

ZIOPHARM ONCOLOGY INC
Form 8-K
November 06, 2006

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): November 3, 2006

ZIOPHARM Oncology, Inc.

(Exact name of registrant as specified in its charter)

| | | |
|---|--------------------------|--------------------------------------|
| Delaware | 0-32353 | 84-1475642 |
| (State or other jurisdiction of incorporation) | (Commission File Number) | (IRS Employer Identification No.) |

1180 Avenue of the Americas, 19th Floor
New York, NY 10036

(Address of principal executive offices) (Zip Code)

(646) 214-0700

(Registrant's telephone number, including area code)

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing 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))
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Item 1.01. Entry into a Material Definitive Agreement.

Purchase Agreement.

On November 3, 2006 (the “Closing Date”), ZIOPHARM Oncology, Inc. (the “Company”) entered into an Asset Purchase Agreement (the “Purchase Agreement”) with Baxter Healthcare S.A., Baxter International, Inc. and Baxter Oncology GmbH, which are affiliates of Baxter Healthcare Corporation (collectively referred to as “Baxter”). Pursuant to the Purchase Agreement, the Company acquired certain assets, including patents, contracts (including all rights and obligations thereunder), regulatory submissions, inventory and related assets relating to an oncology product candidate known as indibulin. Pursuant to the Purchase Agreement, Baxter also granted the Company an exclusive worldwide, non-royalty bearing license (including the right to grant sublicenses) to Baxter’s non-purchased intangible property rights to the extent such rights are required to use, market, sell, make, offer to sell and manufacture indibulin.

Indibulin, which has been designated by the Company as ZIO-301, is a novel anti-cancer agent that targets mitosis like the taxanes, and is available as both an oral and a proprietary nanosuspension intravenous form. The oral form is currently in a Phase I trial, with Phase II expected to initiate in the first half of 2007 under an Investigational New Drug Application expected to be filed in the United States. The nanosuspension intravenous form is currently in late preclinical development with a Phase I trial anticipated in 2007. While the development program for indibulin is evolving, potential application of ZIO-301 is possible in a wide variety of cancer types. Depending upon the ultimate application, the Company believes the worldwide sales potential of ZIO-301 could range from \$500 million to \$2 billion at product maturity. However, the Company can provide no assurance that it will be able to obtain regulatory approvals for ZIO-301, that development efforts relating ZIO-301 will be successful, or that ZIO-301 will be successfully commercialized.

In consideration for the assets and license acquired by the Company under the Purchase Agreement, including Baxter’s inventory of indibulin capsules and powder, the Company is required to make a \$1.225 million up-front cash payment to Baxter. The Company also agreed to make annual payments to Baxter on the sixth through twelfth anniversaries of the Closing Date that total \$1.5 million in the aggregate (the “Annual Payments”). As further consideration, the Company agreed to pay to Baxter up to an aggregate of \$6.625 million upon the achievement of various clinical and regulatory milestones relating to indibulin, commencing with a \$625,000 payment required to be made within 30 days following the first effectiveness of an investigational new drug application submitted to the FDA (or a European equivalent). In addition to milestone payments, the Company is required to pay Baxter royalties based on net sales of products that are covered by the purchased patents, the amount of which may be offset by the amount of any previously-paid Annual Payments. Royalties will be further reduced in the event the Company is required to license third party patent rights in order to make, have made, or sell indibulin without infringing on such rights.

The Company will have the right and obligation to file, prosecute and maintain the purchased patents in various jurisdictions world-wide. Should the Company abandon or fail to continue any required patent filing, prosecution or maintenance obligation, Baxter may elect to assume such obligations, provided that the patents will remain the sole property of the Company.

Each party has agreed to indemnify the other for breaches of their respective representations and warranties and failure to perform their respective obligations under the Purchase Agreement. In addition, Baxter has agreed to indemnify the Company for its ownership and operation of the purchased assets prior to the Closing Date, and the Company has agreed to indemnify Baxter for its ownership and operation of the purchased assets from and after the Closing Date. The parties’ indemnification obligations under the Purchase Agreement also to apply to damages claimed under the License Agreement (as defined below).

License Agreement.

Also on November 3, 2006, the Company entered into a License Agreement (the "License Agreement") with Baxter Healthcare S.A. and Baxter International, Inc. (collectively referred to as the "Licensors"), pursuant to which the Licensors granted the Company an exclusive, world-wide, royalty bearing license (including the right to grant sublicenses) under certain patents (the "Licensed Patents") to use, market, offer to sell and import indibulin-related nanosuspension (the "Licensed Product"). The Licensors also granted the Company an exclusive worldwide, non-royalty bearing license (including the right to grant sublicenses) to other intangible property rights to the extent such rights are required to use, market, sell, make, offer to sell and manufacture Licensed Products. The License Agreement does not grant to the Company a license to manufacture the Licensed Product or have the Licensed Product manufactured by a third party.

In consideration for the licenses, the Company has agreed to make a \$500,000 cash payment to the Licensors within 30 days following the first effectiveness of an investigational new drug application submitted to the FDA (or a European equivalent) permitting the Company to initiate human clinical trials of a Licensed Product in the United States or Europe, whichever occurs first. In addition, the Company agreed to pay royalties to the Licensors based on net sales of a License Product, which may be offset by the amount of any Annual Payments previously made under the Asset Purchase Agreement. The royalty payments will be further reduced in the event the Company is required to license third party patent rights in order to use, market, offer to sell or import a Licensed Product without infringing on such rights.

The Licensors will have the right and obligation to file, prosecute and maintain the Licensed Patents in various jurisdictions world-wide, and the Company has agreed to pay half of the estimated costs associated with such obligations on an annual basis ("the Maintenance Fee"). Should the Licensors abandon or fail to continue any required Licensed Patent filing, prosecution or maintenance obligation, the Company may elect to assume such obligations, provided that the patents will remain the sole property of the Licensors. In such event, the Company will be permitted to deduct 50% of the direct cost associated with assuming such obligation from its payment of the annual Maintenance Fee.

Either the Company or the Licensors may terminate the License Agreement in the event that the other has materially breached its obligations under the License Agreement and fails to remedy such breach within 60 days following notice by the non-breaching party. If such breach is not cured, then the non-breaching party may terminate the License Agreement at the end of such 60 day period. However, if the breach is incapable of cure within 60 days but is otherwise capable of cure, the terminating party will not be materially prejudiced if the cure is effected within a reasonable time and the curing party is proceeding to effect such cure in good faith and with reasonable diligence, the termination shall not become effective until the curing party has had a reasonable time to effect the cure. In addition, the Company may terminate the License Agreement at any time upon 60 days prior written notice, at which time all licenses granted under the License Agreement will terminate and no further payment obligations of the Company under the License Agreement will accrue.

Indibulin is the subject of both issued patents and applications worldwide. Unless terminated earlier, the licenses granted under the License Agreement expire upon the expiration of the last to expire of the Licensed Patents, which for the currently issued patents, is 2017.

On November 6, 2006, the Company issued a press release announcing entry into the above referenced agreements. Such press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

99.1 Press Release dated November 6, 2006.

SIGNATURE

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: November 6, 2006

ZIOPHARM Oncology, Inc.:
(REGISTRANT)

By: /s/ Richard E. Bagley

RICHARD E. BAGLEY, President, *Chief
Operating Officer and Chief Financial Officer*

Exhibit Index

| <u>Exhibit No.</u> | <u>Description</u> |
|--------------------|--------------------------------------|
| 99.1 | Press Release dated November 6, 2006 |
