a capped amount per Product) are payable, on a Product-by-Product basis, upon events further defined in the Ares Trading Agreement with respect to the first four approved indications for the Product. Ares Trading shall also make commercial milestone payments with respect to each Product upon the achievement in a calendar year of tiers of annual worldwide net sales of the Product. In aggregate, the potential payments for development and commercial milestones shall be up to \$413 million per Product (or \$826 million for the first two Products).

Technical milestones. Ares Trading must pay to Intrexon further cash fees upon certain technical achievements further specified in the Agreement.

Responsibilities

For each Target selected by Ares Trading, Intrexon is responsible for conducting research and development and the manufacture and supply of Products for use in each Phase 1 clinical trial. Ares Trading is responsible for manufacturing and supplying Products for development use after each Phase 1 clinical trial and for commercialization in the Field.

Product means (a) any pharmaceutical product containing a Chimeric Antigen Receptor T-Cell Product developed by Intrexon under a research program for which the joint steering committee established under the Ares Trading Agreement determines to file an investigational new drug application or under a research program for which Ares Trading has exercised the Option (as defined below) or (b) any pharmaceutical product containing a Chimeric Antigen Receptor T-Cell Product developed by or on behalf of Ares Trading that is a derivative of or is otherwise developed from or based upon a Chimeric Antigen Receptor T-Cell Product described in clause (a).

Target means a unique molecular species or combination thereof (or naturally occurring allelic variant, glycosylation variant, or mutant thereof) that (a) is chemically distinct from other molecules, (b) is a human peptide, protein, polysaccharide or lipid, and (c) wherein a binding entity derives recognized therapeutic value from binding such molecular species.

Option

Intrexon may suggest a Target to Ares Trading, and if Ares Trading decides not to include such Target in a research program, it would be deemed to be an Out-of-Scope Target under the Ares Trading Agreement, Intrexon may, subject to certain conditions, independently exploit Products directed toward such Out-of-Scope Target at its own cost. We refer to such products as Out-of-Scope Products. Notwithstanding the foregoing, Intrexon may not develop a cell targeting an Out-of-Scope Target in the Field that according to the term defined in the Agreement would qualify as a Competitive Product. At the stage of finalization of the Phase 1 clinical trial enrollment of the first Out-of-Scope Product related to the Out-of-Scope Target, Ares Trading may exercise an option, or the Option, to make the Out-of-Scope Product a Product under the Ares Trading Agreement by notifying Intrexon it is doing so and by paying Intrexon a cash fee and paying increased royalties to Intrexon on such Product covered by the exercise of Ares Trading's Option, subject to the other terms and conditions relating to royalty payments.

If Ares Trading does not exercise the Option related to an Out-of-Scope Target and Out-of-Scope Product, Intrexon may further exploit such Out-of-Scope Target and Out-of-Scope Product independently from Ares Trading (subject to the restrictions on Intrexon contained in the Ares Trading Agreement, including Intrexon's obligation not to develop a Competitive Product), in consideration for which (i) Intrexon must pay to Ares Trading a lower double digit percentage of all financial and non-financial consideration received by Intrexon for or in connection with such Out-of-Scope Product, up to a capped amount, which we refer to as the One-Time Intrexon Program Option Fee and (ii) once the One-Time Intrexon Program Option Fee has been paid by Intrexon, Intrexon must provide a credit to Ares Trading under the Ares Trading Agreement, subject to certain conditions, of a mid-single digit percentage of all

financial and non-financial consideration received by Intrexon for or in connection with such Out-of-Scope Target or Out-of-Scope Product.

Termination and Change in Control

Ares Trading may voluntarily terminate, on a Product-by-Product and country-by-country basis or in its entirety, the Ares Trading Agreement upon 90 days' written notice to Intrexon. Intrexon and Ares Trading may each terminate the Ares Trading Agreement if the other party materially breaches the Ares Trading Agreement and fails to cure the breach.

Upon termination of the Ares Trading Agreement, Ares Trading, upon written notice to Intrexon, may continue to develop and commercialize any Product (i) for which a Phase 3 clinical trial has been initiated and of which development has not been terminated by Ares Trading or (ii) that is then being commercialized by Ares Trading. The Option and the payment obligations due to Ares Trading each survive termination of the Ares Trading Agreement with respect to research programs initiated by Intrexon for Out-of-Scope Products started before the effective date of termination.

If either the Company or Intrexon, which for purposes of this paragraph, we are referring to as the Acquiring Party, acquires a third party that has a program competitive to that described under the Ares Trading Agreement, the Acquiring Party may either divest such competitive program within 12 months or include all products under the acquired program as Out-of-Scope Products, which would then become subject to the Option.

If any of the Company, Intrexon or Ares Trading, which for purposes of this paragraph, we are referring to as the Acquired Party, merges with or consolidates with or is acquired by a third party the exclusivity obligations applicable to such person, as described above, will not apply, so long as (i) the competitive program does not use any intellectual property of the Acquired Party or Ares Trading, and (ii) does not utilize services of the personnel of the Acquired Party.

Amendment to ZIOPHARM Exclusive Channel Partner Agreement

On March 27, 2015, the Company and Intrexon entered into a Second Amendment to Exclusive Channel Partner Agreement, or the ECP Amendment, amending their existing Exclusive Channel Partner Agreement, effective January 6, 2011, as previously amended on September 13, 2011, which we refer to as the Existing ECP Agreement. The ECP Amendment modifies the scope of the parties' collaboration under the Existing ECP Agreement in connection with the Ares Trading Agreement. Pursuant to the ECP Amendment, the chimeric antigen receptor T-Cell products to be developed and commercialized pursuant to the Ares Trading Agreement shall be included within the Intrexon/ZIOPHARM collaboration. The ECP Amendment provides that Intrexon will pay to the Company fifty percent of all payments Intrexon receives for upfronts, milestones and royalties under the Ares Trading Agreement.

The Amendment also reduces Intrexon's aggregate commitment under a Stock Purchase Agreement that the parties executed in connection with the Existing ECP Agreement to purchase the Company's common stock from \$50.0 million to \$43.5 million. As of the date of this Current Report on Form 8-K, Intrexon has purchased the full \$43.5 million of the Company's common stock and has satisfied its purchase commitment to the Company in full.

Randal J. Kirk is a director of the Company and is the Chairman and Chief Executive Officer of Intrexon. As of March 27, 2015, Mr. Kirk and Intrexon, collectively and together with their affiliates, beneficially owned 19,297,415 shares of the Company's common stock, representing approximately 15% of the Company's outstanding common stock.

The foregoing descriptions of the ECP Amendment and the Ares Trading Agreement are qualified in their entirety by reference to the Ares Trading Agreement which is filed as Exhibit 10.1 to this Current Report on Form 8-K, with portions omitted and filed separately with the Securities and Exchange Commission pursuant to a request for confidential treatment and the ECP Amendment which is filed as Exhibit 10.2, to this Current Report on Form 8-K. The benefits of the representations and warranties set forth in each agreement are intended to be relied upon by the parties to such agreement only and were included, in some cases, for the purpose of allocating risk among the parties to such agreements, and,

except as otherwise expressly provided therein, do not constitute continuing representations and warranties to any other party or for any other purpose.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

Exhibit No.	Description
10.1*	License and Collaboration Agreement by and among Intrexon Corporation, ARES TRADING Trading S.A., and ZIOPHARM Oncology, Inc. dated as of March 27, 2015
10.2	Second Amendment to Exclusive Channel Partner Agreement by and between ZIOPHARM Oncology, Inc. and Intrexon Corporation dated as of March 27, 2015

* Confidential treatment has been requested as to certain portions of this exhibit pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

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.

Date: April 2, 2015

By: /s/ Kevin G. Lafond

Name: Kevin G. Lafond

Title: Vice President, Chief Accounting Officer and
Treasurer

INDEX OF EXHIBITS

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