TITAN PHARMACEUTICALS INC
Form 8-K
June 09, 2015

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): June 5, 2015

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 June 8, 2015, Titan Pharmaceuticals, Inc. (the “Company” or “Titan”) reported positive topline results from the Phase 3 double blind, double dummy clinical study of Probuphine®, the Company's subdermal implant containing buprenorphine HCl for the long-term maintenance treatment of opioid addiction. This study met the pre-specified primary endpoint of non-inferiority, as well as all secondary efficacy endpoints. It was conducted by Titan’s commercialization and development partner Braeburn Pharmaceuticals and developed in consultation with the U.S. Food and Drug Administration (“FDA”) prior to initiating the study.

The subjects in this Phase 3 study were clinically stable patients receiving maintenance treatment with an approved sublingual dose of buprenorphine/naloxone at a daily dose of 8mg or less for at least three months prior to entering the trial. The study enrolled 177 subjects who were randomized to receive either the Probuphine implants or sublingual tablets, for a treatment period of six months. Subjects in one group received four Probuphine implants plus daily placebo sublingual tablets, and subjects in the second group received four placebo implants plus daily sublingual buprenorphine/naloxone tablets (£8mg/day).

The objective of the study was to show non-inferiority between the two treatment groups and the primary efficacy analysis was a non-inferiority comparison of the proportions of treatment responders in each group. A responder was defined as having at least four out of six months free of illicit opioids based on urine testing and subject self-report. Analyses conducted according to the pre-planned Statistical Analysis Plan indicate response rates of 96.4% for the Probuphine arm and 87.6% for the sublingual buprenorphine/naloxone arm. The two-sided 95% confidence interval (0.009, 0.167) of the treatment difference (Probuphine - Sublingual Buprenorphine/naloxone) was well above the minimum pre-defined successful margin for non-inferiority. The overall safety and tolerability profiles for each treatment group were also comparable. The implantation procedures were also generally well tolerated and comparable to observations from earlier studies with Probuphine.

This clinical study was designed in consultation with the FDA to address a key question in the Complete Response Letter issued in April 2013 regarding the clinical benefit of Probuphine. Titan and Braeburn intend to resubmit the New Drug Application (“NDA”) for Probuphine to the FDA in the second half of this year. The NDA is still considered to be under priority review by the FDA based on Probuphine’s potential for decreased abuse, diversion, overdose, and pediatric exposure risk.

If approved by the FDA, Probuphine would be the first marketed product to provide maintenance treatment of opioid addiction continuously for six months following a single procedure. Probuphine was developed using Titan's proprietary platform technology, ProNeura™, a non-biodegradable drug delivery implant designed to provide continuous, long- term steady state levels of medication in the blood. It is administered in a short subdermal insertion procedure in a physician’s office, and removed similarly at the end of the treatment period.

A copy of the press release issued by the Company 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 June 8, 2015.

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: June 8, 2015

TITAN PHARMACEUTICALS, INC.

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

Exhibit Index

Exhibit No.	Description
99.1	Press Release, dated June 8, 2015.