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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 13, 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.)

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**400 Oyster Point Blvd., Suite 505, South San Francisco, CA 94080**

(Address of principal executive offices and zip code)

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**650-244-4990**

(Registrant's telephone number including area code)

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(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.

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**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 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
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<a href="#"><u>99.1</u></a>	<a href="#"><u>Corporate Presentation</u></a>
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**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: February 13, 2019

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# Titan Pharmaceuticals

Titan Corporate Presentation | February 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 or incorporated by reference 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 Probuthine is a registered trademark of Titan Pharmaceuticals, Inc.



**A commercial-stage company marketing Probuphine® for the maintenance treatment of Opioid Use Disorder (OUD) in the U.S.**



**Probuphine** implant formulation of buprenorphine that was reacquired by Titan in mid 2018

- Approved in U.S. and Canada, under regulatory review in EU
- An important therapeutic option to fight the growing opioid addiction pandemic



**ProNeura™** platform technology that once implanted, provides continuous delivery, maintaining a stable blood level of selected drugs for the treatment of addiction and other disease categories

- Product Development Pipeline: OUD, Pain, Parkinson's disease, malaria, diabetes, thyroid disease

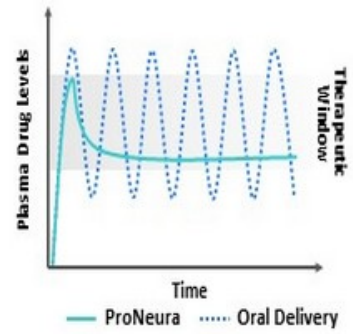
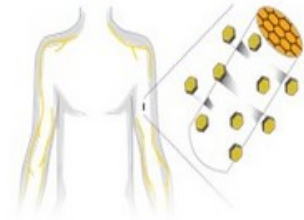
# ProNeura

## Long-Term Drug Delivery Platform



**Drug is released continuously into patient's body through dissolution**

### Subdermal Administration



\*API = Active pharmaceutical ingredient

# ProNeura-Based Products & Product Candidates

## Robust Pipeline

CANDIDATE	INDICATION	STAGE				
		PRECLINICAL	PHASE 1	PHASE 2	PHASE 3	MARKET
<b>Probuphine</b> (United States, Canada)	Opioid Use Disorder	[Progress bar: 100%]				
<b>Probuphine</b> (European Union)	Opioid Use Disorder	[Progress bar: ~85%]				
<b>Ropinirole Implant</b>	Parkinson's Disease	[Progress bar: ~40%]				
<b>Nalmefene</b>	Opioid Use Disorder	[Progress bar: ~20%]				

### Feasibility Programs

- **Malaria prophylaxis** (in collaboration with Walter Reed Army Institute of Research and Southwest Research Institute) non-clinical research funded by WRAIR
- **Type 2 diabetes** with currently approved peptides
- **Peripheral neuropathic pain** with a Kappa opioid receptor agonist in collaboration with JT Pharmaceuticals
- **Hypothyroidism** with triiodothyronine (T3)





## Probuphine (buprenorphine) Implant

### Indication

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PROBUPHINE is an implant that contains the medicine buprenorphine.

PROBUPHINE is indicated for the maintenance treatment of opioid dependence in patients who have achieved and sustained prolonged clinical stability on low-to-moderate doses (doses no more than 8 mg per day) of a transmucosal buprenorphine-containing product.

PROBUPHINE is part of a complete treatment program that also includes counseling and behavioral therapy.

*Please see Important Safety Information including the Full Prescribing Information and **Boxed Warning** regarding Implant Migration, Protrusion, Expulsion and Nerve Damage associated with Insertion and Removal*



# Probuphine

## A Novel Solution

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### Commercial Status:

- North American rights reacquired in mid 2018
- Canadian commercialization by Knight Therapeutics Inc.
- Rights to EU and other select territories acquired by Molteni Farmaceuticci
  - currently under review by the European Medicines Agency (EMA)

### Intellectual Property:

- Patent protection in U.S. and Europe\* into 2024 and 2023, respectively
- Related patents have also been issued 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 a  
First-Line Treatment  
in Medication  
Assisted Therapy  
(MAT)

**\$2B**

Approximate U.S.  
annual sales

## Challenges with sublingual buprenorphine

- Poor compliance, diversion and abuse<sup>1,2,3</sup>
- Variable levels of medication in blood<sup>4</sup>
- Stigma associated with daily dosing<sup>4</sup>

## Treatment landscape is evolving

- Indivior influencing the market from daily to longer-term therapy<sup>5</sup>
- Probuphine can benefit from the changing emphasis to longer term therapeutic options

## U.S. Opioid Overdose Deaths in 2017

**115** Each Day

**40%** From Prescription  
Opioids

**4X** As many as in 1999

28 States Have Limited Opioid Prescriptions



Source: Centers for Disease Control and Prevention, National Conference of State Legislatures, NEJM Catalyst (catalyst.nejm.org) © Massachusetts Medical Society

1. McLellan A et al., JAMA 2000;284(13): 1639-1695
2. Yokell M et al., Curr Drug Abuse Rev 2011;4(1):28-41
3. Sehgal et al., Pain Physician 2012;15:E667-92
4. Earnshaw V et al., Int J Ment Health Addict 2013;11(1): 110-122
5. Indivior Half Year Results 2018 presentation, July 25, 2018



# Market Opportunity

## Growing Unmet Medical Need

In the U.S.  
**50%**  
of the patient population  
with OUD is still **medically  
untreated**

About  
**52,000**  
of physicians, representing **5% of  
the nation's doctors**, are currently  
certified to prescribe buprenorphine

About  
**6,000**  
physicians are writing  
approximately **90% of  
buprenorphine prescriptions**

About  
**1/2**  
of U.S. counties don't have a  
single buprenorphine prescriber\*

Opioid overdoses costing U.S. hospitals an estimated

**\$11B** annually\*\*

\* New York Times, June 23, 2018

\*\* Analysis reported by Premier, Inc., posted on January 3, 2019

### Excerpt from *New York Times*, Editorial Board, August 24, 2018

*"In 2017, overdose deaths in the United States jumped 10% to about 72,000, the CDC said last week. The new data show that people are dying from opioids that are more potent and more dangerous than were available in years past. The CDC also found that many people who overdose are simultaneously using multiple drugs like heroin, fentanyl, cocaine, methamphetamines and benzodiazepine, an anti-anxiety medicine, and that the crisis has spread across the country, from rural and suburban areas to cities."*

## U.S. Regulatory Strategy

### Assess Potential For Label Expansion

#### New FDA guidance on MAT for opioid addiction\*

- Encourages development of longer-acting formulations
- Acknowledges the need for new drugs that don't end addiction, but help with aspects of it, such as cravings, or overdoses, with the goal remaining complete abstinence

#### Evaluate possible options for broadening the target population

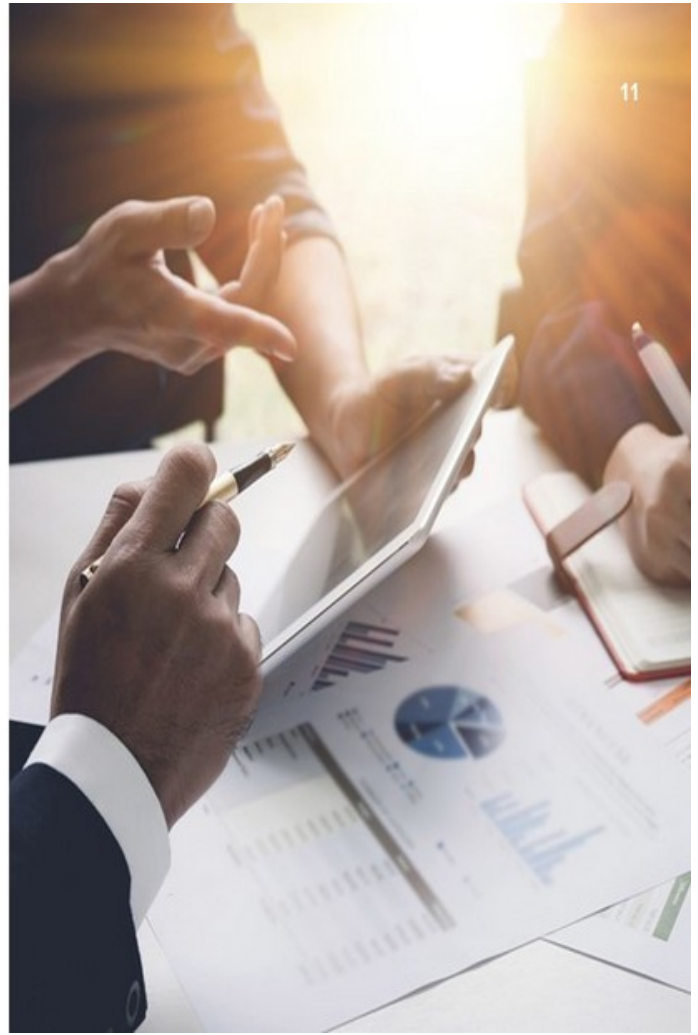
- More severe end of the OUD spectrum
- Use of Probuphine for long-term taper



\* Press announcement from FDA, April 20, 2018

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# Probuphine Relaunch

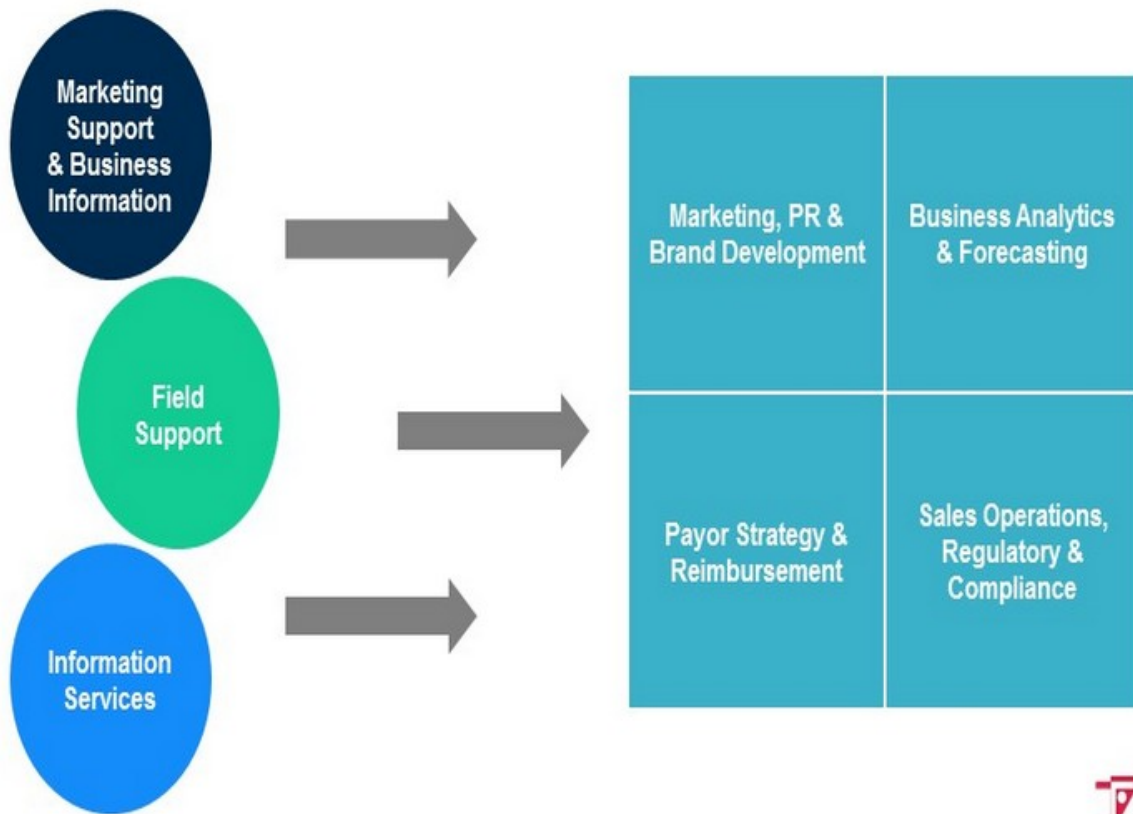


# Q4 2018 90-Day Transition Plan

Complete



# Transition To Commercial-Stage Company





## Titan Transformed

### Development-Stage To Commercial-Stage

#### Built a commercial infrastructure to support growth

- Established a small (~10 seasoned people) commercial and medical affairs team with expertise in:
  - Sales
  - Marketing and supply chain logistics
  - Medical science liaison and training functions
  - REMS program management
  - 3rd party payor and medical access

#### Simplifying system of distribution and reimbursement

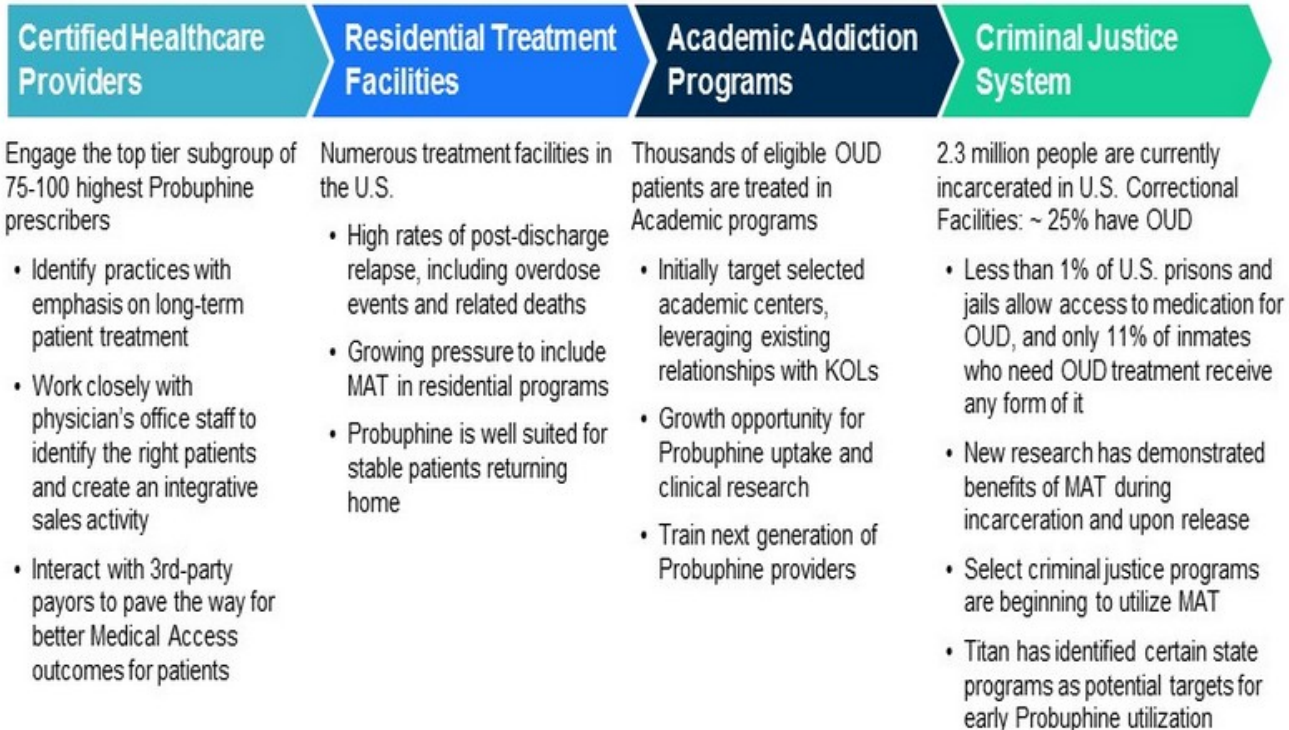
#### Focused market segmentation strategy

#### Ongoing assessment of synergistic partnerships for expanded market access

#### Transition of Probuphine from Braeburn to Titan is complete

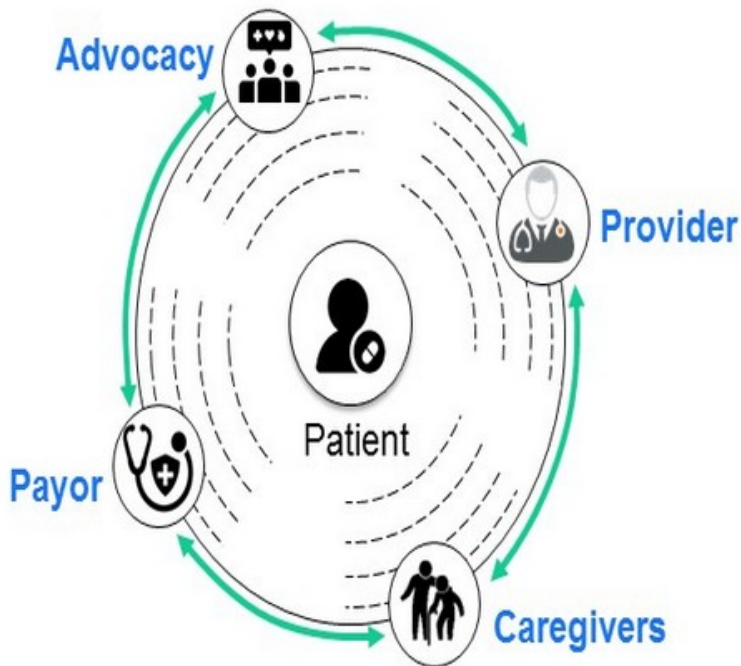
## A Focused Segmentation Strategy Across 4 Key Segments

### 4 KEY SEGMENTS



# Overview Of Key Activities

## Customer Feedback Mechanism – Full PR Program



- Introduced Titan and Probuphine to select payor customers
- Conducted a payor advisory board with large plans, PBMs and select IDNs
- Implement lobbying strategy at Federal & State levels



## Early Signs Of Success

### Probuphine Shipments

- Highly Focused Market Segmentation & Strategy
- Integrative Selling Initiative Showing Positive Impact
- Core Messaging Resonating with the Right Clinicians and Patient Population

**Double-digit increase in Probuphine shipments following assumption of sales responsibilities\***



\*Titan press release Jan 31, 2019



## In Summary

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### ProNeura

Unique and compelling long-term drug delivery platform



### U.S. Commercialization

Probuphine relaunch in early stages showing meaningful growth



### Probuphine

Only product on market to provide six-month, continuous, non-fluctuating blood levels of buprenorphine by Week 4 for maintenance treatment of OUD



### Development Pipeline

ProNeura product candidates for OUD (nalmeffene), Parkinson's disease (ropinirole), malaria prophylaxis (collaboration with Walter Reed Institute), and more



### Partnerships

Established partnerships for Probuphine in Europe and Canada

# Titan Pharmaceuticals

Titan Corporate Presentation | February 2019

