

ZIOPHARM ONCOLOGY INC
Form 8-K
January 12, 2011

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): January 6, 2011

ZIOPHARM Oncology, Inc.
(Exact Name of Registrant as Specified in Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-33038
(Commission File Number)

84-1475642
(IRS Employer
Identification No.)

1180 Avenue of the Americas
19th Floor
New York, NY
(Address of Principal Executive Offices)

10036
(Zip Code)

(646) 214-0700
(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 Partner Agreement

On January 6, 2011, ZIOPHARM Oncology, Inc. (the “Company”) entered into an Exclusive Channel Partner Agreement (the “Channel Agreement”) with Intrexon Corporation (“Intrexon”) that governs a “channel partnering” arrangement in which the Company will use Intrexon’s technology directed towards in vivo expression of effectors in connection with the development of two existing clinical-stage product candidates and generally to research, develop and commercialize products, in each case in which DNA is administered to humans for expression of anti-cancer effectors for the purpose of treatment or prophylaxis of cancer (collectively, the “Cancer Program”). The Channel Agreement establishes committees comprised of Company and Intrexon representatives that will govern activities related to the Cancer Program in the areas of project establishment, chemistry, manufacturing and controls, clinical and regulatory matters, commercialization efforts and intellectual property.

The Channel 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 involving DNA administered to humans for expression of anti-cancer effectors for the purpose of treatment or prophylaxis of cancer (“ZIOPHARM Products”). Such license is exclusive with respect to any clinical development, selling, offering for sale or other commercialization of ZIOPHARM 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 Channel Agreement, and subject to certain exceptions, the Company is responsible for, among other things, the performance of the Cancer Program including development, commercialization and certain aspects of manufacturing of ZIOPHARM Products. Among other things, Intrexon is responsible for the costs of establishing manufacturing capabilities and facilities for the bulk manufacture of products developed under the Cancer Program, 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.

Subject to certain expense allocations and other offsets provided in the Channel Agreement, the Company will pay Intrexon 50% of the cumulative net quarterly profits derived from the sale of ZIOPHARM Products, calculated on a ZIOPHARM Product-by- ZIOPHARM Product basis. The Company has likewise agreed to pay Intrexon 50% of quarterly revenue obtained from a sublicensor in the event of a sublicensing arrangement. In addition, in partial consideration for each party’s execution and delivery of the Channel Agreement, the Company entered into the Stock Purchase Agreement (as defined below).

During the first 24 months, either the Company or Intrexon may terminate the Channel Agreement in the event of a material breach by the other and Intrexon may terminate the Channel Agreement under certain circumstances if the Company assigns its rights under the Channel Agreement without Intrexon’s consent. Following the first 24 months, Intrexon may also terminate the Channel Agreement if the Company elects not to pursue the development of a Cancer Program identified by Intrexon that is a “Superior Therapy” as defined in the Channel Agreement. Also following the first 24 months, the Company may voluntarily terminate the Channel Agreement upon 90 days written notice to Intrexon.

Upon termination of the Channel Agreement, the Company may continue to develop and commercialize any ZIOPHARM 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 ZIOPHARM uncured breach or a voluntary termination by the Company), or an ongoing Phase 1 clinical trial in the Field (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 described above with respect to these "retained" products will survive termination of the Channel Agreement.

Stock Purchase Agreement and Registration Rights Agreement

On January 6, 2011, the Company entered into a Stock Purchase Agreement with Intrexon pursuant to which Intrexon has agreed to purchase a number of shares of the Company's common stock equal to 5.00% of the number of shares of Company common stock issued and outstanding immediately prior to the issuance of such shares (the "Purchase Shares"), at a purchase price equal to \$4.80 per share. At the same time, the Company has agreed to issue to Intrexon a number of additional shares of Company common stock equal to 7.495% of the number of shares of Company common stock issued and outstanding prior to such issuance (the "First Tranche Shares") at a purchase price equal to the \$0.001 par value of such shares, which price will be deemed paid in partial consideration for the execution and delivery of the Channel Agreement. Upon satisfaction of customary closing conditions, the closing of the purchase and sale of the Purchase Shares and the First Tranche Shares (the "First Tranche Closing") is expected to occur on or around January 12, 2011.

The Company has also agreed to issue additional shares of Company common stock to Intrexon upon dosing of the first patient in a ZIOPHARM-conducted Phase II clinical trial in the United States, or similar study as the parties may agree in a country other than the United States, of a product that is created, produced, developed or identified directly or indirectly by the Company during the term of the Channel Agreement and that, subject to certain exceptions, involves DNA administered to humans for expression of anti-cancer effectors for the purpose of treatment or prophylaxis of cancer. Upon satisfaction of such contingency, the Company has agreed to issue to Intrexon an additional number of shares of Company common stock equal to 7.495% of the number of shares Company common stock issued and outstanding immediately prior to the First Tranche Closing (the "Second Tranche Shares") for a purchase price equal to the \$0.001 par value of such shares, which price will be deemed paid in partial consideration for the execution and delivery of the Channel Agreement.

Based on the number of shares of the Company's common stock issued and outstanding on the date of this report, the Purchase Shares will be comprised of 2,426,235 shares, resulting in proceeds from the sale thereof approximately \$11.6 million. Also based on the Company's currently issued and outstanding shares of common stock, the First Tranche Shares and, if issued upon satisfaction of the condition described above, the Second Tranche Shares will each be comprised of 3,636,926 shares. Such share amounts will be adjusted based on changes, if any, in the number of shares of the Company's common stock issued and outstanding between the date of this report and the date of the First Tranche Closing.

Under the Stock Purchase Agreement, if requested by the Company and subject to certain restrictions and limitations, Intrexon has agreed to purchase securities in conjunction with future securities offerings of the Company that constitute "Qualified Financings" and that are conducted while the Channel Agreement remains in effect. For this purpose, a "Qualified Financing" means a sale of common stock or equity securities convertible into common stock in a public or private offering, raising gross proceeds of at least \$10,000,000, where the sale of shares is either registered under the Securities Act of 1933, as amended, at the time of issuance or the Company agrees to register the resale of such shares. In conjunction with a Qualified Financing, Intrexon has committed to purchase up to 19.99% of the securities issued and sold by the Company therein (such amount to be calculated exclusive of Intrexon's purchase). Intrexon will not be obligated to purchase securities in a Qualified Financing unless the Company is then in substantial compliance with its obligations under the Channel Agreement and, with respect to a Qualified Financing that is completed following January 6, 2012, the Company confirms its intent that 40% of the net offering proceeds (the "Use of Proceeds Commitment Amount") shall have been spent, or in the next year will be spent, by the Company under the Channel Agreement. In the case of a Qualified Financing that is completed after January 6, 2012, Intrexon's purchase commitment will be further limited to an amount equal to 50% of the Use of Proceeds Commitment Amount.

Intrexon's aggregate purchase commitment for all future Qualified Financings is capped at \$50,000,000.

Also pursuant to the Stock Purchase Agreement and prior to the First Tranche Closing, the Company will elect Randal J. Kirk, Chairman and Chief Executive Officer of Intrexon, as a director to fill the existing vacancy on the Company's board of directors. In addition, the Company has agreed that at each stockholders' meeting at which directors are to be elected, it will nominate and recommend for election to the Board of Directors an individual designated by Intrexon, provided that the Board of Directors determines that he or she is a suitable candidate. If such Intrexon designee is not elected to the Board of Directors by the Company's stockholders, then, at Intrexon's election, such designee will be entitled to attend all Board of Directors and committee meetings as an observer subject to certain conditions and limitations. At such time as Intrexon controls 20% or more of the Company's stock, the Company will cause a second individual designated by Intrexon to be elected to the Board of Directors and, so long thereafter as Intrexon continues to control 20% or more of the Company's stock, at each stockholders' meeting at which directors are to be elected, the Company will nominate and recommend for election to the Board of Directors a second individual designated by Intrexon, provided that such second designee is an "independent director" under Nasdaq's listing standards and that the Board of Directors determines that he or she is a suitable candidate. The rights of Intrexon to designate director nominees discussed above will terminate upon the termination of the Channel Agreement or upon an earlier sale of the Company.

The Stock Purchase Agreement contains a standstill provision pursuant to which, among other things, Intrexon has agreed that, for a period of three years, subject to certain exceptions and unless invited in writing by the Company to do so, neither Intrexon nor its affiliates will, directly or indirectly: (i) effect or seek, initiate, offer or propose to effect, or cause or participate in any acquisition of securities or assets of the Company; any tender or exchange offer, merger, consolidation or other business combination involving the Company; any recapitalization, restructuring, liquidation, dissolution or other extraordinary transaction with respect to the Company; or any "solicitation" of "proxies" or consents to vote any voting securities of the Company, or in any way advise or, assist any other person in doing so; (ii) form, join or in any way participate in a "group" with respect to any securities of the Company; (iii) otherwise act to seek to control or influence the management, Board of Directors or policies of the Company; provided that the Intrexon director designees, in their capacity as directors, may fully exercise their rights and duties as directors of the Company including freely communicating with the Company's executive management and Board of Directors; (iv) take any action reasonably expected to force the Company to make a public announcement regarding any such matters; or (v) enter into any agreements, discussions or arrangements with any third party with respect to any of the foregoing. Among other things and subject to certain exceptions, the standstill restrictions do not apply to the future purchase by Intrexon and/or its affiliates of up to 10% of the number of shares of the Company's common stock then issued and outstanding in addition to the shares issuable pursuant to the Stock Purchase Agreement.

In connection with the transactions contemplated by the Stock Purchase Agreement, and pursuant to a Registration Rights Agreement to be executed and delivered by the parties at the First Tranche Closing, the Company will agree to file a "resale" registration statement (the "Registration Statement") registering the resale of the Purchase Shares, the First Tranche Shares and the Second Tranche Shares within 120 days of the First Tranche Closing. Under that agreement, the Company will be obligated to use its reasonable best efforts to cause the "resale" registration statement to be declared effective as promptly as practicable after filing and to maintain the effectiveness of the registration statement until all securities therein are sold or are otherwise can be sold pursuant to Rule 144, without any restrictions.

The foregoing description of each of the Channel Agreement, the Stock Purchase Agreement and the form of Registration Rights Agreement is qualified in its entirety by reference to such agreements, which are filed as Exhibits 10.1, 10.2 and 10.3 to this Current Report, respectively, and are incorporated herein by reference. The benefits of the representations and warranties set forth in the Channel Agreement, the Stock Purchase Agreement and the form of Registration Rights Agreement are intended to be relied upon by the parties to such agreements only and, except as otherwise expressly provided therein, do not constitute continuing representations and warranties to any other party or for any other purpose. The press release dated January 6, 2011 announcing the transactions described above is filed as Exhibit 99.1 to this Current Report on Form 8-K and incorporated herein by reference.

Item 3.02 Unregistered Sales of Equity Securities.

The disclosure in Item 1.01 is incorporated herein by reference thereto. The offer and sale of the Purchase Shares, the First Tranche Shares and the Second Tranche Shares will not be registered under the Securities Act of 1933, as amended (the "Securities Act") at the time of sale, and therefore may not be offered or sold in the United States absent registration or an applicable exemption from registration requirements. For these issuances, the Company is relying on the exemption from federal registration under Section 4(2) of the Securities Act and/or Rule 506 promulgated thereunder, based on the Company's belief that the offer and sale of the Shares has not and will not involve a public offering as Intrexon is an "accredited investor" as defined under Section 501 promulgated under the Securities Act and no general solicitation has been involved in the Offering.

Item 5.02 Departure of Directors or Principal Officers; Election of Directors; Appointment of Principal Officers

The disclosure in Item 1.01 is incorporated herein by reference thereto. In accordance with the Stock Purchase Agreement, Randal J. Kirk will be elected as a director of the Company to fill the Board of Director's existing vacancy and to serve as a director until the Company's next annual stockholders' meeting, with such election to be effective immediately prior to the First Tranche Closing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
10.1	Exclusive Channel Partner Agreement by and between ZIOPHARM Oncology, Inc. and Intrexon Corporation dated as of January 6, 2011 **
10.2	Stock Purchase Agreement by and between ZIOPHARM Oncology, Inc. and Intrexon Corporation dated as of January 6, 2011
10.3	Form of Registration Rights Agreement by and between ZIOPHARM Oncology, Inc. and Intrexon Corporation (incorporated by reference to Exhibit A to the Stock Purchase Agreement filed as Exhibit 10.1 to this report)
99.1	Press Release dated January 6, 2011

** 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: January 11, 2011

By: /s/ Richard Bagley
 Name: Richard Bagley
 Title: President, Chief Operating Officer and Chief

INDEX OF EXHIBITS

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