

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): December 10, 2019

Titan Pharmaceuticals, Inc.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of incorporation)

001-13341

(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))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Securities registered pursuant to Section 12(b) of the Act:

<u>Title of each class</u>	<u>Trading Symbol(s)</u>	<u>Name of each exchange on which registered</u>
Common Stock, par value \$0.001	TTNP	Nasdaq Capital Market

Item 7.01. Regulation FD Disclosure.

Titan Pharmaceuticals, Inc. has updated its corporate presentation, which will be posted on its website and used for future presentations. A copy of the presentation 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 Statements 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: Chief Executive Officer and President

Dated: December 10, 2019



Titan Pharmaceuticals

Titan Corporate Presentation | December 2019



Company Confidential | Do Not Copy or Distribute | Copyright © Titan Pharmaceuticals 2019

Forward-Looking Statements

This presentation contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, or the Exchange Act. All statements other than statements of historical facts contained in this presentation, including statements regarding our strategy, future operations, future financial position, future revenue, projected costs, prospects, plans, objectives of management and expected market growth are forward-looking statements. These statements involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements.

The words "anticipate," "believe," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "should," "target," "will," "would" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words.

These forward-looking statements are only predictions and we may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, so you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. We have based these forward-looking statements largely on our current expectations and projections about future events and trends that we believe may affect our business, financial condition and operating results. We have included important factors in the cautionary statements included in this presentation, and in the documents we file with the Securities and Exchange Commission under the Securities Act and Exchange Act, particularly in the "Risk Factors" section, that could cause actual future results or events to differ materially from the forward-looking statements that we make. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments we may make.

The forward-looking statements included in this presentation represent our views as of the date of this presentation. We anticipate that subsequent events and developments will cause our views to change. However, while we may elect to update these forward-looking statements at some point in the future, we have no current intention of doing so except to the extent required by applicable law. You should, therefore, not rely on these forward-looking statements as representing our views as of any date subsequent to the date of this presentation.

This presentation contains estimates made, and other statistical data published, by independent parties and by us relating to market size and growth and other data about our industry. We obtained the industry and market data in this presentation from our own research as well as from industry and general publications, surveys and studies conducted by third parties. This data involves a number of assumptions and limitations and contains projections and estimates of the future performance of the industries in which we operate that are subject to a high degree of uncertainty. We caution you not to give undue weight to such projections, assumptions and estimates.

ProNeura is a trademark and Probuphine is a registered trademark of Titan Pharmaceuticals, Inc.

Sixmo-buprenorphine is a registered trademark of L. Molteni & C. dei F.lli Alitti Società di Esercizio S.p.A. ("Molteni")



Highlights

Innovative & Proprietary Drug Delivery Platform

Refocused Commercialization Strategy

Large & Growing Market Opportunity

Experienced Management Team

Titan's Proprietary Technology

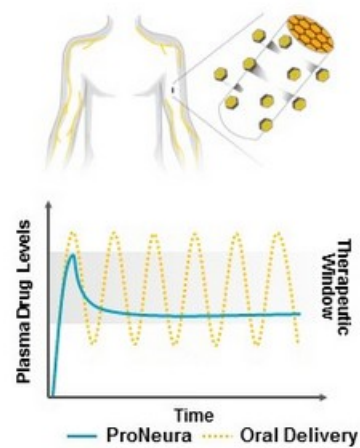
ProNeura™ Long-Term Drug Delivery Platform



Drug is released continuously into patient's body through diffusion controlled dissolution

- Provides continuous delivery of medication into the sub-dermal tissue avoiding daily peak and trough blood levels associated with once a day oral dosing
- Around-the-clock long-term treatment (potentially 3-12 months) in outpatient setting

Subdermal Administration



Transitioned to a Commercial-Stage Company

First Approved ProNeura-Based Product

Marketing Probuphine® (buprenorphine) implant for the maintenance treatment of Opioid Use Disorder (OUD) in clinically stable patients on 8 mg or less a day of oral buprenorphine



Probuphine Commercial Status

- Approved in U.S., Canada and Europe (EU brand name Sixmo®-buprenorphine)
- North American rights reacquired by Titan in mid 2018
 - Relaunched in the U.S. by Titan; marketed in Canada by Knight Therapeutics
- Rights to EU and other select territories acquired by Molteni Farmaceutici of Italy

Product Life Cycle Management

- Additional patent applications directed to the platform technology could potentially provide protection into early 2030s (issued method of use patents provide protection for Probuphine in U.S. and Europe* into 2024 and 2023, respectively)
- Related method of use patents for Probuphine have also been issued and/or filed in Australia, Canada, India, Japan, Mexico, New Zealand and Hong Kong

* European patent was acquired by Molteni in March 2018

Addiction To Opioids

Challenge & Opportunity

Buprenorphine is the gold standard in Medication Assisted Therapy (MAT)

\$2B

Approximate U.S. annual sales¹

Challenges with sublingual buprenorphine potentially addressed with Probuphine

- Poor compliance, diversion and abuse
- Variable levels of medication in blood
- Stigma associated with daily dosing

Treatment landscape is evolving

- Depot technologies influencing the market from daily to longer acting therapy²
- Probuphine can benefit from the changing emphasis to longer term therapeutic options

U.S. Opioid Overdose Deaths in 2017³

130 Each Day³

35% From Prescription Opioids⁴

10% More than in 2016⁵

6X As many as in 1999³

Sources:

1. <https://www.painnewsnetwork.org/stories/taq/buprenorphine>
2. Indivior Jefferies 2019 Global Healthcare Conference Presentation, June 4, 2019
3. <https://www.cdc.gov/drugoverdose/epidemic/index.html>
4. <https://www.cdc.gov/drugoverdose/data/prescribing.html>
5. <https://www.nytimes.com/2018/08/24/opinion/opioid-epidemic-states.html>

Market Opportunity

Unsatisfied Growing Market

Less Than
50%

of the patient population with
OUD is **medically treated**¹

Approximately
46,500

of physicians, representing **5% of
the nation's doctors**, are currently
certified to prescribe buprenorphine²

Approximately
6,000

physicians are writing
approximately **90% of
buprenorphine prescriptions**³

Approximately
1/2

of **U.S. counties** don't have a
single buprenorphine prescriber⁴

**Prescription Opioid Overdose, Misuse &
Dependence Costs the U.S. Over**

\$78B annually⁵

in **health care, criminal justice, and lost productivity costs**

Sources:

1. <https://www.ncbi.nlm.nih.gov/books/NBK534504/>
2. <https://www.medpagetoday.com/psychiatry/addictions/71169>
3. <https://www.cnn.com/2016/07/05/government-expands-access-to-drug-used-to-treat-opioid-abuse.html>
4. <https://www.nytimes.com/2018/06/23/health/opioid-addiction-suboxone-treatment.html>
5. <https://www.pewtrusts.org/en/research-and-analysis/fact-sheets/2017/02/the-case-for-medication-assisted-treatment>

Treatment Paradigm

PROBUPHINE is the first and only implant that provides continuous 6-month maintenance treatment of opioid use disorder in eligible patients¹

Frequency of buprenorphine dosing

6-MONTH IMPLANT (74.2 mg)



Buprenorphine
MONTHLY INJECTION



100 mg/0.5 mL and
300 mg/1.5 mg

Buprenorphine
DAILY SUBLINGUAL



2 mg/naloxone 0.5 mg,
4 mg/naloxone 1 mg, 8 mg/naloxone 2 mg,
and 12 mg/naloxone 3 mg

The World Health Organization has designated buprenorphine an essential medicine for the treatment of opioid use disorder²

WARNING: IMPLANT PROTRUSION, EXPULSION and NERVE DAMAGE ASSOCIATED WITH INSERTION and REMOVAL

- Insertion and removal of Probuphine are associated with the risk of implant migration, protrusion, expulsion, and nerve damage resulting from procedure
- Probuphine is only available through a restricted program called the Probuphine REMS Program
- For more information, see important safety information at www.probuphine.com

Sources:

1. Clinically stable patients on 8 mg or less a day of oral buprenorphine
2. World Health Organization: Model List of Essential Medicines 2019

ProNeura-Based Products & Product Candidates

Robust Addiction Pipeline

CANDIDATE	INDICATION	STAGE				
		PRECLINICAL	PHASE 1	PHASE 2	PHASE 3	MARKET
Probuphine (United States, Canada)	Opioid Use Disorder	[Progress bar spanning Preclinical, Phase 1, Phase 2, and Phase 3]				
Sixmo-buprenorphine (European Union)	Opioid Use Disorder	[Progress bar spanning Preclinical, Phase 1, and Phase 2]				
Nalmefene	Opioid Use Disorder	[Progress bar spanning Preclinical]				

Nalmefene implant

- Nalmefene is a full opioid antagonist in development for treatment of OUD by several companies (daily dosed formulations)
- Titan was awarded a grant of \$8.7 Million by National Institutes of Health (NIH – NIDA) for early stage development of long acting implant (target 6 months) for treatment of OUD¹

Additional ProNeura Programs outside of OUD

- **Malaria prophylaxis** (in collaboration with Walter Reed Army Institute of Research and Southwest Research Institute) non-clinical research funded by WRAIR²
- **Peripheral neuropathic pain** with a Kappa opioid receptor agonist in collaboration with JT Pharmaceuticals

Sources:

1. <https://www.titanpharm.com/news/press-releases/detail/200/titan-awarded-nida-grant-for-the-development-of-a-nalmefene>
2. <https://globalbiodefense.com/2018/05/13/wrair-malaria-implantable-sustained-release-medical-countermeasure/>



Probuphine U.S. Relaunch

Building a Strong Foundation for Growth



Probuphine Highlights

Potential Differentiators



6-month Implant

Administered as a 6-month implant, Probuphine does not require daily supervised use



Maintenance Schedule

May offer advantages for some people who have difficulties adhering to supervised daily pills (e.g. people with mobility problems, who are working, incarcerated or are attending school/college)



Lifestyle

May help remove the stigma and stress of daily dispensing, helping patients and their families maintain a standard lifestyle of employment, relationships and caretaking responsibilities



Continuous 24-hour Delivery

Probuphine delivers medication 24/7, maintaining stable blood levels after four weeks for the six month duration of treatment

Key Areas of Focus

Commenced Q4 2018

Commercial Infrastructure

- Chief Commercial Officer
- New commercial organization
- Small field sales force

Market Access

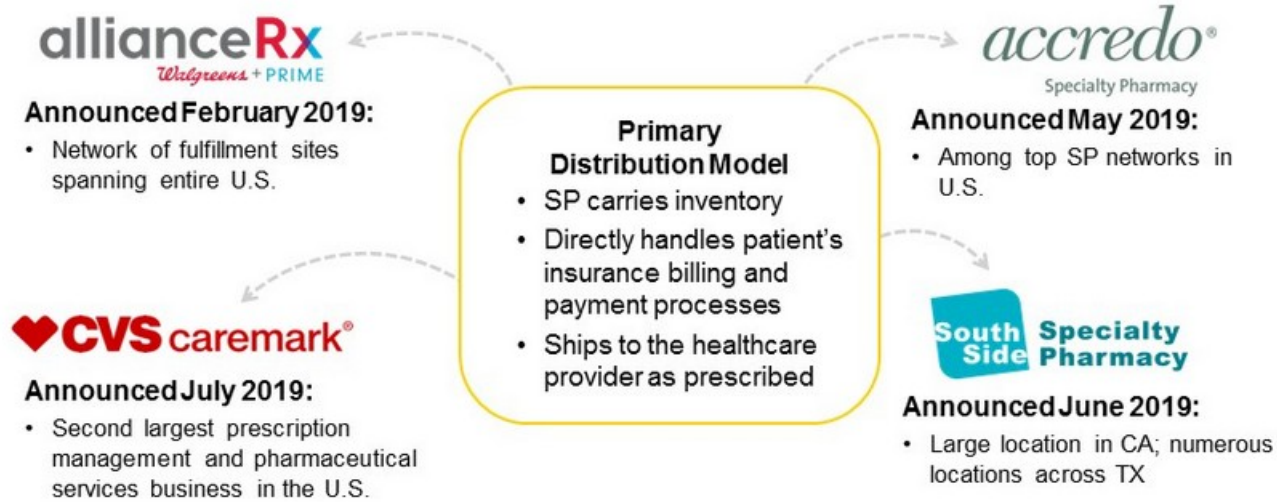
- Market segmentation
- Specialty pharmacy distribution network
- Patient services "hub"
- 3rd party payors

Medical Information

- Regulatory and compliance program
- Healthcare provider training
- Doctor and patient marketing

Key Specialty Pharmacies (SPs) Added to Network

National Coverage & Strong Relationships with 3rd Party Payors



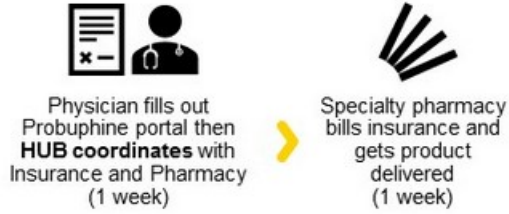
Streamlining the Distribution Process

Shortening the Time from Prescription to Product Delivery

Old Probuphine access process
(pre-May 2019)



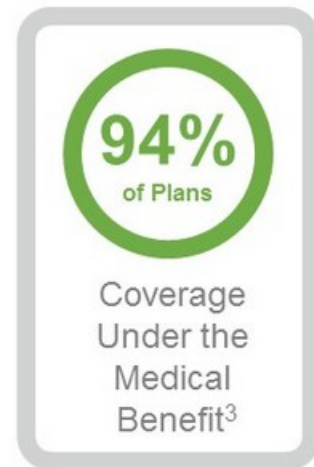
New Streamlined Probuphine access process
(post-May 2019)



3rd Party Payor Update

Gaining Market Access

- Established a Medicaid Drug Rebate Agreement
 - Probuphine added to Medicaid for rebate coverage
 - Medicaid paid for \$917 million of buprenorphine in 2018¹
 - Medicaid covers nearly 40% of adults with an OUD²
- Established Medicare Part B coverage with completion of Centers for Medicare & Medicaid Services Agreement
- Contracted: 340B pricing coverage with disproportionate share hospitals and outpatient clinics
 - Pricing has been submitted and loaded in the chargeback system for processing of any claims
- Contracted with the Medicare Part D Gap Coverage Discount Program
- Initiated process with Dept. of Veteran Affairs (VA) to establish a Federal Supply Schedule Agreement
- Submitted a supplemental rebate offer to the State of Tennessee



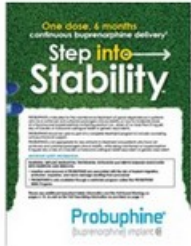
Sources:

1. <https://bipartisanpolicy.org/wp-content/uploads/2019/03/Tracking-Federal-Funding-to-Combat-the-Opioid-Crisis.pdf>
2. <https://www.rwf.org/en/library/research/2019/02/medicaid-s-role-in-fighting-the-opioid-epidemic.html>
3. Internal formulary data on file

Building on STEP INTO STABILITY

Expanding Demand with HCPs

Revised HCP Sales Aid



New In-office Demo



New HCP ePortal TitanProNet.com



New Formulary Access State Specific



New HCP Portal Registration Form



Next Stages of Commercialization



Sales Growth Initiatives

New initiatives:

- Expand reach and frequency with additional sales staff and/or co-promotional partnerships
- Actively pursuing and engaging with key decision makers at residential treatment centers, VA clinics and the federal/state prison systems

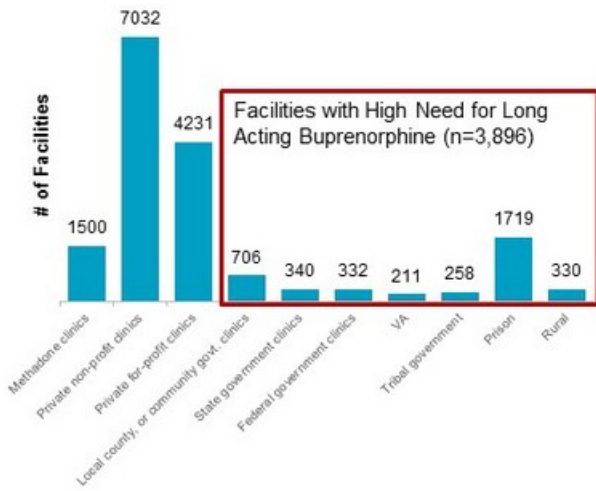
Ongoing initiatives:

- Continue identifying physicians with buprenorphine population under maintenance treatment
- Expand current active prescribers with additional training sessions and focused marketing
- Expand training to advanced practice providers (Nurse Practitioners and Physician Assistants)
- Continue to streamline specialty pharmacy distribution

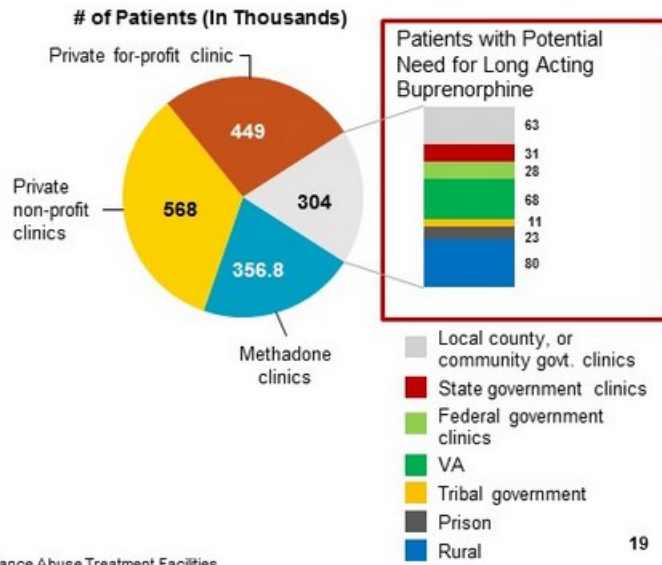
Patients and Treatment Settings

Probuphine Has Highest Potential Within Certain Settings

Total Facilities



Total Current Buprenorphine Patients

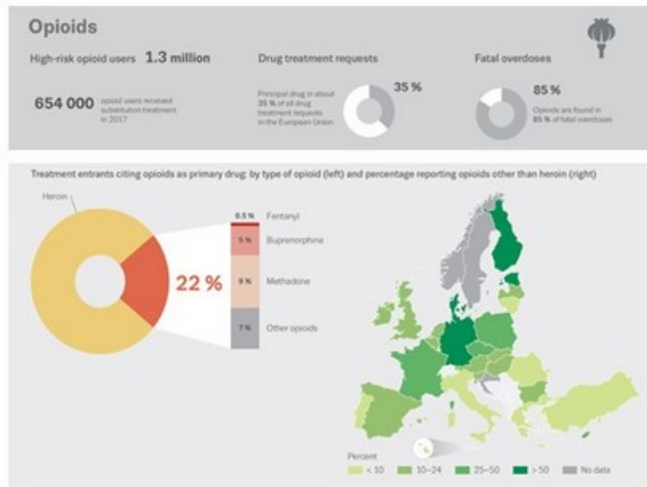


1. National Survey of Substance Abuse Treatment Services (N-SSATS): 2016 Data on Substance Abuse Treatment Facilities

Europe

A Significant Opportunity

- Molteni Farmaceutici of Italy acquired Probuphine EU intellectual property from Titan and will commercialize the product in the EU and certain other territories
- Sixmo (EU name for Probuphine) is the first and only six months substitution treatment for opioid dependence in clinically stable adult patients approved in the EU (MA issued on June 19, 2019)
- We believe Europe is the 2nd largest buprenorphine market in the world after the U.S. It is a growing segment and the launch of long term treatments is expected to expedite this trend¹
- The needs for an aging and increasingly vulnerable cohort of long-term opioid users continue to grow²
- An overall increase in drug-related deaths has been observed over the last 5 years²
- Diversion of daily administered methadone and buprenorphine is increasing in EU²
- Titan will receive double digit % earn-out payments on Molteni net sales in EU



Sources:

1. http://www.emcdda.europa.eu/system/files/publications/11364/20191724_TDAT19001ENN_PDF.pdf
2. Internal IMS data at Molteni

Probuphine Summary



Probuphine

Only product on market to provide six-month, continuous blood levels of buprenorphine for maintenance treatment of OUD in eligible patients



U.S. Commercialization

Probuphine relaunch showing early signs of positive proof of concept; next step = expand outreach



Partnerships

Established in EU and Canada; evaluate growth strategies and opportunities in the U.S.

- Evaluating co-promotion partners in key growth segments



EU Commercialization

Initial Probuphine product shipments to Molteni expected in early 2020

Experienced Management

Executive Team & Board of Directors



Marc Rubin, M.D.
Executive Chairman, Director



Sunil Bhonsle, M.B.A.
President & CEO, Director



Kate DeVarney, Ph.D.
Executive Vice President &
Chief Scientific Officer



Dane Hallberg
Executive Vice President &
Chief Commercial Officer



Joseph Akers
Director



David MacFarlane, Ph.D.
Director



James McNab, Jr.
Director



Scott Smith
Director



Rajinder Kumar, M.D.
Director



Federico Seghi Recli
Board Observer

Investment Highlights

Innovative & Proprietary Drug Delivery Platform

Refocused Commercialization Strategy

Large & Growing Market Opportunity

Experienced Management Team

Titan Pharmaceuticals

Titan Corporate Presentation | December 2019



Company Confidential | Do Not Copy or Distribute | Copyright © Titan Pharmaceuticals 2019