

UNITED STATES
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 of 1934

Date of Report (Date of Earliest Event Reported): July 21, 2014

Titan Pharmaceuticals, Inc.
(Exact name of registrant as specified in its 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 94080

(Address of principal executive offices and zip code)

650-244-4990

(Registrant's telephone number including area code)

(Registrant's former name or former address, if 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))
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Item 7.01. Regulation FD Disclosure.

On July 21, 2014, Titan Pharmaceuticals, Inc. (the "Company") posted a corporate presentation on its website, a copy of which is attached hereto as Exhibit 99.1, and which is incorporated herein by reference.

The foregoing information, including the presentation attached hereto as Exhibit 99.1, is being furnished pursuant to Item 7.01 of this Current Report and shall not be deemed "filed" for the purposes of Section 18 of the Securities and Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that Section. This information shall not be incorporated by reference into any registration statement pursuant to the Securities Act of 1933, as amended.

Item 8.01. Other Events.

On July 21, 2014, the Company issued a press release announcing enrollment of the first patients in the Phase 3 clinical study to support resubmission of the New Drug Application (NDA) for Probuphine®, the Company's investigational subdermal implant for the maintenance treatment of opioid dependence. A copy of the press release is attached hereto as Exhibits 99.2 and is incorporated herein by reference.

tem 9.01. Financial Statement and Exhibits.

(d) Exhibits.

<u>Exhibit No.</u>	<u>Description</u>
99.1	Corporate Presentation
99.2	Press Release dated July 21, 2014

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

TITAN PHARMACEUTICALS, INC.

By: /s/ Sunil Bhonsle

Name: Sunil Bhonsle

Title: President

Dated: July 21, 2014



Innovations
in MEDICINE™

TITAN PHARMACEUTICALS, INC. 

Corporate Presentation

July 2014

Safe Harbor

The presentation 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. Reference is made in particular to the description of our plans and objectives for future operations, assumptions underlying such plans and objectives and other forward-looking terminology such as “may,” “expects,” “believes,” “anticipates,” “intends,” “projects,” or similar terms, variations of such terms or the negative of such terms. Forward-looking statements are based on management’s current expectations. Actual results could differ materially from those currently anticipated and such statements involve risks and uncertainties, including, but not limited to, those risks and uncertainties relating to availability of financing, 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 and the uncertainty of patent protection for the Company’s intellectual property or trade secrets.

Titan Pharmaceuticals Overview

Titan Pharmaceuticals is a specialty pharmaceutical company focused on developing innovative treatments for chronic conditions based on its proprietary long-term drug delivery platform, ProNeura™

- **Probuphine®: A long acting formulation of buprenorphine for the maintenance treatment of opioid dependence**
 - Final Phase 3 clinical study requested by the FDA in progress; expected completion by mid year 2015 and resubmission of the NDA in late 2015
 - Partnership established for the U.S. and Canadian rights on attractive terms
 - Potential application in treatment of chronic pain
- **ProNeura for Parkinson's disease (Ropinirole)**
 - Non clinical proof-of-principle study completed in primate model of PD
 - Expect to file Investigational New Drug application with FDA in 2015
- **ProNeura Technology Platform**
 - Proprietary long-term drug delivery technology providing around-the-clock medication over periods of six months to a year
 - Applications in chronic conditions where clinical benefit could be achieved by continuous, stable medication levels in the blood

Probuphine: Highlights

Probuphine is expected to be the first long acting buprenorphine product on the market for the treatment of opioid dependence

- Probuphine provides six month sustained release of buprenorphine, a drug already on the market as a daily dosed sublingual tablet/film
- Expanding market with U.S. sales of daily dosed buprenorphine products exceeding \$1.5 billion; Probuphine peak sales potential: \$300-\$500 mil
- Strong U.S. and Canadian partnership with Braeburn Pharmaceuticals
 - Upfront: \$15.75 mil; Approval: \$15 mil; Sales Milestones: \$165 mil;
 - Tiered royalties: mid teens – low twenties
- U.S. patent life to 2024
- Potential application in treating chronic pain
- Regulatory status:
 - NDA accepted for Priority Review in January 2013 and FDA Advisory Committee voted in favor of approval of Probuphine in March 2013
 - FDA issued a Complete Response Letter (CRL) on April 30, 2013 requesting additional clinical testing
 - Final clinical study in progress and resubmission of NDA expected in late 2015

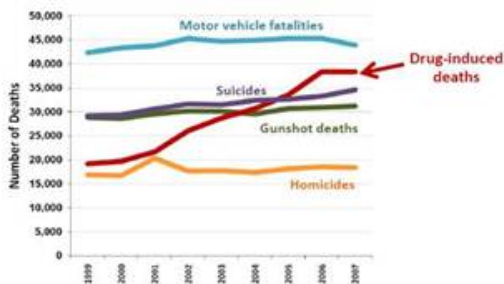
Opioid Dependence - Viewed as an Epidemic

Recognized as an epidemic by the federal government

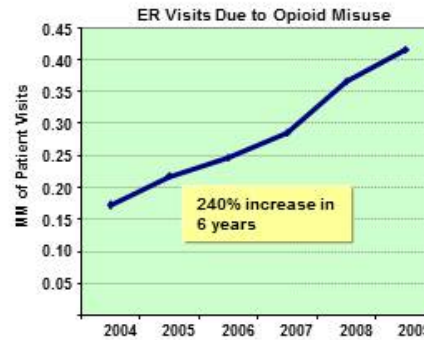
- Opioid dependence is recognized by the government as a medical epidemic that warrants immediate and significant resource allocation
- NIDA (part of NIH) provided a \$7.6 million grant (2010-2011) in support of Buprenorphine development



Drug-Induced Deaths Second Only to Motor Vehicle Fatalities, 1999–2007



Source: National Center for Health Statistics, Centers for Disease Control and Prevention, National Vital Statistics Reports Deaths: Final Data for the years 1999 to 2007 (2001 to 2010).



Sources: EPIDEMIC: RESPONDING TO AMERICA'S PRESCRIPTION DRUG ABUSE CRISIS, Executive Office of the President of the United States (2011); 2009 National Survey on Drug Use and Health (NSDUH); "A Wave of Addiction and Crime, with the Medicine Cabinet to Blame", New York Times (Sept 23, 2010)

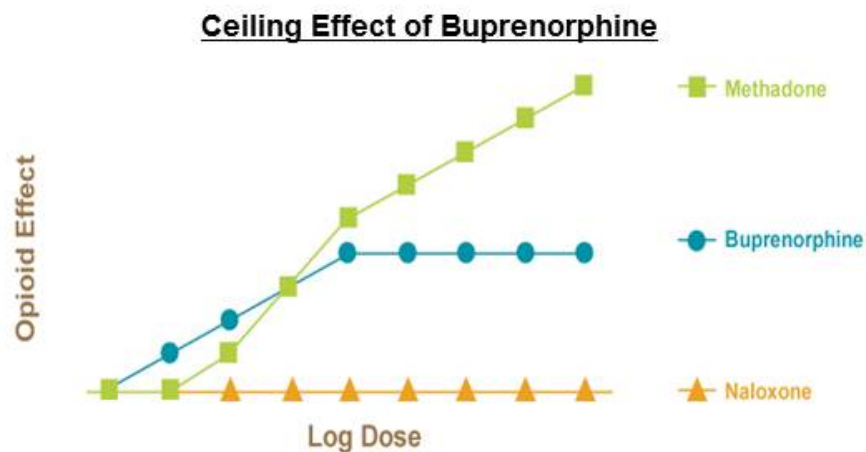
Opioid Dependence - Disease Overview

- **Addiction is a primary, chronic disease of brain reward, motivation, memory and related neurobiological circuitry***
 - Inability to consistently abstain
 - Impairment in behavioral control
 - Craving
 - Diminished recognition of significant problems with one's behaviors
- **Addiction involves cycles of relapse and remission**
- **Without treatment or engagement in recovery activities, addiction is progressive and can result in disability or premature death**

**American Society of Addiction Medicine, Inc., 2011*

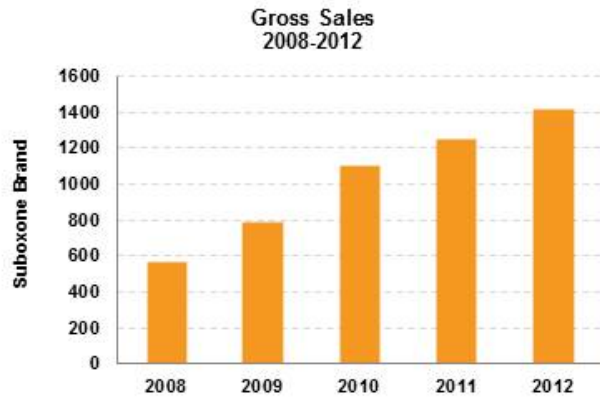
Opioid Dependence - Treatment Overview

- In the U.S. buprenorphine has replaced methadone as the gold standard in treating opioid dependence
- Buprenorphine is a mixed partial agonist at the mu receptor and an antagonist at the kappa receptor
 - Ceiling effect
 - Improved safety profile
 - Lack of euphoria



Opioid Dependence - Expanding Market

- **Daily buprenorphine is the current gold standard**
 - U.S. sales of daily oral formulations of buprenorphine (Suboxone®) exceeded \$1.4B in 2012
 - U.S. buprenorphine prescriptions have far outstripped those of methadone since 2006
- **Challenges with oral buprenorphine**
 - Compliance
 - Fluctuating levels of drug
 - Diversion, abuse



Source: IMS Health

Probuphine: Active Buprenorphine Along with Inert EVA Polymer



Each implant contains 80 mg of buprenorphine HCl which has been blended and extruded with ethylene vinyl acetate (EVA) co-polymer

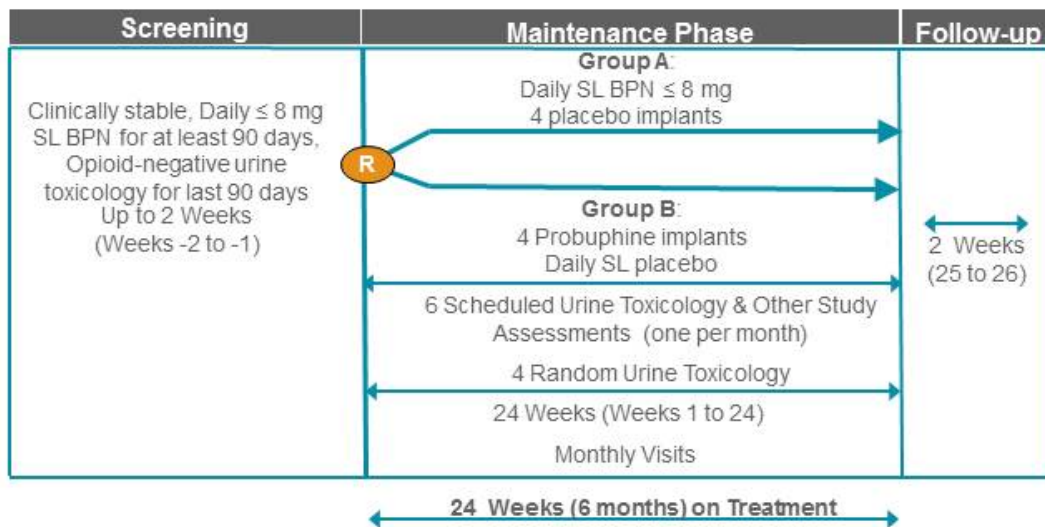
Probuphine is a subdermal implant capable of delivering continuous and persistent around the clock blood levels of buprenorphine for 6 months following a single treatment, enhancing patient compliance and retention

Probuphine Clinical Summary

- **Six clinical studies completed to date with final Phase 3 study under way**
 - Small dose finding study
 - Two well-controlled safety and efficacy studies showing clinical and statistical superiority over placebo and non-inferiority to Suboxone published in *Journal of American Medical Association* and in the journal *Addiction*
 - Two open label long-term treatment safety studies
 - Relative bioavailability study
- **Mild-to-moderate adverse events typical of the safety profile of buprenorphine; low number of serious adverse events similar to placebo**
- **Well-tolerated implant procedure**
- **No evidence of implant diversion or misuse**

Pro-814 Study Design:

The final clinical study is a randomized, double blind and double dummy design that will provide information for a non-inferiority comparison of a six-month treatment with a dose of four Probuphine implants to treatment with 8 mg or less of an approved daily dosed sublingual formulation of buprenorphine.



R Randomization takes place on Day 1 (day of implant)
 SL BPN = sublingual buprenorphine or sublingual buprenorphine/naloxone

Target Patient Profile

Initial market research indicates that physicians would recommend Probuphine across wide patient population

- Patients stabilized on buprenorphine therapy
 - Serious and committed patients with good treatment history
- Patients that have a high relapse history
 - Patients with treatment compliance problems
- New patients
 - Patients seeking discrete treatment or living in remote areas
- Young patients (18-25 yrs)
 - Needing long term maintenance, active lifestyle
- Incarcerated patients – short term
 - Means of controlling incarceration-induced withdrawal

Probuphine Value Proposition

Probuphine is the first and only potential treatment for opioid dependence that can provide continuous and persistent around the clock blood levels of buprenorphine for six months, enhancing patient compliance and retention and preventing diversion

Efficacy	Effective in reducing illicit opioid use Enhanced compliance may lead to superior outcomes
Safety	Lower drug exposure may provide superior safety and tolerability
Ease of Use	Unique delivery system dosed once every six months Continuous buprenorphine delivery <ul style="list-style-type: none">• Non-fluctuating blood levels, around the clock medication• Potential 100% compliance
Diversion	Limited access to implants <ul style="list-style-type: none">• Subdermal placement• Specific distribution (non-retail)

Potential for the Treatment of Chronic Pain

- **Buprenorphine has several advantages over other opioids used for chronic pain**
 - Safer than other opioids
 - Ceiling effect for respiratory depression, relatively long half-life, minimal euphoric effect
- **Buprenorphine transdermal patch (3-7 days) is approved in U.S., Europe and Australia for the treatment of moderate to severe chronic pain**
 - Therapeutic window of 0.1 – 0.5 ng/ml plasma level can be delivered with 1 to 2 Probuphine implants
- **Probuphine value proposition for treating chronic pain**
 - Around the clock non-fluctuating therapeutic levels, no on/off therapy cycling, enhances compliance and increases patient convenience
 - Braeburn Pharmaceuticals holds the U.S. and Canadian rights to the chronic pain indication

Sources: NEJM 2003;349:1943-53 Sittl, Expert Rev. Neurotherapeutics 2005;5(3): 315-323

Titan: Adding Value Beyond Probuphine

Proprietary ProNeura Technology Platform

- Novel long-term drug delivery technology providing around-the-clock medication over periods of six months to a year clinically validated through the Probuphine program
- Applicable to other chronic treatments where clinical benefit is possible through:
 - Low dose around the clock drug administration
 - Stable blood level of medication
 - Subdermal drug delivery eliminating first-pass metabolic effects
- Product development program in Parkinson's disease in progress
 - Established non-clinical proof of concept with continuous dopamine agonist treatment in a PD model with funding from NIH grants
- Evaluation of additional compounds in other disease settings underway
- Titan has an expert team in place with an established product development track record

Parkinson's Disease Overview

Parkinson's Disease

- Parkinson's disease (PD) is characterized by the loss of dopaminergic neurons which leads to increasing activity in the brain region which influences movement and motor function

Treatment

- Early-stage PD patients are treated with drugs designed to replace dopamine in the brain. However, these therapeutics typically lose their benefits after several years of chronic treatment, and trigger serious side effects
- About one third of the treated patients develop motor response fluctuations and/or drug-induced dyskinesias within only 2 years of treatment, increasing to over 50% within 3-5 years of treatment

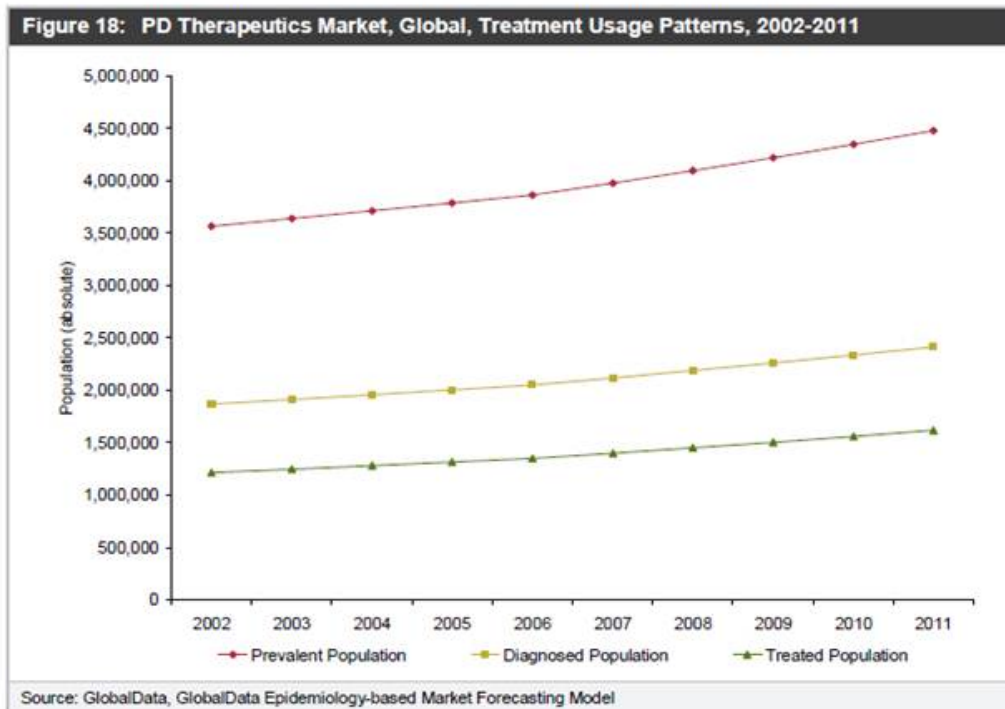
Research

- Clinical and nonclinical research indicates that these motor side effects arise from the pulsatile dopaminergic stimulation resulting from current oral treatment modalities
- Continuous dopaminergic stimulation (CDS) by subcutaneous infusion has been shown to palliate these motor complications and to also delay or prevent the onset of dyskinesias.

Product Opportunity

- Titan's ProNeura™ drug delivery technology provides a clinically-validated platform to safely and conveniently provide CDS for several months from a single treatment. Further, the subdermal placement of these implants eliminates many of the device-related complications associated with existing treatment modalities.

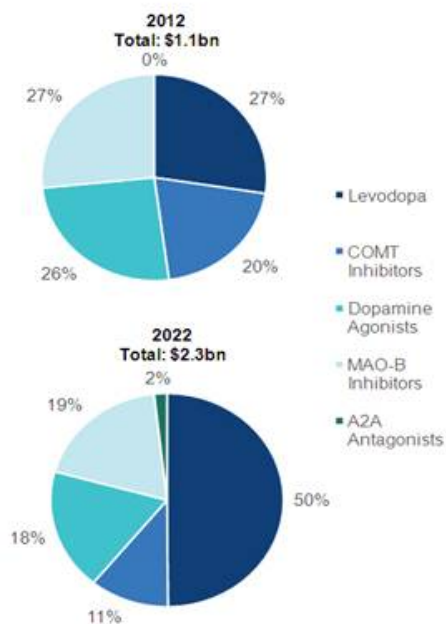
Parkinson's Disease: Treated Population Increasing Worldwide



Based on information from Titan and other sources believed to be reliable and prepared exclusively for Titan. Woodside Capital Partners is not responsible for any use that Titan may make of this material.

Parkinson's Disease: Therapeutics Market

Sales for PD in the US by Drug Class 2012–2022



About 1.5 million people in the U.S. have Parkinson's disease according to the Parkinson's Disease Foundation. The number is expected to double by 2030 because of the aging population.

Sales of Dopamine Agonists, US

Year	Total PD Sales	% DA	\$ DA
2012	\$1.1bn	26%	286m
2022	\$2.3bn	18%	414m

Source: GlobalData

Based on information from Titan and other sources believed to be reliable and prepared exclusively for Titan. Woodside Capital Partners is not responsible for any use that Titan may make of this material.

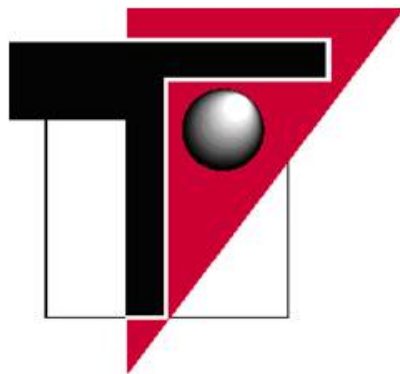
ProNeura – Parkinson’s Disease Program

- **Non-clinical Proof of Concept**
 - Evaluation of ProNeura technology in MPTP Parkinsonian monkey model
 - Ropinirole (Requip®), a dopamine agonist marketed by GSK in the US for PD, was safely and continuously delivered from ProNeura-ropinirole implants inserted subdermally
 - No local skin irritation at implant site
 - Sustained non-fluctuating plasma ropinirole level for several months following implantation
 - Controlled PD symptoms without triggering dyskinesias in severely lesioned primates
- **Next Steps**
 - Optimize implant formulation of ropinirole; develop non-clinical study plan to support Investigational New Drug (IND) application
 - Design POC clinical study with assistance of the Scientific Advisory Board
 - Pre-IND meeting with the FDA
 - Complete non-clinical studies to enable IND filing in late 2015
 - Prepare for conducting clinical study

Titan Pharmaceuticals Summary

Titan Pharmaceuticals is a specialty pharmaceutical company focused on developing innovative treatments for chronic conditions based on its proprietary long-term drug delivery platform, ProNeura™

- **Probuphine, a long-acting controlled-release buprenorphine product for opioid dependence**
 - Growing \$1.5 billion market in opioid dependence; potential in chronic pain
 - \$300-\$500M in potential annual peak sales in opioid dependence alone
 - Addresses significant unmet needs: *reduction in opioid use, increased compliance, avoidance of diversion and abuse*
 - Attractive U.S. partnership: upfront \$15.75M (12/12); approval, \$15M; sales milestones, \$165M; tiered royalties in mid-teens to low-twenties
 - NDA submission in late 2015
- **ProNeura for Parkinson's (ROPINIROLE)**
 - Dopamine Agonist; continuous long term delivery in convenient outpatient setting
 - Potential to reduce motor fluctuations, dyskinesias and increase 'on' time
 - Expected IND filing in 2015; proof-of-principle clinical study in 2016
- **Proprietary ProNeura long-term drug delivery platform**
 - Around-the-clock medications over six months to a year
 - Broad base of potential applications in chronic treatments





Titan Pharmaceuticals, Inc.

FOR IMMEDIATE RELEASE

TITAN PHARMACEUTICALS ANNOUNCES FIRST PATIENT ENROLLMENT IN CLINICAL STUDY OF PROBUPHINE FOR OPIOID DEPENDENCE

Study completion expected in mid-2015 followed by potential resubmission of Probuphine New Drug Application

South San Francisco, CA - July 21, 2014 - Titan Pharmaceuticals, Inc. (TTNP.OB) today announced enrollment of the first patients in the Phase 3 clinical study to support resubmission of the New Drug Application (NDA) for Probuphine®, the company's investigational subdermal implant for the maintenance treatment of opioid dependence. The study, which is expected to be completed by the middle of 2015, is designed to address key questions posed by the U.S. Food and Drug Administration (FDA) in its complete response letter last year after review of the original NDA. Titan's partner Braeburn Pharmaceuticals is sponsoring the trial and anticipates resubmission of the NDA to the FDA in late 2015.

"With more than 2 million people in the U.S. suffering from opioid dependence, there is a strong need for new treatments. If approved, Probuphine would be the first and only commercialized treatment of opioid dependence to provide continuous, around-the-clock blood levels of buprenorphine for six months following a single procedure," said Kate Glassman-Beebe, PhD., Titan's executive vice president and chief development officer.

Investigator training was conducted by Braeburn in June to review clinical study procedures, including special training for implant insertion and removal. Fifteen sites have obtained Institutional Review Board (IRB) approval, and Braeburn expects an additional six sites to be operational within the next few weeks. Fourteen sites are currently screening patients for randomization into the study and five patients have already been enrolled.

"We believe the fast pace with which a number of sites received IRB approval following our recent investigator training indicates the addiction community's support and need for novel treatments like Probuphine. Braeburn is committed to continue working with our clinical investigators to identify appropriate study patients and expedite enrollment in this study," said Behshad Sheldon, president and CEO of Braeburn Pharmaceuticals.

The clinical study is a randomized, double-blind, double-dummy design that is expected to enroll approximately 180 patients into two parallel treatment arms. The study population is clinically stable patients who are receiving maintenance treatment with an FDA-approved sublingual formulation containing buprenorphine at a daily dose of 8mg or less. Patients are being randomized to either receive four Probuphine implants, or to continue the daily sublingual buprenorphine therapy. To enable the double-blind design, those receiving Probuphine implants are required to take daily placebo sublingual pills, while those continuing on their stable dose of sublingual buprenorphine pills are required to be treated with four placebo implants. The patients are expected to be treated for six months, and the primary analysis will be a non-inferiority comparison of responders in the two arms.

Probuphine is designed to deliver continuous, around the clock blood levels of buprenorphine for six months following a single insertion procedure, and to simplify patient compliance and improve retention. It was developed using ProNeura™, Titan's continuous drug delivery system. Titan also has in development a ProNeura technology-based product for the treatment of Parkinson's disease and the company anticipates filing an investigational new drug application for that program in 2015.

About Opioid Dependence

According to recent estimates, 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 2011.

About Probuphine

Probuphine is an investigational subdermal implant designed to deliver continuous, around the clock blood levels of buprenorphine for six months following a single treatment, and to simplify 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 2012 sales of \$1.5 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 over a 24-week period (published in the *Journal of the American Medical Association (JAMA)*), and a follow on study of 287 patients (published in the journal *Addiction*).

About Titan Pharmaceuticals

Titan Pharmaceuticals Inc. (TTNP.OB), based in South San Francisco, CA, is a specialty pharmaceutical company developing proprietary therapeutics primarily for the treatment of serious medical disorders. The company's lead product candidate is Probuphine®, a novel and long-acting formulation of buprenorphine for the long-term maintenance treatment of opioid dependence. Probuphine employs Titan's proprietary drug delivery system ProNeura™, which is capable of delivering sustained, consistent levels of medication for six months or longer. Titan has granted North American commercial rights for Probuphine to Braeburn Pharmaceuticals. If approved, Probuphine would be the first and only commercialized treatment of opioid dependence to provide continuous, around-the-clock blood levels of buprenorphine for six months following a single procedure. The ProNeura technology has the potential to be used in developing products for treating other chronic conditions, such as Parkinson's disease, where maintaining consistent blood levels of a dopamine agonist may benefit the patient and improve medical outcomes. For more information about Titan, please visit www.titanpharm.com.

This 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 our product development programs and any other statements that are not historical facts. Such statements involve risks and uncertainties that could negatively affect our business, operating results, financial condition and stock price. Factors that could cause actual results to differ materially from management's current expectations include those risks and uncertainties relating to the regulatory approval process, the development, testing, production and marketing of our drug candidates, patent and intellectual property matters and strategic agreements and relationships. We expressly disclaim any obligation or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein to reflect any change in our expectations or any changes in events, conditions or circumstances on which any such statement is based, except as required by law.

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