

## Titan Pharmaceuticals, Inc. (TTNP-NASDAQ)

### New CCO Implementing Targeted Strategy

Based on our DCF model and a 15% discount rate, TTNP is valued at approximately \$3.00 per share based on contributions from Probuphine and ropinirole in the US/EU. We currently do not include any contribution from the triiodothyronine or other in-development programs. Valuation for pre-clinical programs will be added upon commencement of clinical trials.

Current Price (11/16/18) **\$0.39**  
Valuation **\$3.00**

### OUTLOOK

Titan Pharmaceuticals first launched its product, Probuphine, with a partner; however, due to poor sales Titan will now commercialize the implant with internal resources. The company is obtaining approval in Europe and has obtained approval in Canada, partnering to commercialize Probuphine in these and other regions.

Ropinirole is in clinical trials and several other candidates are about to enter the clinical phase of the development pipeline. All products use Titan's proprietary ProNeura drug delivery system. Consisting of ethylene-vinyl acetate and a drug substance, ProNeura is a novel approach to drug delivery that benefits from long-duration slow release and has characteristics beneficial to controlled substance programs.

Titan's development products include a treatment for Parkinson's Disease (ropinirole) and hypothyroidism (T3). The company is also working on a variety of other implants both in-house and with partners.

### SUMMARY DATA

52-Week High **\$1.75**  
52-Week Low **\$0.17**  
One-Year Return (%) **-77.7**  
Beta **-0.66**  
Average Daily Volume (sh) **9,104,234**

Shares Outstanding (mil) **78.0**  
Market Capitalization (\$mil) **\$30.4**  
Short Interest Ratio (days) **0.48**  
Institutional Ownership (%) **5.7**  
Insider Ownership (%) **4.3**

Annual Cash Dividend **\$0.00**  
Dividend Yield (%) **0.0**

#### 5-Yr. Historical Growth Rates

Sales (%) **N/A**  
Earnings Per Share (%) **N/A**  
Dividend (%) **N/A**

P/E using TTM EPS **N/A**  
P/E using 2018 Estimate **N/A**  
P/E using 2019 Estimate **N/A**

Zacks Rank **N/A**

Risk Level **Above Average**  
Type of Stock **Small-Growth**  
Industry **Med-Biomed/Gene**

### ZACKS ESTIMATES

#### Revenue (in millions of \$)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2017	\$0.0 A	\$0.1 A	\$0.0 A	\$0.1 A	\$0.2 A
2018	\$1.1 A	\$2.7 A	\$1.7 A	\$0.4 E	\$5.8 E
2019					\$2.1 E
2020					\$12.0 E

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2017	-\$0.14 A	-\$0.16 A	-\$0.20 A	-\$0.17 A	-\$0.68 A
2018	-\$0.12 A	-\$0.04 A	-\$0.11 A	-\$0.06 E	-\$0.33 E
2019					-\$0.17 E
2020					-\$0.02 E

## WHAT'S NEW

### **Third Quarter 2018 Financial and Operational Results**

Titan Pharmaceuticals, Inc. (NASDAQ: TTNP) reported third quarter 2018 results on November 14<sup>th</sup> in a [press release](#) and in a subsequently filed [10-Q](#). During the period, Titan recorded total revenues of \$1.7 million compared to \$40 thousand in 3Q:17. This 3Q:18 total consisted of \$1.4 million of license revenue and \$244,000 in product sales of Probuphine by Titan.

The \$244,000 in Titan-generated Probuphine sales compares to 2Q:18's \$75,000, which was for a partial period. If the partial period rate was grossed up for the full quarter, pro forma second quarter sales would have been ~\$190,000, representing a sequential increase in the sales rate.

Total expenses of \$3.6 million include \$178,000 in cost of goods sold, \$1.9 million of R&D and \$1.5 million of G&A. R&D costs fell 30% while G&A rose 8%. Lower R&D was attributable to decrease in external R&D efforts for ropinirole, while higher G&A stemmed from greater legal and professional fees.

Cash and equivalents as of September 30, 2018 were \$8.4 million, compared to \$7.5 million at the end of 2017. Debt was carried at \$4.1 million. Subsequent to the end of the quarter, Titan raised an additional \$4.5 million after the end of the quarter from the exercise of the overallotment option and the exercise of warrants. Cash burn was (\$2.3) million in 3Q:18 compared to (\$2.5) million in 3Q:17. The company anticipates sufficient cash to fund the company until the third quarter of 2019.

### **Addition of Chief Commercial Officer**

Titan [announced](#) on October 2 the addition of Dane D. Hallberg as Chief Commercial Officer for Titan, who will be responsible for all of the company's commercial activities. Mr. Hallberg had been working as a consultant with the company prior to his addition to the leadership team and has experience commercializing other implants, which includes Merck's Implanon subdermal contraceptive. His background also includes leadership positions at Able Star, Sunovion Pharmaceuticals, Dendrite Japan and Tierra Incorporated. His experience will be critical as Titan launches Probuphine into its four identified market segments.

### **Public Offering**

Titan has outlined a strategy to build a small sales and marketing team to commercialize Probuphine as a specialty product. This objective will require additional capital to hire, train and dispatch sales representatives into the targeted markets. To achieve this objective, Titan [raised](#) \$9.5 million from the issuance of 5.1 million shares of common stock, convertible preferred stock and warrants. The estimated proceeds from the issuance are expected to be sufficient to fund the internal commercialization efforts for Probuphine and the FDA-required Phase IV studies<sup>1</sup> through 2019.

### **Marketing Strategy**

Titan has outlined its internal marketing strategy after the return of rights to commercialize Probuphine in the United States. The company has completed the process of transitioning all of the Probuphine commercialization activities from Braeburn to Titan, including supply chain, logistics, medical affairs, REMS, training and reporting. Titan will pursue a targeted strategy that will employ a small 10-person commercial team that will target four market segments:

- High Probuphine-prescribing physicians with long term recovery oriented treatment programs.
  - Contact information already in database
  - Establish centers of excellence to generate referrals
  - Focus on reduction of complexity for supply chain and reimbursement
  - 90% of buprenorphine certified providers written by 6,000 providers<sup>2</sup>

<sup>1</sup> As a condition of the marketing approval for Probuphine, the FDA required postapproval Phase IV clinical trials to assess potential safety risks associated with the insertion and removal of Probuphine, potential prolongation of the QT interval and to assess the potential for repeat administration of Probuphine into the same insertion site or insertion into an alternate site.

<sup>2</sup> Management cited numbers

- Residential treatment facilities
  - Establish partnership with a few large programs
- Academic institutions with addiction treatment and training programs
  - Providers are trained in the use of this class of therapy
  - Introduce Probuphine to next generation of providers
  - Develop KOLs who can disseminate the benefits of the therapy more widely
  - Generate additional investigator sponsored studies
- Criminal justice system
  - Provide help to high recidivism population
  - Initial focus on a few key programs with success to drive wider adoption
  - Almost 60 million incarcerated suffer from opioid use disorder<sup>3</sup>



Since the release of the quarterly report, Titan has updated shareholders on their commercialization initiatives with a [collaboration](#) with the Nevada Center for Behavioral Health. This collaboration will evaluate the use of Probuphine to treat opioid use disorder (OUD) patients in the Nevada criminal justice system. It is a pilot program and includes the training and certification of seven health care providers regarding the Probuphine Risk Evaluation and Mitigation Strategy (REMS). A grant related to the 21<sup>st</sup> Century Cures Act was provided from state and federal authorities to fund the work. The incarcerated market for OUD in the United States is large. Titan statistics estimate that about a quarter of the 2.3 million confined persons in the U.S. suffer from OUD; however, less than 1% are given access to medications for it. The hesitation to use the opioid-based treatments is due to concerns over diversion, which does occur with sublingual formulations. Given Probuphine’s ability to avoid diversion, it is a particularly attractive alternative in this setting. The focus on this population is supported by a [study](#) in Rhode Island that showed a 61% decrease in post-incarceration deaths and a 12% reduction in statewide overdose deaths a year following the implementation of a treatment program for incarcerated addicts. We expect that success in each of the targeted areas will lead to wider adoption over time.

**Exhibit II – Titan Pipeline**

CANDIDATE	INDICATION	STAGE				
Probuphine (United States)	Opioid Use Disorder	PRECLINICAL	PHASE 1	PHASE 2	PHASE 3	MARKET
Probuphine (European Union)	Opioid Use Disorder	PRECLINICAL	PHASE 1	PHASE 2	PHASE 3	MARKET
Ropinirole Implant	Parkinson’s Disease	PRECLINICAL	PHASE 1	PHASE 2	PHASE 3	MARKET

<sup>3</sup> Management cited numbers

## **Nevada Center for Behavioral Health**

In early September, Titan initiated a pilot program with the Nevada Center for Behavioral Health to use Probuphine to treat opioid use disorder. The goal of the program is to reduce recidivism for individuals in the criminal justice system. The pilot program was put in place in order to establish treatment and design a broader program for the incarcerated and paroled population. Titan's experience here can be helpful for expanding their reach into other states. About 25% of individuals in the criminal justice system have opioid use disorder and it is largely untreated.

## **Phase IV Probuphine Studies**

Titan will initiate two Phase IV post-marketing studies next year. The first will be a small study costing approximately \$3 to \$4 million and last for two to three years. A second, observational study is still in development, but is expected to last approximately four years and will cost approximately twice the initial study. Trial design is still in process.

## **NASDAQ Notices**

On April 9, 2018 the Nasdaq notified Titan that they were not in compliance with exchange listing requirements as they did not maintain minimum stockholders' equity requirements. In response, the company submitted a plan of compliance and was granted an extension to October 8, 2018. On August 15, 2018, Titan received a notification that shares were not in compliance with minimum bid requirements and that they must regain compliance by February 11, 2019.

## **Knight Therapeutics**

Knight launched Probuphine in the fourth quarter and is focused on commercializing the product in rural Canadian areas for patients without ready access to a physician. The company's [press release](#) in late October highlighted Health Canada's approval of the implant earlier in the year, Knight's exclusive right to distribute the drug and their launch of the product.

## **Capital Raise**

In October the company sold 5.7 million shares at \$0.24 per share which included attached warrants. The company also issued Class B units which were converted into 32.9 million shares of stock. The net impact of these issuances raised approximately \$13 million and increased share count to 78.0 million shares as of November 9<sup>th</sup> from 21.2 million shares on August 10<sup>th</sup> 2018. 30.6 million warrants with an exercise price of \$0.25 remain outstanding as of November 9<sup>th</sup> 2018.

## **Valuation**

We update our valuation to reflect the new outstanding share count and the shift to internally generated sales in the United States, from the royalty arrangement that was negotiated with Braeburn. We also advance our discounted cash flow (DCF) model ahead by one year. The more focused end markets will reduce our anticipated revenues as compared to our prior estimates; however, Titan will maintain a higher percentage of sales generated. We anticipate contributions from both Canada and Europe and total product and royalty revenues of \$2.1 million in 2019. The precipitous drop in our target price is entirely due to the substantial increase in shares from approximately 21 million to 78 million, which were a result of the capital raise and warrant issuance. Based on our cash flow estimates and discounted cash flow model our target price for Titan Pharmaceuticals is \$3.00 per share.

## **Pipeline and Marketed Products**

- Probuphine North America
  - Titan and Braeburn completed return of commercialization rights
  - New targeted plan for commercialization
- Probuphine Europe
  - November 6, 2017 filing of MAA
  - Addressing questions from the EMA with response submission expected in Fall 2018
  - Notice of Allowance from European Patent office for methods of use providing protection until 2023
- Ropinirole
  - First patient treated early October 2017
  - Independent Data Safety Monitoring Board to review initial data June 2018
  - Program on hold until additional capital available
- Triiodothyronine (T3)
  - Completing non-clinical evaluation of its re-formulated implant
  - Pre-IND review with the FDA anticipated
- New Candidates being evaluated for ProNeura
  - Opioid antagonist collaboration with Opiant Pharmaceuticals
    - Prevention of opioid relapse and overdose in individuals with opioid use disorder
    - Targeting completion of feasibility assessment in 1H:18
  - Tenofovir and emtricitabine for pre-exposure prophylaxis against HIV acquisition
  - Anti-malarial agents
    - Entered into Cooperative Research and Development Agreement with Reed Army Institute of Research (WRAIR) and Southwest Research Institute (SwRI)
    - Walter Reed pursuing funding opportunities for the program
  - κ-opioid receptor as non-opioid analgesic for chronic pain
  - Liraglutide for Type 2 diabetes
  - Liothyronine (LT3) for treatment of hypothyroidism
  - Oxytocin for autism spectrum disorder

## **Summary**

Despite the dilution as a result of the September and October capital raise, operational momentum is improving for Titan. The rate of internal sales increased sequentially and new initiatives such as the Nevada correctional project are anticipated to drive continued sequential increases in revenues. Other contributions from Europe and Canada are expected in 2019. While cash flow breakeven remains several quarters into the future, we anticipate that when capital is available, other development programs will be advanced.

We are optimistic that early success with the Nevada Center for Behavioral Health is a prelude for additional collaborations. Titan's strategy of hiring a small salesforce and targeting high impact channels appears to be capital efficient and also may ease some of the difficulties suffered by Braeburn, such as REMS compliance and reimbursement difficulties. While our enterprise valuation of the company actually increases due to the roll forward of our DCF model, our per share valuation declines due to the increase in share count resulting from the capital raise. As a result we reduce our valuation to \$3.00 share.

## PROJECTED FINANCIALS

### Titan Pharmaceuticals, Inc. - Income Statement

Titan Pharmaceuticals, Inc.	2017 A	Q1 A	Q2 A	Q3 A	Q4 E	2018 E	2019 E	2020 E
<b>Total Revenues</b>	<b>\$0.2</b>	<b>\$1.1</b>	<b>\$2.7</b>	<b>\$1.7</b>	<b>\$0.4</b>	<b>\$5.8</b>	<b>\$2.1</b>	<b>\$12.0</b>
<i>YOY Growth</i>	-98.6%	2560.0%	3364.9%	4025.0%	589.7%	2589.3%	-63.0%	461.0%
Cost of Goods Sold	\$0.0	\$0.0	\$0.1	\$0.2	\$0.1	\$0.3	\$0.0	\$0.0
R&D	\$9.6	\$1.9	\$1.9	\$1.9	\$2.3	\$7.9	\$9.0	\$7.2
SG&A	\$5.1	\$1.6	\$1.4	\$1.5	\$1.7	\$6.2	\$6.8	\$6.8
<b>Operating Income</b>	<b>(\$14.5)</b>	<b>(\$2.4)</b>	<b>(\$0.6)</b>	<b>(\$2.0)</b>	<b>(\$3.7)</b>	<b>(\$8.7)</b>	<b>(\$13.7)</b>	<b>(\$2.0)</b>
<i>Operating Margin</i>	-6745.1%	-	-	-	-	-149.7%	-638.7%	-16.7%
Total Other Income	\$0.2	(\$0.2)	(\$0.2)	(\$0.4)	\$0.0	(\$0.8)	\$0.0	\$0.0
<b>Pre-Tax Income</b>	<b>(\$14.3)</b>	<b>(\$2.6)</b>	<b>(\$0.9)</b>	<b>(\$2.3)</b>	<b>(\$3.7)</b>	<b>(\$9.5)</b>	<b>(\$13.7)</b>	<b>(\$2.0)</b>
Taxes & Other	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
<i>Tax Rate</i>	0%	0%	0%	0%	0%	0%	0%	0%
<b>Net Income</b>	<b>(\$14.3)</b>	<b>(\$2.6)</b>	<b>(\$0.9)</b>	<b>(\$2.3)</b>	<b>(\$3.7)</b>	<b>(\$9.5)</b>	<b>(\$13.7)</b>	<b>(\$2.0)</b>
<i>Net Margin</i>	-	-	-	-	-	-	-	-
<b>Reported EPS</b>	<b>(\$0.67)</b>	<b>(\$0.12)</b>	<b>(\$0.04)</b>	<b>(\$0.11)</b>	<b>(\$0.07)</b>	<b>(\$0.33)</b>	<b>(\$0.17)</b>	<b>(\$0.02)</b>
<i>YOY Growth</i>	-382.0%	-12.6%	-74.8%	-46.2%	-57.6%	-50.9%	-48.1%	-86.1%
Weight Ave. Shares Out	21.2	21.2	21.2	21.9	50.0	28.6	79.5	84.0

Source: Company Filing // Zacks Investment Research, Inc. Estimates

# HISTORICAL STOCK PRICE

Titan Pharmaceuticals, Inc. – Share Price Chart



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