

**UNITED STATES  
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): January 7, 2013

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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)

**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 7.01 Regulation FD Disclosure**

On January 7, 2013, management of Titan Pharmaceuticals, Inc. will be holding investor presentations. A copy of the January 2013 corporate presentation is attached as Exhibit 99.1 to this Current Report on Form 8-K.

**Item 9.01. Financial Statements and Exhibits.**

(d) Exhibits

99.1 Corporate Presentation dated January 2013

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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: January 7, 2013

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## Exhibit Index

<u>Exhibit No.</u>	<u>Description</u>
99.1	Corporate Presentation dated January 2013



*Innovations*  
*in* MEDICINE™

TITAN PHARMACEUTICALS, INC. 

Corporate Presentation

January 2013

## 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 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: Highlights

- **Specialty pharmaceutical company with drug development expertise and Probuphine® NDA accepted for Priority Review**
  - **Probuphine has the potential to be the first long acting buprenorphine product on the market for the treatment of opioid dependence**
    - Six month sustained release formulation of an approved drug, buprenorphine
    - Addresses U.S. market of approximately \$1.3 billion in 2011 and growing
    - Significant unmet needs continue to exist in the market place
    - Potential peak sales of \$300m – \$500m
    - U.S. patent life to 2024
    - NDA accepted for Priority Review – PDUFA date April 30, 2013
    - Probuphine has the potential to be developed for treating chronic pain
  - **Probuphine commercialization rights for U.S. and Canada granted to Braeburn Pharmaceuticals, Spri (wholly owned by Apple Tree Partners IV, LP)**
    - Upfront: \$15.75 mil Approval: \$50 mil Milestones: \$165 mil Royalties: Tiered double digit
  - **ProNeura™ – unique long term drug delivery platform can provide around the clock medication and has potential in additional applications, e.g. Parkinson's**
- **Near term value-creating milestones**
- **Lean and capital efficient organization**

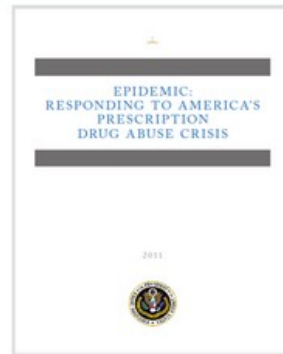
# Opioid Dependence - Viewed as an Epidemic

- **Recognized as an epidemic by the federal government**

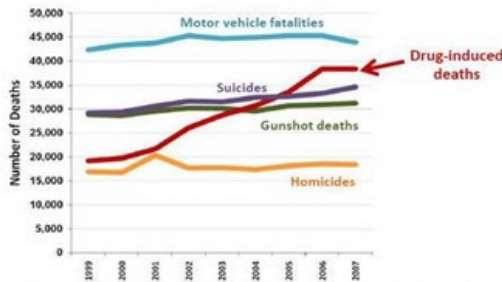
- *“Prescription drug misuse and abuse is a major public health and public safety crisis.”*

Opioid dependence is recognized by the government as a medical epidemic that warrants immediate and significant resource allocation

- NIDA (part of NIH) has provided a \$7.6 million grant in support of Probuphine development

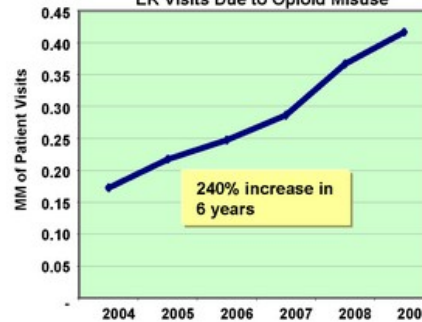


**Drug-Induced Deaths Second Only to Motor Vehicle Fatalities, 1999–2007**



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).

**ER Visits Due to Opioid Misuse**



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)



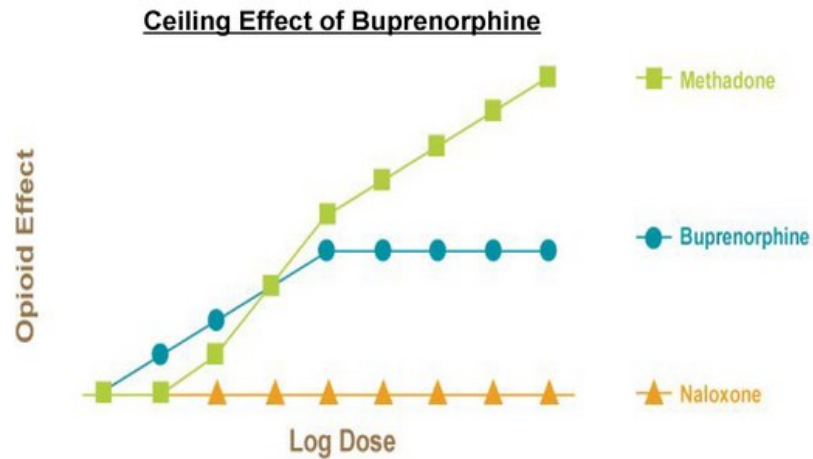
## Opioid Dependence - Disease Overview

- **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

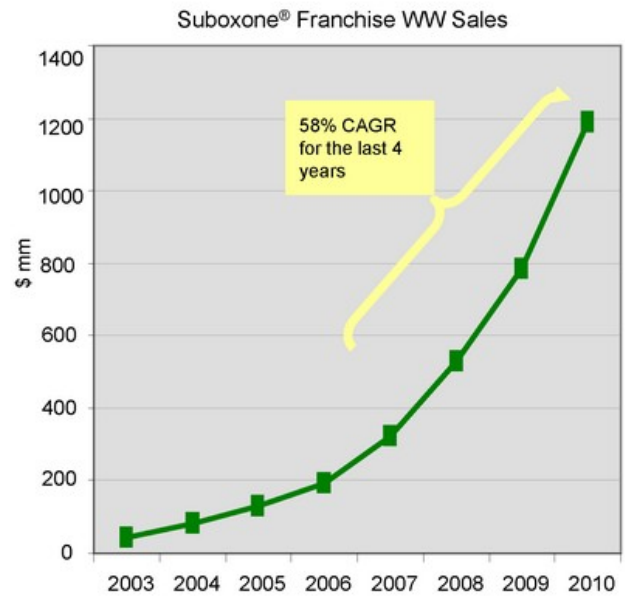
- In the U.S. buprenorphine has replaced methadone as the gold standard in treating opioid dependence
- Buprenorphine is a mixed partial agonist at the mu receptor and an antagonist at the kappa receptor
  - Ceiling effect
  - Improved safety profile
  - Lack of euphoria



## Opioid Dependence - Expanding Market

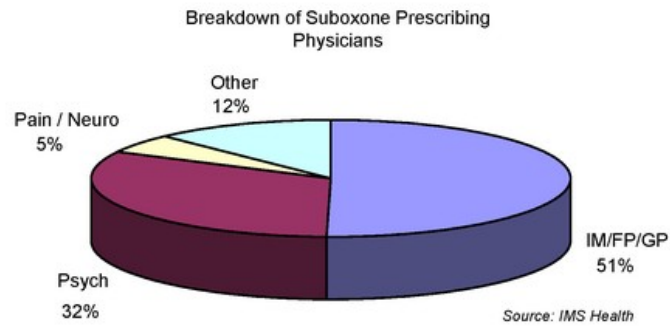
- **Daily buprenorphine is the current gold standard**
  - Global sales of daily oral formulations of buprenorphine (Suboxone) reached \$1.5B in 2011 with US sales of \$1.3B
  - U.S. buprenorphine prescriptions have far outstripped those of methadone since 2006
- **Implications of addiction being treated as a chronic illness**
  - Underlying prevalence continues to grow driven by increasing abuse of Rx opioids
  - Acknowledgement of changes in brain chemistry in addicts drives greater share of patients treated with MAT (currently at 30-40%)
  - Ongoing changes to brain function long after subject is "clean" indicates need for chronic treatment - potentially years rather than months

Source: IMS Health



## Opioid Dependence - Concentrated Prescriber Base

- **Excellent margins due to concentrated, target prescriber population**
  - 5,037 physicians wrote 90% of buprenorphine prescriptions in 2010



- **Challenges with oral buprenorphine**
  - Compliance
  - Fluctuating levels of drug
  - Diversion, abuse

## Probuphine

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

### Solid Matrix Long-Term Delivery

- Non-biodegradable
- Inserted subdermally
- Stable non-fluctuating blood levels of drug maintained for over 6 months

# Probuphine

## EVA polymer



Inert component of several approved products



## Buprenorphine



Approved for treatment of opioid addiction, and acute and chronic pain

Blended  
&  
Extruded



## Probuphine



26 mm long,  
2.5 mm  
diameter

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

## Probuphine Clinical Summary

- Probuphine was clinically and statistically superior to placebo in the treatment of opioid-addicted patients, and demonstrated non-inferiority to Suboxone.
- Adverse events were mild to moderate in severity and generally consistent with the patient population and the known safety profile of buprenorphine in all studies. Early termination due to adverse events was low in all studies.
- The number and profile of serious adverse events was low in all studies and similar to placebo.
- The implant procedure was generally well tolerated in all studies and there was no evidence of implant diversion or misuse.
- Probuphine delivers an efficacious, low level of buprenorphine continuously for six months and is well tolerated by patients.
- Probuphine NDA has been granted a Priority Review designation with the PDUFA date of April 30, 2013. Advisory Committee meeting, if convened, is anticipated in the second half of March.

## 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 high relapse history
    - Patients with treatment compliance problems
  - New patients
    - Patients seeking discrete treatment or live in remote areas
  - Young patients (18-25 yrs)
    - Needing long term maintenance, active lifestyle
  - Incarcerated patients – short term
    - It's a way to control incarceration-induced withdrawal



## Probuphine 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

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

## Probuphine Intellectual Property

Country	Opioid Dependence	Pain Treatment
U.S.	Granted (to 2024)	Pending
Europe	Pending	Pending
Japan	Granted (to 2023)	Granted (to 2023)
Canada	Pending	Pending
Mexico	Granted (to 2023)	Granted (to 2023)
Australia	Granted (to 2023)	Granted (to 2023)
New Zealand	Granted (to 2023)	Granted (to 2023)
Hong Kong	Pending	Pending
India	Pending	Pending

- Patent applications are for method-of-use claims
- Method-of-use and similar claims provide strong protection of commercial product:
  - Alternate device or alternate indication would require de novo clinical trials

## 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

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

## Probuphine Commercial Partner

- **Exclusive commercialization rights for U.S. and Canada licensed to Braeburn Pharmaceuticals, Sprl**
  - Upfront payment: \$15.75 million
  - All Potential Milestones : \$215 million
    - First potential milestone of \$50 million upon FDA approval
  - Tiered double digit royalty on net sales
  - Braeburn has allocated in excess of \$75 million to launch, commercialize and continue development of Probuphine
- **Braeburn Pharmaceuticals, Sprl**
  - Wholly-owned by Apple Tree Partners IV, L.P. a partnership affiliated with Apple Tree Partners (ATP). ATP founded and built Aileron Therapeutics, Gloucester Pharmaceuticals (acquired by Celgene), Heartware International and Tokai Pharmaceuticals. The goal for the partnership is to build Apple Tree Consolidated, Sprl (ATC), a holding company that will create and own complementary life sciences businesses. Braeburn Pharmaceuticals is the first division of the holding company.

## Probuphine Commercial Partner

- **Experienced Team**
  - Rose Crane - Partner at ATP and Head of Pharmaceutical Commercialization at ATC
    - Former Company Group Chair OTC, Specialty and Nutritionals at Johnson & Johnson and President, Primary Care at Bristol Myers Squib
  - Garry Neil, M.D. - Partner at ATP and Head of Pharmaceutical Research and Development at ATC
    - Former Group President, Pharmaceutical R&D at Johnson & Johnson
  - Senior Management - Key personnel in commercial and operations areas with related expertise already engaged
- **Commitment to the Product**
  - High priority for Probuphine will be maintained
- **Right level of Resources**
  - Well funded organization with more than \$75 million allocated to Probuphine
- **Strong conviction that Probuphine will make a difference to the patients and the physicians**

## Titan: Adding Value Beyond Probuphine

- **ProNeura Technology Platform**
  - The ProNeura technology platform is applicable to other chronic treatments where clinical benefit is possible through:
    - Low dose around the clock drug administration
    - Stable blood level of medication
    - Sub-dermal drug delivery eliminating first-pass metabolic effects
  - Titan has an expert team in place with an established product development track record
  - Parkinson's Disease (PD)
    - Established non-clinical proof of concept with continuous dopamine agonist treatment in a PD model with funding from NIH grants
    - Assessment of product development path in progress
  - Evaluation of additional compounds in other disease settings underway

## Financial Summary

- **Equity (Dec 31, 2012)**

- Common Stock Outstanding 75.2 m
- Stock Options/ Restricted Stock 6.8 m
  - weighted-average exercise price of \$1.33 per share
- Warrants 12.8 m
  - exercise price range \$1.15 -\$2.13 per share

- **Cash Position (unaudited)**

- September 30, 2012
  - Cash \$ 5.1m
  - Debt \$ 12.1m
    - Principal \$10m + Present Value of Interest \$2.1m
- October 15, 2012
  - Proceeds from exercise of 4.6 million Series B warrants: \$3.9 million
- December 17, 2012
  - Probuphine licensing agreement - upfront payment: \$15.75 million

## Goals for 2013

- **Support NDA review, including possible advisory committee meeting, and obtain FDA approval to market Probuphine in the U.S. – PDUFA date April 30, 2013**
- **Support market launch of Probuphine in the U.S.**
- **Seek regulatory approval and commercialization partner in select countries where buprenorphine therapy is approved for treatment of opioid dependence**
- **Support ongoing development of Probuphine for additional indications and Phase IV commitments**
- **Apply for listing the Company's common stock on NASDAQ**
- **Capitalize on drug development expertise with additional products using ProNeura technology platform**
  - Parkinson's disease – establish product development program
  - Identify additional drug candidates for development
- **Maintain lean and capital efficient organization**



