

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 29, 2012

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 October 29, 2012, Titan Pharmaceuticals Inc. (the “Company” or “Titan”) issued a press release announcing the submission of a New Drug Application to the U.S. Food and Drug Administration for the investigational product Probuphine®. The submission includes a request for Priority Review and a proposed Risk Evaluation and Mitigation Strategy (REMS). Titan also announced that its potential licensing partner has advised the Company that its internal structuring tasks continue to progress, and that the option to execute the proposed licensing agreement has been extended in accordance with its terms to December 31, 2012.

A copy of the press release is attached to this Current Report on Form 8-K as Exhibit 99.1 and is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits

99.1 Press Release dated October 29, 2012

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 30, 2012

Exhibit Index

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release dated October 29, 2012



FOR IMMEDIATE RELEASE

**Titan Pharmaceuticals Announces Submission of New Drug Application
for Probuphine for the Treatment of Opioid Dependence**

*Submission Includes Request for Priority Review and Proposed REMS
Progress Continues with Potential Partner*

SOUTH SAN FRANCISCO, CA October 29, 2012 – Titan Pharmaceuticals, Inc. (TTNP) today announced the submission of a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for the investigational product Probuphine® for the maintenance treatment of opioid dependence in adult patients. Probuphine, a novel, subdermal implant, is the first long-acting product designed to deliver six months of the drug buprenorphine hydrochloride (“buprenorphine”) following a single treatment. The NDA has been submitted under Section 505(b)(2) of the Food, Drug and Cosmetic Act and references the approved sublingual tablet formulations of buprenorphine. U.S. sales of daily dosed sublingual formulations containing buprenorphine indicated for the treatment of opioid dependence were approximately \$1.3 billion in 2011.

“We are extremely pleased to submit this NDA, including our request for a Priority Review of Probuphine, following the successful manufacture of the first commercial scale batch in the new production facility,” said Sunil Bhonsle, president of Titan. “Not only does this key milestone mark a significant step forward for Titan and our shareholders but, most importantly, we believe that Probuphine, if approved, will provide an important treatment option for patients and physicians.”

NDA Submission Includes Request for Priority Review Designation and Proposed Risk Evaluation and Mitigation Strategy (REMS)

Titan has included a request for Priority Review designation in the Probuphine NDA submission, based upon feedback from the FDA at the pre-NDA meeting. Priority designation is given to therapies that offer major advances in treatment, including improved safety, or provide a treatment where no adequate therapy exists. Based upon the Prescription Drug User Fee Act (PDUFA), the FDA has set a target date for FDA action on Priority designated submissions at six months (as opposed to a 10-month target action date for Standard Review submissions). Titan has also included a detailed Risk Evaluation and Mitigation Strategy (REMS) following specific guidance from the FDA on this key document.

Positive Phase 3 Probuphine Data Support NDA Submission

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 the two open label safety studies that provided treatment with Probuphine for an additional six months to patients who completed the six-month controlled study.

Partnership Activities Continue to Advance

In addition to the \$4.25 million investment in Titan that was announced in September, Titan's potential licensee has committed significant resources to activities in support of the future commercialization of Probuphine, including the ongoing establishment of an accomplished commercial team. The potential partner has advised Titan that its internal structuring tasks continue to progress, and the option to execute the proposed licensing agreement has been extended in accordance with its terms to December 31, 2012.

About Opioid Dependence

Worldwide, it is estimated that there are 6 million opioid addicts. Approximately one-half of this potential patient population is addicted to illicit opioids, such as heroin, and the other half to prescription drugs, such as oxycontin, methadone, and codeine. Until recently, medication-assisted therapies for opioid addiction had been sanctioned to a limited number of facilities in the U.S. Today, physicians can be certified to prescribe opioid addiction medications in an office setting, which has greatly expanded patient access to opioid addiction pharmaceutical therapies and buprenorphine has become the preferred medication for this illness. As a result, it is estimated that there are more than 750,000 people receiving medicinal treatment for opioid dependence.

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, potentially enhancing patient compliance and retention. Buprenorphine, an approved agent for the treatment of opioid dependence, is currently available in the form of daily dosed sublingual formulations, with reported 2011 annual sales of approximately \$1.3 billion in the United States. Probuphine was developed using ProNeura™, 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 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.

About Titan Pharmaceuticals

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

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, the Company’s ability to establish corporate partnerships to support the development and commercialization of its products, 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:**For Media:**

Pure Communications
Susan Heins, (864) 286-9597
sjheins@purecommunicationsinc.com

For Investors:

Titan Pharmaceuticals, Inc.
Sunil Bhonsle, President
650-244-4990