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Titan Pharmaceuticals, Inc. (TTNP-NASDAQ)

Waiting for Revenue Turn

Based on our DCF model and a 15% discount rate, TTNP is valued at approximately $1.00 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 (11/15/19)	$0.16
Valuation	**$1.00**

OUTLOOK

Titan Pharmaceuticals is commercializing Probuphine with a multi-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. First European sales are expected in 1Q:20.

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 it 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	**$2.46**
52-Week Low	**$0.15**
One-Year Return (%)	**-93.3**
Beta	**1.15**
Average Daily Volume (sh)	**4,165,777**
Shares Outstanding (mil)	**55.5**
Market Capitalization ($mil)	**$8.9**
Short Interest Ratio (days)	**2.4**
Institutional Ownership (%)	**5.0**
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)
2018	$1.1 A	$2.7 A	$1.7 A	$1.2 A	$6.6 A
2019	$0.9 A	$0.5 A	$0.9 A	$1.4 E	$3.8 E
2020					$7.7 E
2021					$6.0 E

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2018	-$0.74 A	-$0.25 A	-$0.64 A	-$0.29 A	-$1.64 A
2019	-$0.34 A	-$0.38 A	-$0.18 A	-$0.08 E	-$0.72 E
2020					-$0.18 E
2021					-$0.30 E

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WHAT'S NEW

Third Quarter 2019 Financial and Operational Results

During the third quarter and to date, Titan Pharmaceuticals, Inc. (NASDAQ: TTNP) has expanded its network to include CVS Caremark, raised additional capital to support its sales and marketing efforts, received approval for additional NIDA funding and presented a pair of posters on Probuphine. Late last week, Titan submitted its quarterly update which was provided in the November 14th press release and concurrently filed 10-Q. Total revenues were $0.9 million compared to $1.7 million in the comparable period last year. Revenues for the quarter declined sequentially; however, prescriptions were similar for both periods with higher levels of patient assistance in the third quarter explaining the product revenue difference. Operating expenses were $4.6 million, up 36% from the $3.4 million expended in 3Q:18. Net loss of ($2.8) million or ($0.18) per share compares to prior year net loss of ($2.3) million and ($0.64) per share.[1] Net loss benefitted from a non-cash gain related to warrant valuation and would have been ($0.25) without the one-time item.

Over the last year, Titan has taken several steps to advance the commercialization of Probuphine. The company is forging partnerships with AllianceRx to help with payors and fulfillment, with AppianRx to provide patient support and with Accredo for product inventory management, billing and payment as well as deep relationships with third party payors. These agreements were signed in the first half of 2019 and are taking time to fully implement. We see value in Titan given the backdrop and the success of the drug in clinical trials and its unique profile which can provide steady drug distribution and evade diversion.

During the third quarter, Titan continued to build its relationships initiating an agreement with CVS Caremark in July for specialty product distribution, adding to its stable of distributors. The company also streamlined distribution, reducing the time from prescription to product delivery. Websites for both patients and providers have been established to help patients locate qualified providers and improve the product ordering process. Benefits verification has been reduced from over 90 days to three days with the help of Appian RX. The company is conducting targeted training of providers with a focus on the most productive prescribers and nurse practitioners. Training is taking place at drug and alcohol rehabilitation facilities, prominent medical groups and outreach is taking place at residential treatment centers, the Veteran's Administration (VA) and federal and state prison systems. Titan is assuming numerous initiatives to stimulate sales of this important product; however, results have been slow to date. Back in the Old World, Titan partner Molteni received approval for Sixmo and is currently in pricing negotiations. First product shipments and sales are expected in 1Q:20.

Third quarter 2019 revenues of $0.9 million were comprised of $190,000 of product revenue and $757,000 of grant revenue. No license revenues were recognized. License revenues from Canada are progressing at a slow pace until pricing can be established with all the provinces and none were recognized in the quarter. Grant revenue was related to the National Institute on Drug Abuse (NIDA) nalmefene implant project.

Cost of goods sold was $188,000, equivalent to a 1.1% product 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 $4.6 million which consists of $1.6 million in research and development costs and $3.0 million in selling, general and administrative expenses. The 15% decrease in R&D expenses reflected lower Probuphine related expenses and lower compensation expenses, partially offset by an increase in expenses related to the nalmefene program. SG&A expenses doubled due to greater commercialization activities for Probuphine, higher consulting and professional fees, greater spend on outside services and travel costs.

Cash and equivalents as of September 30, 2019 were $0.9 million, compared to $9.3 million at the end of 2018. Debt was carried at $3.9 million. During the quarter, Titan received $2.0 million from equity offerings and cash burn was ($3.4) million in 3Q:19 compared to ($2.3) million in the comparable prior year period. Following the end of the quarter, Titan raised net proceeds of $8.1 million in a public offering. Management believes that cash levels are sufficient to fund the company until 3Q:20.

[1] Note that per share amounts are adjusted for the 1:6 reverse stock consolidation that occurred on January 24, 2019. Note that share count increased dramatically from 3Q:18 to 3Q:19.

Exhibit I – Titan Pipeline[2]



Partners

During 2019 Titan announced partnerships with AllianceRx Walgreens Prime, AppianRx, Accredo, Southside Specialty Pharmacy and CVS Caremark to provide distribution and patient support services. These relationships are expected to shorten the time between product order and delivery, improve payment dynamics and improve Probuphine availability throughout the United States. Some of the changes that have been made include specialty pharmacy relationships with payors, a streamlined benefits authorization process, and holding inventory on-site. These improvements can accelerate the process of delivering Probuphine to physicians and providing timely reimbursement. AllianceRx will carry inventory, manage insurance billing, offer payment processing and ship product to the provider. AppianRx will manage benefit verification, prior authorization, appeals and co-pay/patient assistance, which should reduce time from prescription to payment. Accredo has also moved necessary paperwork to an online platform, automating the procurement process, providing real time information and satisfying REMS and verifying eligibility. Southside is anticipated to expand the presence of Probuphine into California and Texas and CVS Caremark will provide broad distribution of the implant throughout the country. We anticipate that Titan will continue to develop additional specialty pharmacy relationships to improve penetration.

Phase IV Probuphine Studies

Titan is required to conduct two Phase IV post-marketing studies. The first will be a small study estimated to cost from $3 to $4 million and will last for two to three years. It 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 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. On the 3Q:19 conference call, management announced that it had postponed the post-marketing studies given Titan's current financial condition and low volume of sales to date and have advised the FDA of their status. Titan is also participating in an industry consortium study to perform a QT prolongation study for patients treated with various forms of buprenorphine.

Raising Capital

In April 2019 Titan entered into an at the market (ATM) facility with Alliance Global Partners to sell up to $8.6 million worth of stock in the open markets. In August, the company entered into a securities purchase agreement with an institutional investor and raised $2.1 gross and $1.83 million net from the issuance of 2.85 million shares and warrants. In October, Titan sold an additional 40.3 million shares/pre-funded warrants and warrants to raise $9.1 million gross and $8.1 million net.

[2] Source: Titan February 2019 Corporate Presentation.

Molteni and the EMA

On April 29th, Titan announced that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has adopted a positive opinion regarding the approval of the Probuphine implant in the European Union. The product will be branded Sixmo and will be indicated for substitution treatment for opioid dependence for stable patients. Following the recommendation, the CHMB was forwarded to the European Commission (EC) which provided the final approval in late June for the 28 member states. The launch of Sixmo will be accompanied by a clinical and medical affairs program and a Phase IV post marketing safety study. Initial efforts will focus on high volume addiction centers that have a wide reach into the adjacent community. Pricing approval for the first country is expected in 1Q:20 simultaneous with product shipments and we anticipate license revenues to be recognized with a delay.

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 in 2018 and Knight's exclusive right to distribute the drug and their launch of the product. Knight is currently in negotiations with provincial pricing authorities. When this is complete, sales and their accompanying license revenues are expected to be recognized.

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 Titan must contribute $1.33 million in year one, but does not have an obligation in year two. Approval for the second year of the grant was given in September along with a change to the grant award terms which now allows total potential expense reimbursement of up to $8.7 million. There are an additional three years of funding that may be accessed if certain milestones are achieved. Titan expects to file an IND for ProNeura based nalmefene for the prevention of opioid relapse in 3Q:20.

Valuation

We roll our estimates forward by a year and reduce our revenue and expense estimates for 2020 and 2021. Revenues come down to reflect the slower than expected ramp in the US and Canada and our cost estimates are reduced based on the delay of the Phase IV study and management and board salary and compensation cuts in 2020. We adjust the share count and warrants outstanding to reflect the October capital raise which reduces our target price to $1.00 per share. Probuphine and the ProNeura implant are a valuable drug and technology that fill an important need in opioid use disorder and other indications where steady drug delivery is important and diversion can be a problem. We think a large investor or pharmaceutical company could acquire the shares of Titan as the current enterprise value is low compared to the potential of the product and pipeline.

Summary

Titan is developing the necessary infrastructure for growing sales despite slow progress. Near term revenue catalysts exist including development of US partnerships and Canadian and European sales. We are hopeful that the relationships with dominant specialty pharmacies will shorten the time between order and delivery and also simplify the payor approval and REMS processes. Based on the adjustment to our revenue estimates and dilutive securities, our target price moves to $1.00 per share.

PROJECTED FINANCIALS

Titan Pharmaceuticals, Inc. - Income Statement[3]

Titan Pharmaceuticals, Inc.	2018 A	Q1 A	Q2 E	Q3 A	Q4 E	2019 E	2020 E	2021 E
Total Revenues	**$6.6**	**$0.9**	**$0.5**	**$0.9**	**$1.4**	**$3.8**	**$7.7**	**$6.0**
YOY Growth	*2978.6%*	*-11.2%*	*-81.2%*	*-42.6%*	*13.2%*	*-42.7%*	*103.0%*	*-22.1%*
Cost of Goods Sold	$0.538	$0.3	$0.2	$0.2	$0.1	$0.9	$0.5	$0.9
R&D	$7.5	$1.8	$1.9	$1.6	$1.8	$7.2	$6.5	$10.0
SG&A	$6.9	$3.1	$3.2	$3.0	$3.1	$12.4	$12.4	$16.0
Operating Income	($8.3)	($4.3)	($4.9)	($3.9)	($3.6)	($16.7)	($11.7)	($20.9)
Operating Margin	*-124.9%*	-	-	-	-	*-439.4%*	*-151.6%*	*-348.0%*
Total Other Income	($1.0)	($0.2)	($0.3)	$1.1	($0.2)	$0.3	($0.6)	$0.0
Pre-Tax Income	($9.3)	($4.5)	($5.2)	($2.8)	($3.8)	($16.3)	($12.3)	($20.9)
Taxes & Other	$0	$0	$0	$0	$0	$0	$0	$0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	($9.3)	($4.5)	($5.2)	($2.8)	($3.8)	($16.3)	($12.3)	($20.9)
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($1.64)**	**($0.34)**	**($0.38)**	**($0.18)**	**($0.08)**	**($0.72)**	**($0.18)**	**($0.30)**
YOY Growth	*-59.6%*	*-53.6%*	*55.7%*	*-71.7%*	*-73.4%*	*-56.3%*	*-74.4%*	*62.9%*
Weight Ave. Shares Out	5.7	13.2	13.6	15.5	49.0	22.8	67.0	70.0

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

[3] Note: 2021 revenue decline represents the end of nalmafene grant revenues.

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HISTORICAL STOCK PRICE

Titan Pharmaceuticals, Inc. – Share Price Chart



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