TITAN PHARMACEUTICALS INC
Form 8-K
November 28, 2017

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 27, 2017

Titan Pharmaceuticals, Inc.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of incorporation)

001-13341 **94-3171940**
(Commission File Number) (IRS Employer Identification No.)

400 Oyster Point Blvd., Suite 505, South San Francisco, CA 94080

(Address of principal executive offices and zip code)

650-244-4990

(Registrant's telephone number including area code)

(Registrant's 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 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))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ¨

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ¨

Item 1.01. Entry into a Material Definitive Agreement.

On November 27, 2017, Titan Pharmaceuticals, Inc. ("Titan" or the "Company") entered into a binding term sheet (the "Term Sheet") with L. Molteni & C. dei F.lli Alitti Società di Esercizio S.p.A. ("Molteni"), pursuant to which the parties agreed to the principal terms upon which the Company will grant Molteni an exclusive right and license to commercialize Probuphine® in the European Union (including the United Kingdom and Northern Ireland), Switzerland, Norway, Iceland, Liechtenstein, Bosnia, Serbia, Montenegro, Macedonia and Albania (the "Territory"). Titan and Molteni expect to enter into the definitive license and distribution agreement (the "License Agreement") during the first quarter of 2018.

The Term Sheet provides that in consideration of the rights to be granted to Molteni, Molteni will pay the Company an upfront, non-refundable license fee of € 2.0 million upon execution of the License Agreement. Additionally, Titan will receive (i) a €1.0 million milestone payment upon release of a written positive scientific advise by the Committee for Medicinal Products for Human Use (CHMP) on Probuphine for the treatment of opioid addiction with the desired label, (ii) a €1.0 million milestone payment upon the issuance by the European Medical Authority ("EMA") of marketing authorization, and (ii) an aggregate of € 2.0 million of milestone payments upon approval of the product reimbursement price in certain key countries, provided that the payments in (ii) and (iii) are subject to a 50% reduction if the EMA marketing authorization is not received on or prior to September 30, 2019. Molteni will also pay the Company tiered royalties on net sales of Probuphine ranging from the low-teens to the mid-twenties.

Titan is seeking EMA approval of a Probuphine label that will permit the marketing of the product for use in a broad population of opioid use disorder patients starting with initial treatment and continuing through maintenance treatment. Molteni will have the right to terminate the License Agreement if the broad label is not approved by the EMA.

Molteni will have the right, exercisable on or prior to June 30, 2019, to expand the Territory to include one or both of the following groups: one, the Middle East and North Africa and two, the Commonwealth of Independent States (comprised of 11 former Soviet Republics), upon the payment to Titan of €1.0 million per group.

The Term Sheet provides that Titan will supply Molteni with semi-finished product (i.e., the implant, the applicator and related technology) on an exclusive basis at a fixed price through December 31, 2019, with subsequent price increases not to exceed annual cost increases to Titan for active pharmaceutical ingredient and under its current manufacturing agreement.

Molteni will be prohibited from marketing a Competitor Product (as defined in the Term Sheet) in the Territory for the five year period following execution of the License Agreement. Thereafter, Molteni will be required to pay Titan a low single digit royalty on net sales of any Competitor Product.

The License Agreement will remain effective until the later of (i) termination of any applicable data exclusivity period, (ii) expiration of the last valid claim of patent rights covering the product in the Territory and (iii) fifteen (15) years from the execution of the License Agreement, provided that clause (iii) will terminate when any third party substantially similar product enters the market. To the extent Molteni exercises its right to expand the Territory as set forth above, the License Agreement will remain in effect for fifteen (15) years from the written notice of such extension, provided that the term for the additional territories will terminate when any third party substantially similar product enters the relevant market. The expansion into additional territories will not affect the term of the License Agreement as to the original Territory. In addition to standard termination clauses and to the other termination clauses provided in the Term Sheet, either party will be entitled to immediately terminate the License Agreement in the event the EMA marketing authorization is not obtained on or prior to March 31, 2020 or upon withdrawal of the product from the market by any regulatory authorities within the Territory.

The foregoing is a summary description of certain terms of the Term Sheet and does not purport to be complete, and it is qualified in its entirety by reference to the full text of the Term Sheet, 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 Term Sheet is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

Item 8.01. Other Events

On November 27, Titan announced that the European Medicines Agency ("EMA") has accepted for review the Company's Marketing Authorization Application for Probuphine, marking the beginning of the EMA's regulatory review process. A copy of the press release is attached hereto as Exhibit 99.2 and is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	**Description**
10.1	Binding Term Sheet dated November 28, 2017 between the Registrant and L. Molteni & C. dei F.lli Alitti Società di Esercizio S.p.A. *
99.1	Press Release, dated November 28, 2017
99.2	Press Release dated November 27, 2017

* Confidential treatment has been requested with respect to portions of this exhibit

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 thereunto duly authorized.

TITAN PHARMACEUTICALS, INC.

By: /s/ Sunil Bhonsle
Name: Sunil Bhonsle
Title: Chief Executive Officer and President

Dated: November 28, 2017