ZIOPHARM ONCOLOGY INC Form 8-K October 01, 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): September 28, 2015

ZIOPHARM Oncology, Inc.

(Exact Name of Registrant as Specified in Charter)

Delaware (State or Other Jurisdiction **001-33038** (Commission

84-1475642 (IRS Employer

of Incorporation)

File Number)

Identification No.)

One First Avenue, Parris Building 34, Navy Yard Plaza

Boston, Massachusetts (Address of Principal Executive Offices)

02129 (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)).

Item 1.01. Entry into a Material Definitive Agreement.

Exclusive Channel Collaboration Agreement

On September 28, 2015, ZIOPHARM Oncology, Inc., or the Company, entered into an Exclusive Channel Collaboration Agreement, or the Agreement, with Intrexon Corporation, or Intrexon, whereby the Company will use Intrexon s technology directed towards *in vivo* expression of effectors to research, develop and commercialize products for use in the treatment or prevention of graft-versus-host disease, or GvHD. The exclusive collaboration, or the GvHD Program, will focus on the pursuit of the following engineered cell therapy strategies, used either separately or in combination, for the targeted treatment of GvHD: (i) the infusion of regulatory T-cells expressing membrane-bound and/or soluble interleukin-2 and (ii) the deployment of orally delivered, genetically modified *L. lactis* that express interleukin-2 to modulate immune function. The Agreement establishes committees comprised of Company and Intrexon representatives that will govern activities related to the GvHD Program in the areas of project establishment, chemistry, manufacturing and controls, clinical and regulatory matters, commercialization activities and intellectual property.

The Agreement grants the Company a worldwide license to use specified patents and other intellectual property of Intrexon in connection with the research, development, use, importing, manufacture, sale, and offer for sale of products developed under the GvHD Program, or the Products. Such license is exclusive with respect to any clinical development, selling, offering for sale or other commercialization of the Products, and otherwise is non-exclusive. Subject to limited exceptions, the Company may not sublicense the rights described without Intrexon s written consent.

Under the Agreement, and subject to certain exceptions, the Company is responsible for, among other things, the performance of the GvHD Program including development, commercialization and certain aspects of manufacturing of the Products. Among other things, Intrexon is responsible for the costs of establishing manufacturing capabilities and facilities for the bulk manufacture of the Products, certain other aspects of manufacturing, costs of discovery-stage research with respect to platform improvements and costs of filing, prosecution and maintenance of Intrexon s patents.

The Company will pay Intrexon a technology access fee of \$10 million in cash and will reimburse Intrexon for all research and development costs. Subject to certain expense allocations and other offsets provided in the Agreement, the Agreement also provides for equal sharing of the profits derived from the sale of the Products.

During the first 24 months after September 28, 2015, the Agreement may be terminated by (i) either party in the event of a material breach by the other, except for the failure of the other party to use diligent efforts or to comply with any diligence obligations set forth in the Agreement and (ii) Intrexon under certain circumstances if the Company assigns its rights under the Agreement without Intrexon s consent. Following such twenty-four month period, Intrexon may also terminate the Agreement if the Company elects not to pursue the development of the GvHD Program identified by Intrexon that is a Superior Therapy, as such term is defined in the Agreement. Also following such period, the Company may voluntarily terminate the Agreement upon 90 days written notice to Intrexon.

Upon termination of the Agreement, the Company may continue to develop and commercialize any Product that, at the time of termination:

is being commercialized by the Company,

has received regulatory approval,

is a subject of an application for regulatory approval that is pending before the applicable regulatory authority, or

is the subject of at least an ongoing Phase 2 clinical trial (in the case of a termination by Intrexon due to a Company uncured breach or a voluntary termination by the Company), or an ongoing Phase 1 clinical trial (in the case of a termination by the Company due to an Intrexon uncured breach or a termination by Intrexon following an unconsented assignment by the Company or the Company s election not to pursue development of a Superior Therapy).

The Company s obligation to pay 50% of net profits or revenue with respect to these retained products will survive termination of the Agreement.

The foregoing description of the Agreement is only a summary and is qualified in its entirety by reference to the full text of the Agreement, which is filed in redacted form as Exhibit 10.1 to this Current Report on Form 8-K. The Company intends to seek confidential treatment for certain portions of the Agreement pursuant to a request submitted to the Securities and Exchange Commission pursuant to Rule 24b-2 under the Securities Exchange Act of 1934, as amended.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
10.1*	Exclusive Channel Collaboration Agreement by and between ZIOPHARM Oncology, Inc. and Intrexon Corporation dated September 28, 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.

Date: October 1, 2015

ZIOPHARM Oncology, Inc.

By: /s/ Kevin G. Lafond Name: Kevin G. Lafond

Title: Vice President, Chief Accounting Officer and

Treasurer

INDEX OF EXHIBITS

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