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John D. Vandermosten, CFA
312-265-9588 / jvandermosten@zacks.com

scr.zacks.com 10 S. Riverside Plaza, Chicago, IL 60606

Titan Pharmaceuticals, Inc. (TTNP-NASDAQ)

EMA Approval of Probuphine Expected 2Q:19

Based on our DCF model and a 15% discount rate, TTNP is valued at approximately $16.00 per share based on contributions from Probuphine in the US/EU and Canada. We do not include contribution from other in-development programs.

Current Price (4/2/19)	$1.75
Valuation	**$16.00**

OUTLOOK

Titan Pharmaceuticals is commercializing Probuphine with a four pronged strategy in the US and with partners in Canada and the European and contiguous region. Approval has been secured in the US and Canada. European approval is expected in 2Q:19.

Titan has received a two year grant to develop nalmefene using ProNeura for opioid relapse and overdose and may receive additional grants if milestones are met. The company has other projects in clinical and preclinical development that will advance based on the availability of funding. 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 conducive to settings that require long-duration slow release and controlled substance programs.

SUMMARY DATA

52-Week High	**$2.45**
52-Week Low	**$0.17**
One-Year Return (%)	**-70.8**
Beta	**-0.29**
Average Daily Volume (sh)	**1,624,788**
Shares Outstanding (mil)	**13.4**
Market Capitalization ($mil)	**$23.5**
Short Interest Ratio (days)	**0.78**
Institutional Ownership (%)	**5.2**
Insider Ownership (%)	**4.5**
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	$1.2 A	$6.6 A
2019					$6.6 E
2020					$13.9 E

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2017	-$0.84 A	-$0.98 A	-$1.19 A	-$1.04 A	-$4.05 A
2018	-$0.74 A	-$0.25 A	-$0.64 A	-$0.29 A	-$1.64 A
2019					-$0.59 E
2020					-$0.09 E

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WHAT'S NEW

Full Year 2018 Financial and Operational Results

Titan Pharmaceuticals, Inc. (NASDAQ: TTNP) reported full year 2018 results in an April 1st press release and in a subsequently filed 10-K. During the year, Titan recorded total revenues of $6.6 million compared to $0.2 million in 2017. Net loss of ($9.3) million or ($1.64) per share compared to prior year net loss of ($14.3) million and ($4.05) per share.[1] Highlights for 2018 include the return of the Probuphine license from Braeburn, an asset purchase and license agreement with Molteni for Eurasiafrica,[2] the approval and launch of Probuphine in Canada by Knight and the launch of the internal sales strategy for Probuphine.

Total 2018 revenues of $6.6 million were comprised of $5.4 million of license revenue and $535,000 in product sales of Probuphine and $707,000 of grant revenue. License revenue was comprised of $2.1 million related to Molteni's acquisition of European intellectual property rights, $1.1 million related to the purchase agreement with Molteni, $2.1 million related to the termination of the Braeburn license and $32,000 related to the recognition of royalties earned on Probuphine sales. Grant revenue was related to the National Institute on Drug Abuse (NIDA) nalmefene implant project.

Cost of goods sold was $538,000, essentially equal to product revenues, yielding a -0.6% gross margin. Cost of goods sold includes both the product cost, which is less than 10% of price and distribution cost, which is relatively fixed in dollar terms. Operating expenses were $14.3 million which consists of $7.5 million in research and development costs and $6.9 million in selling, general and administrative expenses. The 22% decline in R&D expenses was attributable to a pullback in the Ropinirole program and cycling higher marketing authorization expenses in the prior year. SG&A expenses rose 35% due to greater commercial activities for Probuphine, higher employee related costs and legal fees.

Cash and equivalents as of December 31, 2018 were $9.3 million, compared to $7.5 million at the end of 2017. Debt was carried at $4.3 million. During the year, Titan raised $13 million from sale of stock and warrants and exercise of warrants. Cash burn was ($8.8) million in 2018 compared to ($13.2) million in 2017. The company anticipates that year-end cash plus an additional $0.6 million from warrant exercises after year-end are sufficient to fund the company until the third quarter of 2019.

Exhibit I – Titan Pipeline



Partners

In the first quarter of 2019 Titan announced partnerships with AllianceRx Walgreens Prime and AppianRx to provide distribution and patient support services. These relationships are expected to shorten the time between product order and delivery. Specialty pharmacy relationships with payors, a streamlined benefits authorization process, and holding inventory on-site are changes expected to accelerate the process of delivering Probuphine to physicians and providing timely reimbursement. AllianceRx will carry inventory, manage insurance billing, offer payment processing and ship Probuphine to the provider. AppianRx will manage benefit verification, prior authorization, appeals and co-pay/patient assistance, which should reduce time from prescription to payment. We anticipate that Titan will continue to develop additional specialty pharmacy relationships to improve penetration.

[1] Note that per share amounts are adjusted for the 1:6 reverse stock split that occurred on January 24, 2019.
[2] The Molteni Territory includes Europe, certain countries of the Commonwealth of Independent States, the Middle East and North Africa. Eurasiafrica is not a real word.

Marketing Strategy

Titan outlined its internal marketing strategy after the return of Probuphine rights. The company has completed the transition process, including supply chain, logistics, medical affairs, REMS, training and reporting. Titan will pursue a targeted strategy with a 10-person commercial team targeting 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
- Residential treatment facilities and Veteran's Administration Hospitals
  - Establish partnership with a few large programs
  - Train staff at VA hospitals
- Academic institutions with addiction treatment and training programs
  - Providers are trained in the use of this class of therapy
  - Over 40 nurse practitioners received training at Drexel University
  - 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

Veteran's Administration

The Veteran's Administration (VA) was recently added to the target groups in the marketing strategy. Titan has held discussions with the VA to make the case for Probuphine and to begin REMS training. A contract is in place with the agency and there will be additional discussions to set up training for VA providers so that they will be able to order the product.

Phase IV Probuphine Studies

Titan will initiate two Phase IV post-marketing studies this year. The first will be a small study estimated to cost from $3 to $4 million and will last for two to three years. It is slated to begin in the second quarter of 2019 and will evaluate the safety and pharmacokinetics of re-implantation of Probuphine into a previously used site on a patient's inner upper arm as well as implantation into an alternate location in the lower abdomen. A second, observational study is still in development and will start in the second half of the year. Trial cost for the second study is estimated to be around $8 million and will last for four years. It will assess implant procedure safety in an observational cohort design and is still being finalized.

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 to address it 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. On January 24th, 2019 Titan effected a 1:6 stock split which brought the company back into compliance. We have adjusted historical share balances to reflect this change.

Knight Therapeutics

Canadian partner Knight launched Probuphine in October 2018 and is focused on commercializing the product in rural Canadian areas for patients without ready access to a physician. The company's press release 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. Titan has received product and royalty revenues from the relationship.

Nalmefene

Beginning in October 2017, Titan conducted a feasibility assessment with Opiant to develop a product for prevention of opioid relapse and overdose in individuals with opioid use disorder (OUD). In September of 2018, Titan secured a grant from the National Institute for Drug Addiction (NIDA) to further this research using a ProNeura based six-month implantation formulation of nalmefene. The grant will provide $2.67 million during the first year and $6.08 million in the second year. The goal during the first two years is to complete IND-enabling work. Fund matching requirements exist and equal $1.33 million in year one, but are absent in year two. There are an additional three years of funding that may be accessed if certain milestones are achieved.

Valuation

We update our valuation to reflect the new outstanding share count and the impact of the reverse stock split. Based on our cash flow estimates and discounted cash flow model our target price for Titan Pharmaceuticals is approximately $16.00 per share.

Summary

Titan is putting the necessary infrastructure in place for long term success and implementing its four pronged growth strategy. Many near term revenue catalysts exist including a ramp up from Canadian sales in 1H:19 and MAA approval in Europe in 2Q:19. Internal efforts are also yielding sales and we anticipate sequential improvements in product revenue each quarter in 2019. Relationships with dominant specialty pharmacies are expected to shorten the time between order and delivery and also simplify the payor approval and REMS processes. While cash flow breakeven remains several quarters into the future, we anticipate that when capital is available, other development programs will be advanced. Our target price is approximately $16.00 per share.

PROJECTED FINANCIALS

Titan Pharmaceuticals, Inc. - Income Statement

Titan Pharmaceuticals, Inc.	2017 A	Q1 A	Q2 A	Q3 A	Q4 A	2018 A	2019 E	2020 E
Total Revenues	**$0.2**	**$1.1**	**$2.7**	**$1.7**	**$1.2**	**$6.6**	**$6.6**	**$13.9**
YOY Growth	*-98.6%*	*2560.0%*	*3364.9%*	*4025.0%*	*2032.8%*	*2978.6%*	*-0.3%*	*110.6%*
Cost of Goods Sold	$0.0	$0.0	$0.1	$0.2	$0.3	$0.538	$1.8	$2.2
Product Gross Margin	*100.0%*	*100.0%*	*6.7%*	*27.0%*	*-33.6%*	*-0.6%*	*29.2%*	*68.6%*
R&D	$9.6	$1.9	$1.9	$1.9	$1.9	$7.5	$9.8	$7.2
SG&A	$5.1	$1.6	$1.4	$1.5	$2.4	$6.9	$6.6	$6.8
Operating Income	($14.5)	($2.4)	($0.6)	($2.0)	($3.3)	($8.3)	($11.6)	($2.3)
Operating Margin	*-6745.1%*	-	-	-	-	*-124.9%*	*-175.3%*	*-16.5%*
Total Other Income	$0.2	($0.2)	($0.2)	($0.4)	($0.2)	($1.0)	$0.0	$0.0
Pre-Tax Income	($14.3)	($2.6)	($0.9)	($2.3)	($3.5)	($9.3)	($11.6)	($2.3)
Taxes & Other	$0	$0	$0	$0	$0	$0	$0	$0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	($14.3)	($2.6)	($0.9)	($2.3)	($3.5)	($9.3)	($11.6)	($2.3)
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($4.05)**	**($0.74)**	**($0.25)**	**($0.64)**	**($0.29)**	**($1.64)**	**($0.59)**	**($0.09)**
YOY Growth	*-1791.9%*	*-12.6%*	*-74.8%*	*-46.2%*	*-71.7%*	*-59.6%*	*-63.6%*	*-85.1%*
Weight Ave. Shares Out	3.5	3.5	3.5	3.7	12.0	5.7	19.5	26.0

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

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HISTORICAL STOCK PRICE

Titan Pharmaceuticals, Inc. – Share Price Chart



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