

# SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

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## FORM 8-K

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### CURRENT REPORT

Pursuant to Section 13 or 15(d) of the  
Securities Exchange Act 1934

Date of Report (Date of earliest event reported): February 9, 2012

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## Titan Pharmaceuticals, Inc.

(Exact name of registrant as specified in charter)

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Delaware

(State or other jurisdiction of incorporation)

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)

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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))

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**Item 8.01. Other Events.**

On February 9, 2012, Titan Pharmaceuticals, Inc. (the “Company”) issued a press release announcing the positive results of an open-label, six-month safety re-treatment study of patients with opioid dependence who previously completed a full six months of treatment in the Company’s confirmatory Phase 3 clinical trial of the investigational drug Probuphine™.

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 February 9, 2012

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**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: February 10, 2012

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Exhibit Index

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release dated February 9, 2012



Titan Pharmaceuticals, Inc.

**FOR IMMEDIATE RELEASE**

**TITAN PHARMACEUTICALS ANNOUNCES POSITIVE RESULTS OF SIX-MONTH  
OPEN-LABEL SAFETY RETREATMENT STUDY OF PROBUPHINE**

*Patients Report High Satisfaction, Decreased Opioid Dependence Problems and  
Significant Overall Improvement with Probuphine; NDA Expected to Be Filed in 3Q 2012*

**South San Francisco, CA – February 9, 2012** – Titan Pharmaceuticals, Inc. (TTNP.OB) today announced the results of an open-label, six-month safety re-treatment study (PRO-811) of patients with opioid dependence who previously completed a full six months of treatment in Titan’s confirmatory Phase 3 clinical trial of the investigational drug Probuphine<sup>TM</sup>. In the 85 patients enrolled in this retreatment study, Probuphine was shown to be well tolerated, including the implant insertion and removal procedures, with a low incidence of adverse events and overall safety profile similar to that observed in the confirmatory Phase 3 study. Patients also reported a decreased use of illicit opioids, good control of opioid withdrawal and cravings and high overall satisfaction with Probuphine. These data build upon the positive results of the Probuphine Phase 3 program reported to date and further support the company’s preparation of a New Drug Application (NDA) for Probuphine.

Titan also provided an update on the preparation of the NDA for Probuphine, which it now plans to submit in the third quarter of this year. The company is on track to complete its analytical testing of Probuphine to provide additional Chemistry, Manufacturing and Control (CMC) data requested by the U.S. Food and Drug Administration (FDA) along with its preparation of the integrated clinical data, summary reports and electronic document preparation by mid-year. The manufacturing facility expansion and qualification for commercial scale production of Probuphine is in process, but has been slightly delayed due to longer than expected lead-time on air handling equipment and the manufacturing of three qualification batches is now expected to be completed in September.

“As a clinician, I know first-hand how desperate the patient need is for a safe and effective treatment for opioid dependence, especially one that patients feel improves their condition and their compliance,” said Walter Ling, M.D., Professor of Psychiatry and Director, Integrated Substance Abuse Programs at the David Geffen School of Medicine at UCLA. “These data continue to show that Probuphine could represent a new and potentially improved method of delivering buprenorphine to patients – one that improves the quality of life of patients, lessens physicians’ concerns about compliance and medication diversion and shifts the treatment landscape.”

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**Safety Re-treatment Study (PRO-811) Results:**

The safety re-treatment study enrolled 85 patients at 18 sites and provided six months of open-label treatment with Probuphine. The study protocol included standard safety monitoring of patients similar to the previous clinical studies, including periodic evaluation of opioid withdrawal and craving symptoms and self report of illicit drug use. Additionally, the study included a patient satisfaction survey that was completed by 53 of the 67 patients who finished the study. Highlights of the findings include:

- Overall, more than 80 percent of eligible patients from the confirmatory Phase 3 clinical trial consented for treatment in this follow-on safety study; of these, 86 percent of the patients who had been treated with Probuphine in the Phase 3 trial consented for re-treatment (patients in the Phase 3 trial received Probuphine, placebo or sublingual buprenorphine)
- 67 patients (79 percent) completed the six-month retreatment study, with more than 90 percent of the completers indicating that, if given the option, they would elect to receive further treatment with Probuphine
- At the end of treatment, 80 percent of patients reported that they had not used illicit opioids within the last two weeks
- According to patient-reported data, as well as clinician assessments, symptoms of opioid withdrawal were well-controlled during the study
- Patients self-reported that opioid cravings were also well-controlled throughout the study
- Nearly 95 percent of patients reported that they were able to improve their lives while taking part in the study
- More than 90 percent of the patients that were randomized to sublingual buprenorphine in the previous Phase 3 trial reported that Probuphine made it easier to comply with taking their medication
- 17 of the 85 patients used supplemental rescue medication with a mean of 10 days and median of seven days of use out of the possible 168 days of the study
- Approximately 11 percent of treated patients received a dose increase to a total of five Probuphine implants during the study
- Probuphine was well-tolerated, including the implant insertion and removal procedures; the most common adverse events reported were headache (12 percent), upper respiratory infection (8 percent), back pain (6 percent) and urinary tract infection (6 percent)

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“I believe that Probuphine’s combination of the right medication, buprenorphine, with a new implant delivery system offers the potential for a significant improvement in the way opioid addiction is treated today,” said Dr. Richard N. Rosenthal, Chairman of Psychiatry at St. Luke’s-Roosevelt Hospital Center, a teaching hospital of Columbia University, and past president of the American Academy of Addiction Psychiatry. “I continue to be encouraged by the findings in the Probuphine program and am hopeful that this new medication strategy will offer patients a much-needed, safe and effective treatment that also lowers the risk from missed doses.”

The full data from this safety re-treatment study will be submitted for future publication. Additionally, Dr. Rosenthal is scheduled to present topline findings from this study at the Whistler Winter Conference on Addiction of the University of British Columbia, Vancouver, Canada in Whistler, BC, on February 21, 2012.

“We are extremely pleased with these additional safety results as they continue to support the potential of Probuphine as a new and innovative treatment option for patients suffering from opioid dependence,” said Katherine L. Beebe, Ph.D., Principal Investigator for the study and Executive Vice President and Chief Development Officer of Titan. “These results complete the planned clinical development program and are an important addition to the database necessary to establish potential safety and efficacy of Probuphine, and fully support our ongoing discussions with potential partners for the future commercialization of Probuphine.”

### **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™, 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](http://www.titanpharm.com).

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*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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