TITAN PHARMACEUTICALS

PRESENTER(S): Sunil Bhonsle

DATES(S): Sep 2015

TITLE:

Corporate Presentation

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.

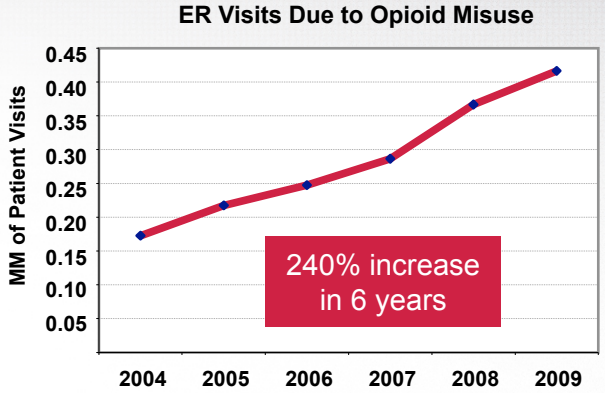
Company Overview

Titan Pharmaceuticals specializes in the development of treatments for select chronic diseases utilizing its proprietary ProNeura™ technology platform

- ProNeura: Proprietary Long Term Drug Delivery Platform
  - Provides non-fluctuating medication levels over periods of three months to a year
  - Ideal for use in the treatment of chronic diseases for which maintenance of non-fluctuating medication levels may offer advantages over oral administration
- Probuphine® for the Treatment of Opioid Addiction
  - Long acting formulation of buprenorphine providing six months of steady-state levels
  - FDA requested final Phase 3 clinical study completed in June 2015 with strong positive results
  - Probuphine NDA resubmitted to FDA at the end of August 2015, with potential approval in Q1, 2016
- ProNeura for Parkinson's Disease (ropinirole)
  - Demonstrated non-clinical proof of concept in a parkinsonian primate model
  - Conducting IND enabling non-clinical studies with the goal to commence clinical testing in H2, 2016

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



Source: American Society of Addiction Medicine, Inc., 2011

Opioid Addiction: Treatment Overview

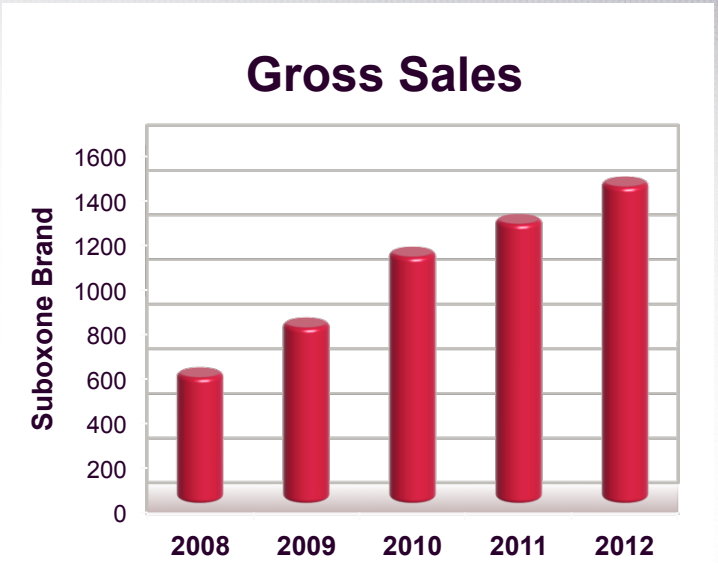
Buprenorphine is the Gold Standard in the U.S., Replacing Methadone

- 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

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

Treatment of Opioid Addiction: Expanding the Market

- Buprenorphine is the gold standard in the U.S., replacing methadone
  - U.S. sales of daily oral formulations approximately $1.7B in 2014
  - U.S. prescriptions have exceeded methadone since 2006
  - Market growth (units) continues ~ 9%
- Challenges with sublingual buprenorphine
  - Compliance
  - Dosing results in variable levels of medication in blood
  - Diversion and abuse associated with current daily dosed formulations



Sources: IMS Health, Wolters Kluwer

Proprietary ProNeura Technology: Probuphine Implant

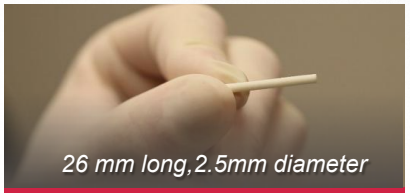
- Implant contains 80 mg of buprenorphine HCl, uniformly distributed throughout the ethylene vinyl acetate co-polymer (EVA) matrix
- No reservoir, therefore no risk of drug dumping
- Probuphine implant is inserted subdermally in the upper arm in a simple office procedure and delivers continuous, stable blood levels of buprenorphine for 6 months

EVA polymer

+

Buprenorphine

Blended & Extruded



Probuphine

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

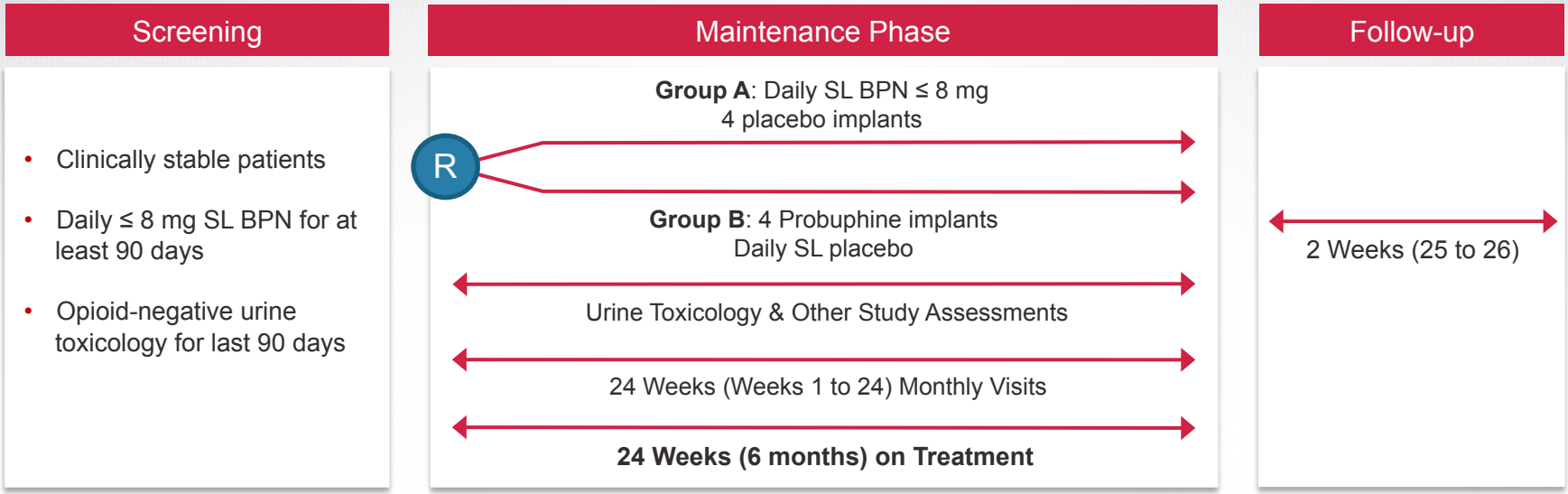
Efficacy	Effective in reducing illicit opioid use
Safety	Non-fluctuating drug exposure over six months may provide superior safety and tolerability
Compliance	Treatment with implant expected to enhance compliance
Ease of Use	Patients dosed once every six months in an outpatient setting
Diversion	Limited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

Probuphine Clinical and Regulatory Summary

- Six clinical studies completed and NDA submitted in October 2012
  - Initial small dose finding study
  - Two well controlled Phase 3 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 and one 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 with no evidence of implant diversion or misuse
  - 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

FDA Requested Phase 3 Clinical Study Completed (PRO 814)

Randomized, double blind and double dummy design. Primary efficacy endpoint based on a non-inferiority comparison of 'responders' following six months of treatment with either a dose of four Probuphine implants or treatment with 8 mg or less of an approved daily dosed sublingual tablet formulation of buprenorphine.



R *Randomization takes place on Day 1 (day of implant)*

SL BPN = sublingual buprenorphine or sublingual buprenorphine/naloxone

Positive Topline Phase 3 Study Results

- 177 subjects randomized in the study and 173 subjects were included in the ITT population; 84 in the Probuphine arm and 89 in the sublingual buprenorphine/naloxone arm
- Primary endpoint of non-inferiority met with 81(96.4%) responders in the Probuphine arm and 78(87.6%) responders in the sublingual buprenorphine/naloxone arm; two-sided 95% confidence interval (0.009, 0.167) well within the pre-defined success margin
- Overall safety and tolerability profiles for each treatment group were comparable, and generally similar to those observed in prior Phase 3 clinical studies

Positive Topline Phase 3 Study Results

- Sequential superiority analysis indicated a statistically significant difference in favor of Probuphine over the sublingual buprenorphine/naloxone treatment arms ($p < 0.05$)
- Number of subjects with all six months testing negative for urines with no evidence of illicit opioid use was significantly higher in Probuphine arm (88%) than sublingual buprenorphine/naloxone arm (72%), ($p < 0.05$)
- Symptoms of opioid withdrawal and cravings across six month study comparable in both treatment arms

Probuphine: The First of its Kind

- NDA resubmitted at the end of August, 2015 with potential approval by the FDA in Q1, 2016
- Peak sales potential: $300-$500 mil in U.S. and partnership with Braeburn Pharmaceuticals for commercialization in U.S. and Canada
  - Upfront: $15.75 mil; Approval: $15 mil; Sales Milestones: $165 mil; Tiered Royalties: mid teens-low 20s (%)
- 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

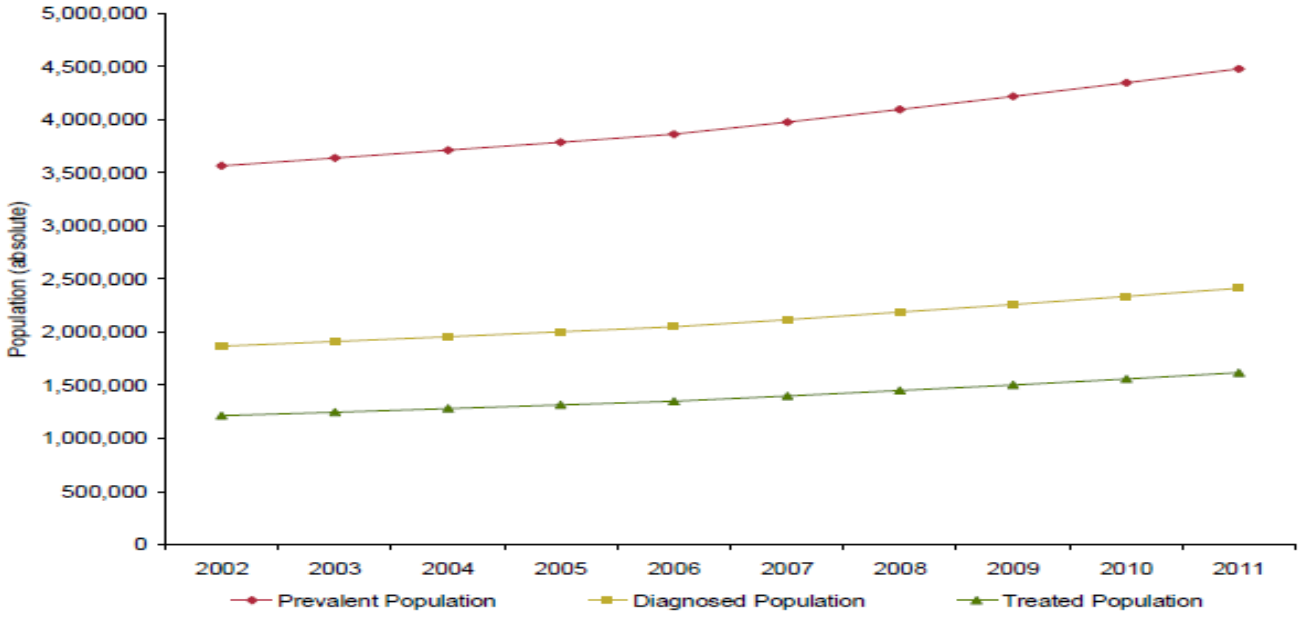
- Long term drug delivery technology validated through the Probuphine program
- Potential for the treatment of select chronic diseases for which low dose long term delivery and stable drug levels may offer advantages over oral administration
- Product development program in Parkinson's disease (PD) in progress
- Evaluation of additional compounds in other chronic disease settings under way

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.

Parkinson's Disease Population Increasing Worldwide

Figure 18: PD Therapeutics Market, Global, Treatment Usage Patterns, 2002-2011



Source: GlobalData, GlobalData Epidemiology-based Market Forecasting Model

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

- 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

Sales of Dopamine Agonists, U.S.*			
Year	Total Sales	% DA	$ DA
2012	$1.1 Billion	26%	$286 Million
2022	$2.3 Billion	18%	$414 Million

Cost to American Society **

$14.4 Billion Annually

Treatment Costs	Indirect Costs
$8.1 Billion	$6.3 Billion

If costs continue to rise they will double by 2040

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

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ProNeura Parkinson's Disease Program

Non-clinical Proof of Concept

- Ropinirole (Requip®), a generic dopamine agonist marketed by GSK for PD, was evaluated in a non-clinical Parkinsonian primate model using ProNeura implant technology
- Results demonstrated:
  - Sustained plasma ropinirole levels for several months following implantation
  - No local skin irritation at implant site
  - Controlled Parkinsonian symptoms without triggering dyskinesias

ProNeura Parkinson's Disease Program

Next Steps

In consultation with the Scientific Advisory Board:

- Optimize implant formulation for sustained release of ropinirole
- Conduct non-clinical studies to support Investigational New Drug (IND) application
- Design a proof of concept, first-in-human clinical study
- Submit briefing material and request a pre-IND meeting with the FDA in Q4, 2015
- Complete non-clinical studies to enable timely submission of IND and commence proof of concept clinical study in H2, 2016

ProNeura: Building a Product Pipeline

- The ProNeura platform is ideal for the treatment of select chronic diseases for which low dose, long term treatment with stable drug levels may offer advantages over oral administration, diseases such as
  - Hormonal Deficiencies
  - Type 2 Diabetes
  - Attention Deficit Hyperactivity Disorder
  - Benign Prostate Hyperplasia
  - Pre-exposure prophylaxis therapy for HIV-1 prevention
- Titan is reviewing potential compounds that fit the ProNeura implant profile and conducting early feasibility experiments with the goal to add at least one more product to the pipeline in the next few months
- Titan plans to explore other opportunities for the delivery of proprietary compounds through joint development projects or potential licensing of the ProNeura technology to other companies

Titan Pharmaceuticals Summary

- Titan Pharmaceuticals specializes in the development of treatments for select chronic diseases, utilizing its innovative ProNeura technology platform
- Probuphine, a six month buprenorphine implant for the maintenance treatment of opioid addiction; NDA resubmitted at the end of August 2015 with potential product approval in Q1, 2016
  - U.S. and Canadian partnership with Braeburn Pharmaceuticals
  - Pursuing ex-U.S. opportunities for approval and commercialization
  - Potential for treatment of chronic pain
- ProNeura for Parkinson's (ropinirole) has the potential to significantly enhance Titan value
- Active evaluation of ProNeura long-term drug delivery for other chronic diseases
- Proven management team with strong track record of success
- Strong news flow expected to provide multiple value inflection opportunities

Titan Executive Management

- Marc Rubin, M.D, *Executive Chairman and Director*
  - Eight 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. Twenty-five years in the pharmaceutical industry following seven years at NIH.
- Sunil Bhonsle, M.B.A., *President and Director*
  - Nineteen years with Titan Pharmaceuticals. Twenty years with Bayer Corporation in Biological and Pharmaceutical finance and operations management.
- Kate Glassman Beebe, Ph.D., *Executive Vice President, Chief Development Officer*
  - Eight years with Titan Pharmaceuticals. Nineteen years in pharmaceutical industry, with senior positions in clinical development and medical affairs at GSK and Merck. Ten years in academic medicine.

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Thank You