### 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): February 2, 2016

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))

### Item 7.01. Regulation FD Disclosure.

Commencing February 2, 2016, Titan Pharmaceuticals, Inc. will present and post on its website an updated corporate presentation, a copy of which is attached hereto as Exhibit 99.1 and incorporated herein by reference.

The foregoing information, including the presentation attached hereto as an exhibit, 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 9.01. Financial Statement and Exhibits.

(d) Exhibits.

Exhibit No.

Description

99.1 Corporate Presentation

### 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: February 1, 2016





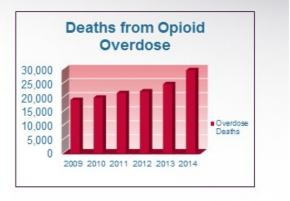
# Forward-Looking Statements

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.

1000

# The Epidemic of Opioid Addiction

- · Increasingly recognized as a global epidemic by world health authorities
- Addiction a primary, chronic disease of brain reward, motivation, memory and neurobiological circuitry
  - · Cravings, accompanied by lack of impulse control
  - · Abstinence is rarely a successful therapeutic approach
  - · Cycles of relapse and remission
  - Progressive, and often results in disability or premature death if untreated



TITAN

Carls

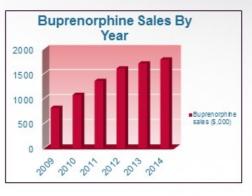
Source: National Center on Health Statistics, CDC WONDER

# **Opioid Addiction: Treatment Overview**

- · Buprenorphine pharmacology makes it an effective, safer and more convenient treatment option
  - · Controls withdrawal symptoms and cravings without inducing opioid euphoria in patients
  - · Convenient outpatient treatment allowing take home medication, unlike methadone
  - · Low risk of respiratory depression compared to other opiates
- Buprenorphine treatment is the gold standard in the U.S.
  - Annual U.S. sales of daily dosed formulations approaching \$1.8 billion
- · Challenges with daily dosed formulations
  - Compliance
  - · Sublingual dosing results in variable blood levels
  - Diversion and abuse

INNOVATIONS IN MEDICINE

Titan Pharmaceuticals Company Overview | Proprietary & Confidential | 02014 1



Int

# Proprietary ProNeura Technology: Probuphine Implant

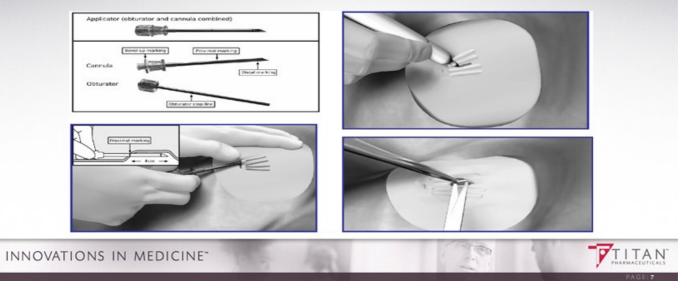
- Implant contains 80 mg of buprenorphine HCI, uniformly distributed throughout the ethylene vinyl acetate co-polymer (EVA) matrix
- No reservoir, therefore no risk of drug dumping

e ticels Concern Overview | Proprietary & Conf



# **Probuphine Administration**

Four probuphine implants are inserted subdermally in the inner, upper arm in a brief office procedure. After six months, the implants are removed and new implants may be inserted in the opposite arm.



# Probuphine Value Proposition

Probuphine is the first and only potential treatment for opioid dependence that provides non-fluctuating blood levels of buprenorphine around-the-clock for a period of six months

Efficacy	Effective in reducing illicit opioid use
Safety	Non-fluctuating drug exposure over six months may provide superior safety and tolerability
Compliance	Treatment with implant expected to enhance compliance
Ease of Use	Patients dosed once every six months in an outpatient setting
Diversion	Limited access to implants

Ten

TITAN

# Probuphine Clinical and Regulatory Background

- Six clinical studies completed and NDA submitted in October 2012
  - NDA accepted for Priority Review in January 2013
  - Positive advisory committee vote (10-4 for approval) in March 2013
  - · Receipt of CRL in April 2013 requesting additional clinical testing and a few other items
- Additional Phase 3 study, as requested by FDA
  - A randomized, double blind, double dummy study evaluating a dose of four Probuphine implants in stable patients who have been receiving maintenance therapy at a dose of 8mg/day or less of buprenorphine. The primary efficacy analysis will be a non-inferiority comparison between the two arms.
  - · Trial enrollment initiated in July 2014 and completed in November 2014
  - Study enrolled 177 subjects who were randomized to receive either the Probuphine implants or sublingual tablets for a treatment period of six months

TIM

TITAN

# Positive Results From PRO 814 Phase 3 Study

 Primary efficacy endpoint based on non-inferiority comparison of 'responders' following six months of treatment with either four Probuphine implants or 8 mg or less of an approved daily dosed sublingual tablet formulation of buprenorphine

Scree	ening		Maintenanc	e Phase	Follow-up
		Gr	oup A: Daily Sl 4 placebo ir	_	
Clinically sta	ble patients				
	SL BPN for at	Group B: 4 Probuphine implants Daily SL placebo			2 Weeks (25 to 26)
least 90 days	5	Urine Toxicology & Other Study Assessments			
• Opioid-nega	itive urine	24 Weeks (Weeks 1 to 24) Monthly Visits			
toxicology for last 90 days		24 Weeks (6 months) on Treatment			
Randomization takes pla	ce on Day 1 (day of Implant) SLBPN = se	bihguai buprenomhhe or s	ublingual buprenorphine	haloxone	
Results:		Probuphine	SL BPN	Proportion Difference(95% CI)	Superiority P value
Re	sponder - ITT population	81/84 (96%)	78/89 (88%)	0.088 (0.009, 0.167)	0.03
	sponder - modified ITT	81/87 (93%)	78/89 (88%)	0.055 (-0.032, 0.141)	0.22
Re					
	IN MEDICINE"	1000	land a	- Ch	

# Advisory Committee Meeting (January 2016)

### Focus of the discussion:

- Efficacy What is the most appropriate definition of a treatment responder, given the use of supplemental "dose adjustments," and missing or incomplete urine toxicology data?
- Safety/HF validation Given the possibility of procedural complications (e.g. expulsions and protrusions), is the training program adequate to insure that clinicians will be able to safely perform Probuphine insertion and removals?
- FDA explained that it was seeking guidance from the committee on the best way to analyze the data
  and presented several sensitivity analyses focused on measuring efficacy
  - · FDA recommended method for analysis included
    - $\ensuremath{\,\bullet\,}$  zero months with illicit opioid use
    - · missing urines considered positive
    - up to two instances of supplemental buprenorphine use in the Probuphine arm / unlimited supplemental use in the SL BPN arm

Call

τιταν

- Non-inferiority endpoint met with lower bound of CL at -0.09, once again favoring Probuphine
- The safety data and HF validation were discussed and the FDA indicated general acceptance of the submitted Risk Evaluation and Mitigation Strategy (REMS)
- The committee voted 12 5 in favor of approval of Probuphine

# Probuphine Summary - The First of its Kind NDA review in process with FDA action date of February 27, 2016 Partnership with Braeburn Pharmaceuticals for development and commercialization in U.S. and Canada Upfront: \$15.75 mil; Approval: \$15 mil; Sales Milestones: \$165 mil; Tiered Royalties: mid teens-low 20s (%) Analyst projections of peak sales: \$300 - \$500 million U.S. patent to 2024 Pursuing ex-U.S. opportunities for approval and commercialization in treatment of opioid addiction Opportunity to develop Probuphine for treatment of chronic pain

# Titan: Adding Value Beyond Probuphine

Proprietary ProNeura Technology Platform

- Long-term drug delivery technology validated through the Probuphine program
- Potential for the treatment of select chronic diseases for which low dose, long-term delivery and stable drug levels may offer advantages over other forms of administration
- Product development programs in progress:
  - Ropinirole implant for the treatment of Parkinson's disease (PD)
  - Triidothyronine (T3) implant for the treatment of hypothyroidism
- Conducting feasibility evaluation of additional compounds in other chronic disease settings to add to the product pipeline
  - Benign Prostate Hyperplasia, Pre-exposure prophylaxis therapy for HIV-1 prevention, Type 2 Diabetes, Attention Deficit Hyperactivity Disorder

Tent

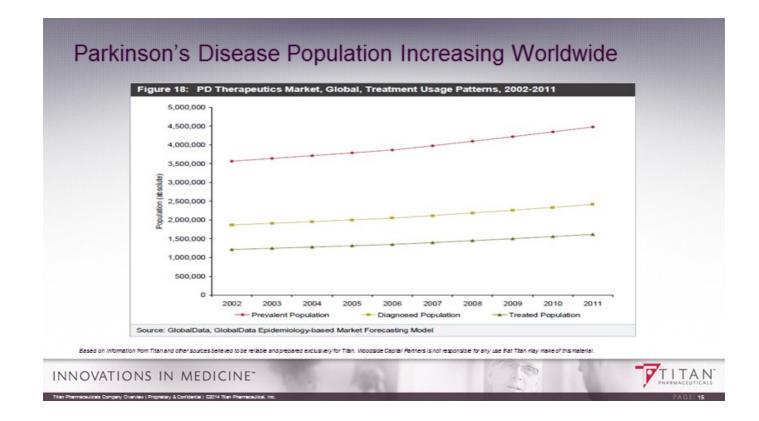
# Parkinson's Disease Overview

Definition	Characterized by the loss of dopamine, which alters activity in the brain region impacting movement and motor function
Treatment	Treated with drugs designed to replace or mimic dopamine in the brain Following several years of chronic treatment, these drugs lose their benefit and trigger serious side effects in up to 80% of patients
Research	Pulsatile dopaminergic stimulation from current oral treatment may cause motor side effects Continuous dopaminergic stimulation (CDS) by systemic infusion of dopamine replacement medications has been shown to palliate these motor complications and also delay or prevent the onset of dyskinesias
Product Opportunity	Titan's ProNeura drug delivery technology has the potential to deliver continuous non- fluctuating levels of dopamine agonists and provide CDS for three months or longer from a single treatment

10

### INNOVATIONS IN MEDICINE"

Titan Pharmaceuticals Company Overview | Proprietary & Confidential | E2014 Titan Pharmaceutical, Inc



# Parkinson's Disease - Therapeutics Market

- · As many as one million people in the US affected by Parkinson's disease
- The number is expected to almost double by 2030 because of the aging population
- About 60,000 newly diagnosed for Parkinson's disease annually
- · More than 23,000 die from Parkinson's disease each year

Cost to American Society **		Sales of Dopamine Agonists, U.S.*			
n Annually	\$ DA \$14.4 Billion Annu		% DA	Total Sales	Year
Indirect Costs \$6.3 Billion	Treatment Costs \$8.1 Billion	\$286 Million	26%	\$1.1 Billion	2012
If costs continue to rise they will double by 2040		\$414 Million	18%	\$2.3 Billion	2022

1000

TITAN

\* GlobalData; \*\*Farkinson's Action Network; National Center for Health Statistics; \*The Current and Rejected Economic Burden of Parkinson's Disease in the United States' Movement Disorders; March 2013 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

- Ropinirole (Requip<sup>®</sup>), a generic dopamine agonist marketed by GSK for PD, was evaluated in a Parkinsonian primate model using ProNeura drug delivery platform
- · Results demonstrated
  - Sustained plasma ropinirole levels for several months following implantation
  - · No local skin irritation at implant site
  - · Controlled PD symptoms without triggering dyskinesias

### Ropinirole implant program status

- · Implant formulation selected for clinical development
- · Non-clinical development program defined and initial clinical study design established

(mag

TITAN

- · Pre-IND meeting briefing material provided for FDA review and comment
- · On target to commence initial clinical study in late 2016

# Hypothyroidism Disease Overview

Definition	Hypothyroidism is a disorder that occurs when the thyroid gland does not make enough thyroid hormone to meet the body's needs
	Thyroid hormone regulates metabolism and affects nearly every organ in the body
	Primary hypothyroidism is caused by a problem with the thyroid gland
Cause	Secondary hypothyroidism occurs when another problem interferes with the thyroid's ability to produce hormones, such as the inability of the pituitary gland and hypothalamus to produce hormones that trigger the release of thyroid hormone
Treatment	Estimated number of people affected with hypothyroidism in the U.S. – 14 million Patients diagnosed using standard blood tests and receive treatment typically consisting of synthetic prohormone thyroxine (T4) given orally once a day, which in turn is converted by the body to the active triiodothyronine (T3)
	Based upon symptoms and blood tests it is estimated that 15-20% of patients are not adequately treated with T4 and physicians typically add an oral T3 dose to the treatment regimen
Product Opportunity	Oral T3 treatment is effective but comes with potential side effects like headache, nervousness, irritability, depression and arrhythmia caused by the peak and trough blood level fluctuations
Product Opportunity	Titan's ProNeura drug delivery platform has the potential to deliver continuous, non-fluctuating levels of T3 and provide a stable blood level for several months following a single treatment.

# ProNeura Hypothyroidism Program

- Completed initial formulation development of the implant and conducted in-vitro and in-vivo drug release studies to further define implant formulation
- In-vivo non-clinical studies in progress evaluating implant formulations for drug release characteristics
  - Demonstrated non-fluctuating release of T3 over several months in small and large animal models
  - Testing in a non-clinical model of hypothyroidism will be conducted during H1-2016

Tent

- Next steps
  - · Establish proof-of-concept in non-clinical model of hypothyroidism
  - · Establish the non-clinical study plan that will provide safety data for the IND
  - Target meeting with the FDA for a pre-IND meeting before the end of 2016
  - · Goal is to start a proof of concept clinical study in H2-2017

## **Titan Executive Management**

- Marc Rubin, M.D, Executive Chairman and Director
  - 8 years with Titan Pharmaceuticals
  - · Former Head of Global Research & Development and member of the Board of Management at Bayer Pharma
  - Executive R&D and commercial responsibilities at GSK for 13 years
  - 25 years in the pharmaceutical industry following 7 years at NIH
- Sunil Bhonsle, M.B.A., President, CEO and Director
  - 19 years with Titan Pharmaceuticals
  - · 20 years with Bayer Corporation in Biological and Pharmaceutical finance and operations management
- Kate Beebe, Ph.D., Executive Vice President, Chief Development Officer
  - 9 years with Titan Pharmaceuticals
  - · 19 years in industry, with senior positions in clinical development and medical affairs at GSK and Merck

Tent

τιταν

10 years in academic medicine



PRESENTER(S) Sunil Bhonsle

# Thank You

