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April 2, 2020
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Titan Pharmaceuticals, Inc. (TTNP-NASDAQ)

Stepping Into Stability

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 (4/1/20)	$0.22
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 regions. Approval has been secured in the US, Canada and Europe. First European sales are expected in 1H: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	**$2.18**
52-Week Low	**$0.14**
One-Year Return (%)	**-88.3**
Beta	**0.79**
Average Daily Volume (sh)	**17,642,536**
Shares Outstanding (mil)	**93.5**
Market Capitalization ($mil)	**$20.2**
Short Interest Ratio (days)	**0.33**
Institutional Ownership (%)	**5.6**
Insider Ownership (%)	**0.3**
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 2019 Estimate	**N/A**
P/E using 2020 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	$1.2 A	$3.6 A
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 A	-$0.72 A
2020					-$0.13 E
2021					-$0.17 E

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WHAT'S NEW

Full Year 2019 Financial and Operational Results

During 2019 and to date, Titan Pharmaceuticals, Inc. (NASDAQ: TTNP) has expanded its distribution network to cover the entire United States working in partnership with several well-known specialty pharmaceutical players. The company also improved its distribution process, taking what had been up to three months to deliver a prescription after it was written to a few weeks assisted by the new online portal. Other partners including Knight Therapeutics and Molteni Farmaceuticci are advancing Probuphine and Sixmo respectively in Canada and Europe. Financial performance continues to proceed slowly. Titan received $2.3 million in grant revenue in 2019 which comprised the majority of revenues; however, there was limited contribution from product sales and license revenue. Titan submitted its earnings release and Form 10-K on March 30 along with a conference call after market close.

Total revenues for 2019 were $3.6 million compared to $6.6 million in the comparable prior year period. License revenues in 2018 included $2.1 million related to up-front payments from Molteni, $1.1 million related to the amendment of the purchase agreement with Molteni and $2.1 million from the termination of the Braeburn license. None of these contributions recurred to the same extent in 2019. License revenues of $315,000 in 2019 represented the amortization of deferred revenue related to the sale of Probuphine IP to Molteni. Product revenue was $1.0 million in 2019, up from $535,000 in 2018. Grant revenue increased to $2.3 million in 2019, rising from $707,000 in the prior year on increased contributions to the Nalmefene project.

Gross margin for product revenues was negative for the year, representing the high level of fixed costs relative to product sales. Research and development expenditures totaled $7.2 million down from $7.5 million in the prior year while selling, general and administrative spend was $11.9 million for the year, up 74%. Higher SG&A is attributable to greater marketing expenses related to establishing the infrastructure to streamline the Probuphine ordering and distribution network and the increased expenses associated with expanding commercial activities.

Management noted on the call that fourth quarter prescriptions rose 18.6% sequentially compared to the third quarter. This compares to the prior third quarter trend which was flat sequentially with the second quarter. Total operating expenses were $19.2 million, up 34% from the $14.3 million expended in 2018. Net loss of ($16.5) million or ($0.72) per share compares to prior year net loss of ($9.3) million and ($1.64) per share.[1] Net loss benefitted from a non-cash gain related to warrant valuation adding $1.1 million to the bottom line.

Over the last year, Titan has taken several steps to advance the commercialization of Probuphine. The company has forged 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. Titan initiated an agreement with CVS Caremark in July 2019 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 the parties find each other and improve the product ordering process. Benefits verification has been reduced from over 90 days to 24 hours with the help of Appian RX and best practices. 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. Since the outbreak of the coronavirus, there has been a shift to virtual training for providers learning to implant Probuphine and for Risk Evaluation and Mitigation Strategy (REMS) training. Sales activities have also moved online or to the phone as the teams adjust to the new environment.

Step Into Stability

Titan launched a new campaign to increase awareness for Probuphine called Step Into Stability. This is an effort to educate patients, health plan members and providers by partnering with public health officials and other institutions to reduce daily buprenorphine dosing. The effort identifies the benefits of the Probuphine implant compared to current therapy for the target patient which is taking 8 mg or less of oral buprenorphine for opioid use disorder.

[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 2018 to 2019.

Exhibit I – Step Into Stability Flyer[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 internally and one Phase IV in conjunction with other buprenorphine manufacturers. 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. Management has announced that the post-marketing studies are on hold given Titan's current financial condition and low volume of sales. The company has advised the FDA of their status and will provide updates to the agency as new information arises.

[2] Source: Probuphine website accessed March 30, 2020. https://probuphine.com/wp-content/uploads/2019/11/TTN-PRO-107-1-AUG19-TPPR-1920-Probuphine-Patient-Brochure_StepStability_PDF_M6.pdf

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 is compiling the non-clinical data necessary to file and investigational new drug application (IND) and expects to file prior to year-end 2020.

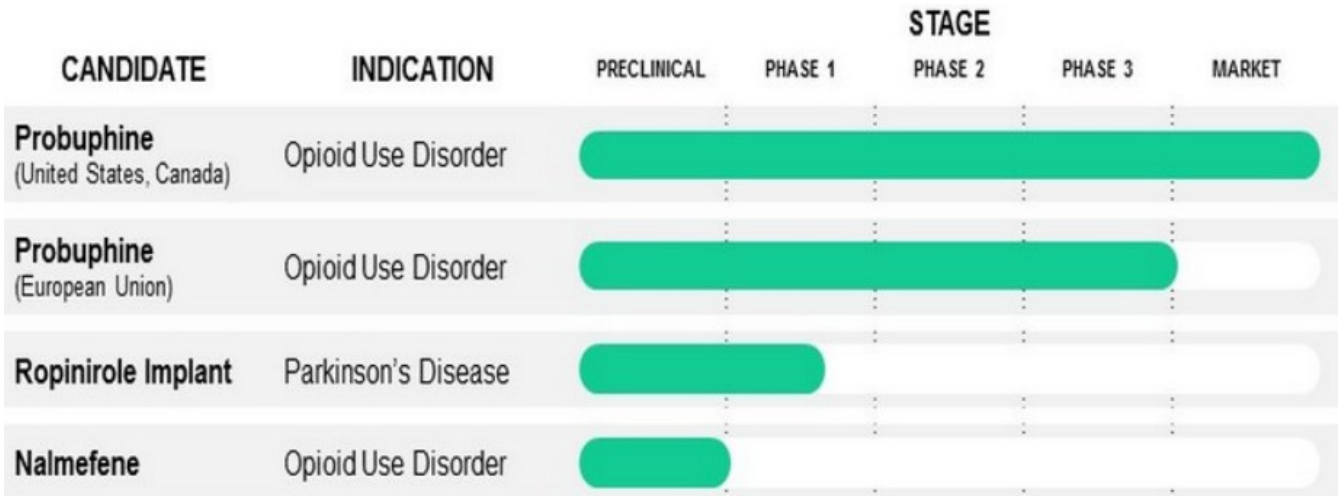
Molteni and the EMA

Sixmo, Probuphine's trade name in Europe, was approved by the European Commission (EC) in late June 2019 for all 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 in the top two or three countries in the EU. Pricing approval is expected in the first half and manufacturing of the buprenorphine implants is being planned. However, disruptions related to the coronavirus could also cause a delay for both activities in Europe and in manufacturing efforts. The pandemic may also affect Molteni's ability to package and test the kits when received, given the massive impact Italy has suffered from the virus.

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. To date, Knight has been able to obtain product pricing approval and formulary listing from health authorities in Quebec, New Brunswick, Newfoundland, Nova Scotia, Manitoba, Alberta and Saskatchewan. Current efforts are focused on obtaining listings in British Columbia and Ontario.

Exhibit II – Titan Pipeline[3]



[3] Source: Titan February 2019 Corporate Presentation.

Additional Funds

Since the end of the 2019 reporting period Titan has announced two capital inflows. The first, on January 7th, 2020 was a $2.2 million registered direct offering. 8.7 million shares were issued at $0.25 per share. The arrangement included the issue of 8.7 million warrants exercisable at $0.25. After financing and other related costs, net proceeds are expected to be $1.9 million. The second capital inflow announced on March 5th, 2020 was related to the exercise of warrants which raised $5.9 million from 26.2 million class B securities. Combined with cash on the balance sheet, the funds from these activities is expected to provide sufficient funds to support operations into the fourth quarter.

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 pleased to see the improvements in prescription approval rates and time between prescription and shipment. Titan still needs to see the benefits of all their hard work building a well-oiled distribution system and achieve sufficient sales to generate a profit. We maintain our target price of $1.00 per share.

PROJECTED FINANCIALS

Titan Pharmaceuticals, Inc. - Income Statement[4]

Titan Pharmaceuticals, Inc.	2018 A	Q1 A	Q2 E	Q3 A	Q4 A	2019 A	2020 E	2021 E
Total Revenues	**$6.6**	**$0.9**	**$0.5**	**$0.9**	**$1.2**	**$3.6**	**$7.7**	**$6.0**
YOY Growth	*2978.6%*	*-11.2%*	*-81.2%*	*-42.6%*	*-1.6%*	*-45.4%*	*113.2%*	*-22.1%*
Cost of Goods Sold	$0.5	$0.3	$0.2	$0.2	$0.6	$1.3	$0.5	$0.9
R&D	$7.5	$1.8	$1.9	$1.6	$1.9	$7.2	$6.5	$10.0
SG&A	$6.9	$3.1	$3.2	$3.0	$2.6	$11.9	$12.4	$16.0
Operating Income	($8.3)	($4.3)	($4.9)	($3.9)	($3.8)	($16.8)	($11.7)	($20.9)
Operating Margin	*-124.9%*	-	-	-	-	*-466.5%*	*-151.6%*	*-348.0%*
Total Other Income	($1.0)	($0.2)	($0.3)	$1.1	($0.1)	$0.4	($0.6)	$0.0
Pre-Tax Income	($9.3)	($4.5)	($5.2)	($2.8)	($3.9)	($16.5)	($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)	($3.9)	($16.5)	($12.3)	($20.9)
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($1.64)**	**($0.34)**	**($0.38)**	**($0.18)**	**($0.08)**	**($0.72)**	**($0.13)**	**($0.17)**
YOY Growth	*-59.6%*	*-53.6%*	*55.7%*	*-71.7%*	*-72.7%*	*-56.2%*	*-82.0%*	*29.3%*
Weight Ave. Shares Out	5.7	13.2	13.6	15.5	49.2	23.0	95.0	125.0

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

[4] 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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