TITAN PHARMACEUTICALS INC
Form 8-K
December 23, 2013

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

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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): December 19, 2013

Titan Pharmaceuticals, Inc.

(Exact Name of Registrant as Specified in Charter)

Delaware	0-27436	94-3171940
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(IRS Employer Identification No.)

400 Oyster Point Blvd., Suite 505, South San Francisco, CA	94080
(Address of Principal Executive Offices)	(Zip Code)

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

(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 (see General Instruction A.2. below):

¨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 8.01. Other Events.

On December 23, 2013, Titan Pharmaceuticals, Inc. (the "Company" or "Titan") announced the receipt of the official minutes (the "Minutes") from a Type C meeting with the U.S. Food and Drug Administration (the "FDA") on November 19, 2013 to discuss the Complete Response Letter (the "CRL") to its New Drug Application (the "NDA") for Probuphine®, an investigational subdermal implant for the maintenance treatment of opioid dependence in adult patients.

The Minutes reflect the discussions among the FDA, the Company and its partner, Braeburn Pharmaceuticals Sprl ("Braeburn") that seeking an indication in individuals stabilized on 8 mg/day or less of sublingual buprenorphine (SL BPN) may be a suitable approval pathway for Probuphine. Titan and Braeburn proposed the revised indication following a review of the FDA's comments on the briefing material and to address one of the primary concerns in the CRL regarding dose adequacy among the original study population (newly inducted patients maintained at 12-16 mg SL BPN/day). The Minutes confirm that FDA approval of Probuphine for the revised indication will require the submission of additional clinical data in this patient population from a study it stipulated "*need not be large,*" "*be adequate and well-controlled,*" and "*must support labeling for the duration of treatment (6 months)*". Titan and Braeburn are working with experts in the field to develop a clinical study design for submission to the FDA within the next few weeks. The amended NDA will be resubmitted following completion of the clinical study and analysis of the resulting data.

A copy of the press release issued by the Company with respect to the Minutes is attached hereto as Exhibit 99.1 and is incorporated herein by reference,

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	**Description**
99.1	Press Release, dated December 23, 2013.

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.

Dated: December 23, 2013

TITAN PHARMACEUTICALS, INC.

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

Exhibit Index

Exhibit No.	Description
99.1	Press Release, dated December 23, 2013.