

# 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): June 17, 2011

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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 June 17, 2011, Titan Pharmaceuticals, Inc. issued press releases providing information about its ongoing dialogue with the U.S. Food and Drug Administration regarding the Statistical Analysis Plan for its confirmatory Phase 3 study of Probuphine. The press releases are attached to this Current Report on Form 8-K as Exhibits 99.1 and 99.2.

**Item 9.01. Financial Statements and Exhibits**

(d) Exhibits

99.1 Press Release dated June 17, 2011

99.2 Press Release dated June 17, 2011

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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: June 21, 2011

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Exhibit Index

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Releases dated June 17, 2011
99.2	Press Release dated June 17, 2011



**Titan Pharmaceuticals, Inc.**

**FOR IMMEDIATE RELEASE**

**TITAN PHARMACEUTICALS PROVIDES UPDATE ON  
CONFIRMATORY PHASE 3 STUDY OF PROBUPHINE**

**South San Francisco, CA – June 17, 2011** – Titan Pharmaceuticals, Inc. (TTNP.OB) today announced the receipt of a letter from the U.S. Food and Drug Administration (FDA) on June 16, 2011, providing comments on the revised Statistical Analysis Plan (SAP) for the confirmatory Phase 3 study of Probuphine™ for patients with opioid dependence. Although the data review at all clinical sites is complete and the blinded data set is ready for analysis, Titan will need to delay the analysis of the data briefly to allow time for a discussion with the FDA and subsequent modification of the SAP as necessary.

“We are very pleased with the progress made by the clinical team and the clinical sites in completing the data review at the beginning of June, and preparing the blinded database for further analysis,” said Sunil Bhonsle, president of Titan Pharmaceuticals. “We will continue working closely with the FDA to finalize the statistical analysis plan and complete the analyses expeditiously, although it is unlikely that all this can be completed by the end of June as previously expected. We will provide an update on a revised timeline for reporting results of the study once we have spoken with the Agency in the next few days.”

The Phase 3 clinical trial is a randomized, placebo and active controlled, multi-center study conducted at 20 sites in the U.S. treating approximately 285 patients, aged 18 to 55 years across three dosing arms: Probuphine, Titan’s innovative, subcutaneous implant formulation that delivers a steady dose of the marketed drug buprenorphine over six months following a single treatment; SUBOXONE®, the approved and widely-used sublingual formulation of buprenorphine; and placebo. Patients in the trial were treated for 24 weeks and the Probuphine and placebo dosing arms were double-blinded, while the SUBOXONE arm was open-label. Titan’s first placebo controlled Phase 3 clinical trial of Probuphine was completed in 2008 with positive findings published in the *Journal of the American Medical Association (JAMA)* in October 2010.

**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:**

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

Pure Communications  
Dan Budwick, 973-271-6085  
dan@purecommunicationsinc.com

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**Titan Pharmaceuticals, Inc.**

**FOR IMMEDIATE RELEASE**

**TITAN PHARMACEUTICALS PROVIDES ADDITIONAL DETAILS ON  
CONFIRMATORY PHASE 3 STUDY OF PROBUPHINE**

**South San Francisco, CA – June 17, 2011** – Titan Pharmaceuticals, Inc. (TTNP.OB) today announced additional information following on its press release issued earlier today about its ongoing dialogue with the U.S. Food and Drug Administration (FDA) regarding the Statistical Analysis Plan (SAP) for its confirmatory Phase 3 study of Probuphine™.

The SAP for the confirmatory Phase 3 study of Probuphine™ was submitted to the FDA in the third quarter of last year and included statistical analyses similar to those previously agreed upon with the FDA and performed in the first controlled Phase 3 study. In late March this year Titan received comments from the FDA on the study protocol as a whole that included a comment on the primary analysis which needed further clarification. Titan immediately requested a meeting with the FDA to obtain further clarification.

In early May, Titan and FDA met via teleconference, clarifying the earlier comment and reaching an understanding on a type of additional analysis to be performed. The revised SAP submitted to the FDA included this analysis as an additional secondary endpoint. Titan also provided to the FDA this same type of analysis conducted retrospectively on the data from the first controlled Phase 3 study (PRO-805), which fully supported the previously reported positive results.

The letter from the FDA received yesterday essentially agrees with the proposed statistical analysis methodology, but requests that this be part of the primary analysis. Titan is seeking a telephonic meeting with the FDA to obtain clarity regarding their request and finalize the SAP expeditiously, and conduct the appropriate analyses. Additional information on the timeline will be provided following this discussion with the FDA.

Importantly, Titan has not unblinded the database nor analyzed any findings for the Phase 3 confirmatory trial and will not do so until final agreement on the SAP has been reached with the FDA.

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**CONTACT:**

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

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