

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 1934

Date of Report (Date of earliest event reported): March 21, 2013

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.)

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))

Item 8.01. Other Events.

On March 21, 2013, Titan Pharmaceuticals, Inc. announced that the majority of the members of the Psychopharmacologic Drugs Advisory Committee of the U.S. Food and Drug Administration (the "FDA") voted in favor of approval of Probuphine for the maintenance treatment of adult patients with opioid dependence. The FDA is not bound by the recommendation of its advisory committee, but will consider the committee's guidance as it evaluates the Probuphine New Drug Application.

The press release dated March 21, 2013 is attached to this Current Report on Form 8-K as Exhibit 99.1 and incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

99.1 Press Release dated March 21, 2013

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: March 22, 2013

Exhibit Index

| <u>Exhibit No.</u> | <u>Description</u> |
|--------------------|------------------------------------|
| 99.1 | Press Release dated March 21, 2013 |



Titan Pharmaceuticals, Inc.

FOR IMMEDIATE RELEASE

Titan Pharmaceuticals Announces FDA Advisory Committee Recommends Approval of Probuphine for the Treatment of Adult Patients with Opioid Dependence

Psychopharmacologic Drugs Advisory Committee Meeting Voted in Favor of Approval Citing Favorable Benefit-Risk Profile and Unmet Need

SOUTH SAN FRANCISCO, March 21, 2013 – Titan Pharmaceuticals, Inc. (OTCBB:TTNP) today announced that the majority of Psychopharmacologic Drugs Advisory Committee (PDAC) of the U.S. Food and Drug Administration (FDA) members recognized the favorable benefit-risk profile of Probuphine® and voted for approval (10 positive votes, 4 negative votes and 1 abstention). Probuphine® is a long-acting, subdermal implant formulation of buprenorphine for the maintenance treatment of adult patients with opioid dependence. Titan submitted a New Drug Application (NDA) for Probuphine on October 29, 2012 under Section 505(b)(2) of the Food, Drug and Cosmetic Act, referencing the approved sublingual tablet formulations of buprenorphine. The Probuphine NDA was granted priority review designation with a Prescription Drug User Fee Act (PDUFA) target action date of April 30, 2013. In December 2012, Titan announced an exclusive license agreement with Braeburn Pharmaceuticals to the commercialization rights for Probuphine in the United States and Canada.

“We are pleased the Committee recognized the favorable benefit-risk profile of Probuphine and voted in strong favor of its approval,” said Kate Glassman-Beebe, Ph.D., executive vice president and chief development officer of Titan. “We look forward to working with the FDA to complete its review of Probuphine and remain committed to addressing the growing unmet needs in managing patients with opioid dependence.”

The committee also voted in favor of the effectiveness (10 positive votes to 5 negative votes) and safety (12 positive votes to 2 negative votes, with 1 abstention) of Probuphine. The largest portion of committee members abstained (6 abstentions, 5 positive votes and 4 negative votes) on the vote pertaining to the Risk Evaluation and Mitigation Strategy (REMS) program, as the program is still in discussion with the FDA.

The FDA is not bound by the recommendation of its advisory committee, but will consider the committee’s guidance as it evaluates the Probuphine NDA.

Titan Conference Call and Webcast

Members of the Titan management team will host a conference call to discuss this update on March 22 at 9:00 a.m. ET. Participating on the call will be Sunil Bhonsle, president, Marc Rubin,

M.D., executive chairman and Katherine Glassman-Beebe, Ph.D., executive vice president and chief development officer. The live webcast of the call may be accessed by visiting the Titan website at www.titanpharm.com. The call can also be accessed by dialing 888-737-3703, Participant Code: 9448389 five minutes prior to the start time. A replay of the call will be available on the Titan website approximately two hours after completion of the call and will be archived for two weeks.

About Opioid Dependence

According to recent estimatesⁱ, there are 2.2 million people with opioid dependence in the U.S. Approximately 20 percent of this population is addicted to illicit opioids, such as heroin, and the other 80 percent to prescription opioids, such as oxycodone, hydrocodone, methadone, hydromorphone and codeine. Before the year 2000, medication-assisted therapies for opioid dependence had been sanctioned to a limited number of facilities in the U.S. The Drug Addiction Treatment Act of 2000 (DATA 2000) allowed medical office-based treatment of opioid dependence and greatly expanded patient access to medication-assisted treatments. As a result, an estimated 1.2 million people in the U.S. sought treatment for opioid dependence in 2011ⁱⁱ.

About Probuphine®

Probuphine is an investigational subdermal implant capable of delivering continuous and persistent, around the clock blood levels of buprenorphine for six months following a single treatment, simplifying patient compliance and retention. Buprenorphine, an approved agent for the treatment of opioid dependence, is currently available in the form of daily dosed sublingual tablets and film formulations, with reported 2011 sales of \$1.3 billion in the United States. Probuphine was developed using ProNeura™, Titan's continuous drug delivery system that consists of a small, solid implant made from a mixture of ethylene-vinyl acetate (EVA) and a drug substance. The resulting construct is a solid matrix that is placed subdermally, normally in the upper arm in a simple office procedure, and removed in a similar manner at the end of the treatment period. The drug substance is released slowly and continuously through the process of dissolution resulting in a steady rate of release.

The efficacy and safety of Probuphine has been studied in several clinical trials, including a 163-patient, placebo-controlled study that demonstrated clinically meaningful and statistically significant treatment benefits with Probuphine over a 24-week period (published in the *Journal of the American Medical Association (JAMA)*), and a confirmatory study of 287 patients that showed statistically significant improvement in efficacy versus placebo, and non-inferiority with a currently marketed sublingual formulation of buprenorphine. Results of the confirmatory study were announced in July 2011. Probuphine was well-tolerated in all clinical studies, including in two open label safety studies that provided treatment with Probuphine for an additional six months to patients who completed the six-month controlled study.

About Titan Pharmaceuticals

For information concerning Titan Pharmaceuticals, Inc., please visit the company's website at www.titanpharm.com.

- ⁱ Substance Abuse and Mental Health Services Administration, *Results from the 2011 National Survey on Drug Use and Health: Summary of National Findings*, NSDUH Series H-44, HHS Publication No. (SMA) 12-4713. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2012.
- ⁱⁱ Substance Abuse and Mental Health Services Administration, *Results from the 2011 National Survey on Drug Use and Health: Summary of National Findings*, NSDUH Series H-44, HHS Publication No. (SMA) 12-4713. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2012.

Safe Harbor Statement

The press release may contain “forward-looking statements” within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. Such statements include, but are not limited to, any statements relating to the Company’s development program and any other statements that are not historical facts. Such statements involve risks and uncertainties, including, but not limited to, those risks and uncertainties relating to difficulties or delays in development, testing, regulatory approval, production and marketing of the Company’s drug candidates, adverse side effects or inadequate therapeutic efficacy of the Company’s drug candidates that could slow or prevent product development or commercialization, the uncertainty of patent protection for the Company’s intellectual property or trade secrets. Such statements are based on management’s current expectations, but actual results may differ materially due to various factors, including those risks and uncertainties mentioned or referred to in this press release.

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