

TITAN PHARMACEUTICALS INC
Form 8-K/A
February 28, 2013

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 8-K/A

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the
Securities Exchange Act 1934

Date of Report (Date of earliest event reported): December 14, 2012

Titan Pharmaceuticals, Inc.

(Exact name of registrant as specified in charter)

Delaware
(State or Other Jurisdiction of

Incorporation)

0-27436
(Commission File Number)

94-3171940
(IRS Employer Identification No.)

Edgar Filing: TITAN PHARMACEUTICALS INC - Form 8-K/A

400 Oyster Point Blvd., Suite 505, South San Francisco, CA
(Address of Principal Executive Offices)

94080
(Zip Code)

Registrant's telephone number, including area code: 650-244-4990

(Former Name or Former Address, is Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of 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(b) under the Exchange Act (17 CFR 240.14a-12(b))
- .. 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))

EXPLANATORY NOTE

This Amendment (the Amendment) to the Current Report on Form 8-K filed by Titan Pharmaceuticals, Inc. (the Company) on December 19, 2012 provides additional disclosure regarding the following terms of the License Agreement (as defined in the Amendment) (i) the circumstances under which the Company will be entitled to receive regulatory milestone payments under the License Agreement and (ii) the range of royalties to be paid to the Company with respect to net sales of Probuphine®.

Item 1.01. Entry into a Material Definitive Agreement.

On December 14, 2012, Titan Pharmaceuticals, Inc. (Titan or the Company) entered into a License Agreement (the License Agreement) with Braeburn Pharmaceuticals Sprl (Braeburn), wholly owned by Apple Tree Partners IV, L.P., a partnership affiliated with Apple Tree Partners. Pursuant to the License Agreement, the Company has granted Braeburn an exclusive right and license to commercialize Probuphine® in the United States of America and its territories, including Puerto Rico, and Canada (the Territory). Titan will retain all of the rights to Probuphine® outside the Territory.

In consideration of the rights granted to Braeburn under the License Agreement, Braeburn has paid the Company an upfront, non-refundable license fee of \$15.75 million. Additionally, Titan will receive \$50 million upon FDA approval of the New Drug Application (NDA) for Probuphine® and at such time ownership of the NDA will transfer to Braeburn. The Company is also eligible to receive up to an additional \$130 million upon the achievement of specified sales milestones and up to \$35 million in regulatory milestones in the event of future NDA submissions and approvals for additional indications, including chronic pain. Braeburn will also pay the Company tiered royalties on net sales of Probuphine ranging from the mid-teens to the low-twenties. In addition to the potential milestone payments, Apple Tree Partners IV has allocated in excess of \$75 million to launch, commercialize and continue the development of Probuphine.

Braeburn Pharmaceuticals is led by a strong, highly experienced team that includes Rose Crane, former Company Group Chair OTC, Specialty and Nutritionals at Johnson & Johnson, and President, Primary Care at Bristol Myers Squibb, and Garry Neil, M.D., former Group President Pharmaceutical R&D at Johnson & Johnson.

The License Agreement provides for the creation of a four person Development Committee, consisting of two appointees from each of Titan and Braeburn, that will oversee the overall strategic objectives and plans relating to the development of Probuphine®, including regulatory strategy with respect to any Phase IV clinical trials, communications with regulatory authorities and clinical programs for chronic pain and any other potential indications.

Until the six month anniversary of the NDA transfer date, the Company and Braeburn will use reasonable efforts to cooperate with each other in the negotiation and implementation of third party supply agreements for Probuphine®. During this period, Braeburn will retain the Company, at its expense, to provide it with services, expertise, training and assistance related to the manufacturing and supply of Probuphine®, including services associated with Braeburn assuming responsibility for the manufacturing of Probuphine®.

Neither party may assign the License Agreement without the prior written consent of the other, except to an affiliate or, in certain cases, to a third party acquirer of such party.

The License Agreement will expire on the later of the 15th anniversary of the date of the launch of the last product in the Territory and the expiration of the last to expire patent included in the Company's patent rights in the Territory. In addition, the License Agreement may be terminated by either party in the event that the other party has materially breached the agreement and has not cured such breach within a specified time period. In addition, subject to certain exceptions, the Company may terminate the License Agreement (i) if Braeburn discontinues the commercial sale of Probuphine® for a period of at least three months and fails to resume sales within the cure period or (ii) in the event that Braeburn commences any legal proceedings seeking to challenge the validity of any of Titan's patents in the Territory. Braeburn may terminate the License Agreement (i) in the event that it is unable to enter into a commercial supply agreement for the ethylene vinyl acetate (EVA) component of Probuphine® or if it terminates such supply agreement due to a material breach by the supplier, (ii) if the FDA does not approve the NDA and/or requires that additional clinical studies be conducted and the completion of such studies would either cause the NDA transfer date to occur on or after January 1, 2015 or the costs of the additional studies would exceed a specified amount, (iii) on a country-by-country basis upon six months prior written notice in the event that a competing product enters the market or (iv) in the event that Braeburn determines that there is an actual or perceived serious safety issue regarding Probuphine®.

The foregoing is a summary description of certain terms of the License Agreement and does not purport to be complete, and it is qualified in its entirety by reference to the full text of the License Agreement, a copy of which is attached hereto as Exhibit 10.1 and is incorporated herein by reference.

A copy of the press release issued in connection with the parties' announcement of the License Agreement is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

Item 8.01. Other Events

The warrants issued in Company's December 2007 financing, each exercisable to purchase one share of the Company's common stock at an exercise price of \$2.00 per share, will expire as of 5:30 P.M., New York City time, on Friday, December 21, 2012.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits

Exhibit No.	Description
10.1	License Agreement by and between Titan Pharmaceuticals, Inc. and Braeburn Pharmaceuticals Sprl, dated December 14, 2012
99.1*	Press Release, dated December 17, 2012

Confidential treatment has been requested with respect to certain portions of this exhibit. Omitted portions have been filed separately with the Securities and Exchange Commission.

* Previously filed.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Company has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

TITAN PHARMACEUTICALS, INC.

By: /s/ Sunil Bhonsle
Name: Sunil Bhonsle
Title: President

Dated: February 28, 2013

Exhibit Index

Exhibit No.	Description
10.1	License Agreement by and between Titan Pharmaceuticals, Inc. and Braeburn Pharmaceuticals Spri, dated December 14, 2012
99.1*	Press Release, dated December 17, 2012

Confidential treatment has been requested with respect to certain portions of this exhibit. Omitted portions have been filed separately with the Securities and Exchange Commission.

* Previously filed.