# 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): October 25, 2011

# **Titan Pharmaceuticals, Inc.**

(Exact name of registrant as specified in charter)

Delaware (State or other jurisdiction of incorporation)

Delaware (State or Other Jurisdiction of Incorporation) 0-27436 (Commission File Number)

400 Oyster Point Blvd., Suite 505, South San Francisco, CA (Address of Principal Executive Offices) 94-3171940 (IRS Employer Identification No.)

> 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 October 26, 2011, Titan Pharmaceuticals, Inc. (the "Company") issued a press release providing initial feedback from its pre-NDA meeting with the U.S. Food and Drug Administration ("FDA").

The press release 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 October 26, 2011

## **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: October 31, 2011

Exhibit No.Description99.1Press Release dated October 26, 2011



Titan Pharmaceuticals, Inc.

## TITAN PHARMACEUTICALS PROVIDES PROBUPHINE UPDATE AFTER MEETING WITH U.S. FOOD AND DRUG ADMINISTRATION

#### **Regulatory Path Defined for New Drug Application**

**South San Francisco, CA – October 26, 2011** – Titan Pharmaceuticals, Inc. (TTNP.OB) today announced that it met with the U.S. Food and Drug Administration (FDA) for a Pre-New Drug Application (Pre-NDA) meeting regarding Probuphine<sup>TM</sup>, an innovative subcutaneous implant formulation of the marketed drug buprenorphine. Based upon this meeting, Titan believes that its Phase 3 clinical program completed to date is acceptable to the FDA to support submission of an NDA via the 505(b)(2) pathway and that no additional clinical efficacy or safety studies are required to support the submission. The company has also received clear guidance from the FDA on the requirements for submitting an NDA for consideration to be designated as a Priority Review. Titan has received initial comments from the FDA regarding manufacturing and non-clinical information and is in ongoing discussions with the agency to confirm these requirements. The company will confirm the overall regulatory path forward upon receipt of formal meeting minutes from the FDA in the coming weeks and will provide a further update at that time.

"We are extremely pleased with this preliminary outcome as we believe it enables Titan to move forward rapidly and efficiently with our ongoing partnership discussions for Probuphine and continue to advance the program's regulatory process toward an NDA submission," said Sunil Bhonsle, president of Titan.

#### **About Probuphine**

Probuphine is designed to deliver six months of continuous round-the-clock, long-term therapeutic levels of the drug buprenorphine following a single subcutaneous treatment. Buprenorphine, an approved agent for the treatment of opioid addiction, is currently available mainly in the form of sublingual tablet and film formulations. The safety and effectiveness of treatment with Probuphine has been demonstrated in several late-stage and Phase 3 studies conducted to date, including a 163-patient placebo-controlled study which demonstrated clinically meaningful and statistically significant treatment with Probuphine over a 24-week period and was published in the *Journal of the American Medical Association (JAMA)* and a confirmatory study of 287 patients that showed statistically significant efficacy versus placebo and non-inferiority with a currently marketed sublingual formulation of buprenorphine.

Probuphine was developed using ProNeura<sup>TM</sup>, Titan's continuous drug delivery system that consists of a small, solid rod made from a mixture of ethylene-vinyl acetate (EVA) and a drug

substance. The resulting product is a solid matrix that is placed subcutaneously, normally in the upper arm in a simple office procedure, and is removed in a similar manner at the end of the treatment period. The drug substance is released slowly, at continuous levels, through the process of diffusion. This results in a constant rate of release similar to intravenous administration.

#### **About Titan Pharmaceuticals**

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

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, and the Company's ability to obtain additional financing. 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.

#### CONTACT:

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