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Titan Pharmaceuticals, Inc. (TTNP-NASDAQ)

Coronavirus Delays European Launch

Based on our DCF model and a 15% discount rate, TTNP is valued at approximately $0.80 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 (5/15/20)	$0.28
Valuation	**$0.80**

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 2H: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	**$1.96**
52-Week Low	**$0.14**
One-Year Return (%)	**-83.9**
Beta	**0.79**
Average Daily Volume (sh)	**13,209,350**
Shares Outstanding (mil)	**93.5**
Market Capitalization ($mil)	**$25.7**
Short Interest Ratio (days)	**0.58**
Institutional Ownership (%)	**5.7**
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)
2019	$0.9 A	$0.5 A	$0.9 A	$1.2 A	$3.6 A
2020	$1.3 A	$1.6 E	$1.7 E	$2.8 E	$7.4 E
2021					$6.0 E
2022					$6.0 E

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2019	-$0.34 A	-$0.38 A	-$0.18 A	-$0.08 A	-$0.72 A
2020	-$0.07 A	-$0.03 E	-$0.03 E	-$0.01 E	-$0.13 E
2021					-$0.17 E
2022					-$0.15 E

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WHAT'S NEW

First Quarter 2020 Financial and Operational Results

Titan Pharmaceuticals, Inc. (NASDAQ: TTNP) has been working hard to set up the ecosystem required for successful commercialization of Probuphine. The company has expanded its distribution network to cover the entire United States working in partnership with several well-known specialty pharmaceutical players and has improved its distribution process. Other partners including Knight Therapeutics and Molteni Farmaceuticci are advancing Probuphine and Sixmo in Canada and Europe respectively. Despite all of the effort, product sales growth has been elusive. In the first quarter, revenues were $1.3 million, with the majority sourced from grant revenues. The first quarter was summarized in Titan's earnings release, Form 10-Q and conference call presented to investors on May 15, 2020.

Management announced an upcoming special meeting of shareholders to include shareholders of record on May 22nd, 2020. The company requires additional shares of authorized common stock so that it may raise additional capital to fund the R&D and commercialization efforts. Proxy materials will be send to shareholders later in May.

Total revenues the first quarter were $1.3 million compared to $945 thousand in the comparable prior year period. License revenues in 1Q:20 were zero, compared to $313,000 in 1Q:19; product revenue fell to $210,000 from $317,000 and grant revenue rose to $1.1 million from $315,000. Gross margin for product revenues improved over prior year levels to 18.6%; however, it remains on a very small base with the proportion of fixed costs distorting the potential for this line item. Research and development expenditures totaled $2.3 million increasing from $1.8 million the year before as Titan increased its activities related to the NIDA grant. General and administrative spend clocked in at $3.1 million, essentially flat with last year's level. Total operating expenses were $5.4 million, up 9% from the first quarter last year. Net loss was ($5.6) million or ($0.07) per share compared to a net loss of ($4.5) million and ($0.34) 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. Titan initiated an agreement with CVS Caremark in July 2019 for specialty product distribution, adding to its stable of distributors. Other milestones:

- Streamlined distribution, reducing the time from prescription to product delivery.
- Websites established for both patients and providers.
- Benefits verification duration reduced from over 90 days to 24 hours
- Targeted training of providers with a focus on the most productive
    - Approximately 300 trained
- Shift to virtual training for providers over last few months
- Sales activities moved online or to the phone

Up until a few weeks ago, these efforts were led by Chief Commercial Officer Dane Hallburg. An 8-K announcement disclosed his departure on April 24th. His responsibilities will be taken over by others on the team.

Step Into Stability

Titan launched a new campaign to increase awareness for Probuphine called Step Into Stability. This is an effort, in partnership with public health officials and other institutions, to reduce daily buprenorphine dosing by educating patients, health plan members and providers. 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 share count increased materially from 2018 to 2019.

Exhibit I – Step Into Stability Flyer[2]



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, which 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 cost 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.

Nalmefene

Starting 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. Based on further discussions with the FDA during the second quarter, Titan was advised to pursue the traditional 505(b)(1) pathway for approval of nalmefene due to the lack of safety data in a long acting formulation. This approach will require an additional study to be performed and additional preclinical work to be completed for another project that is already underway. There are additional years of funding that may be accessed if certain milestones are achieved. With the additional work required, Titan expects to file the investigational new drug application (IND) in the second quarter of 2021.

[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

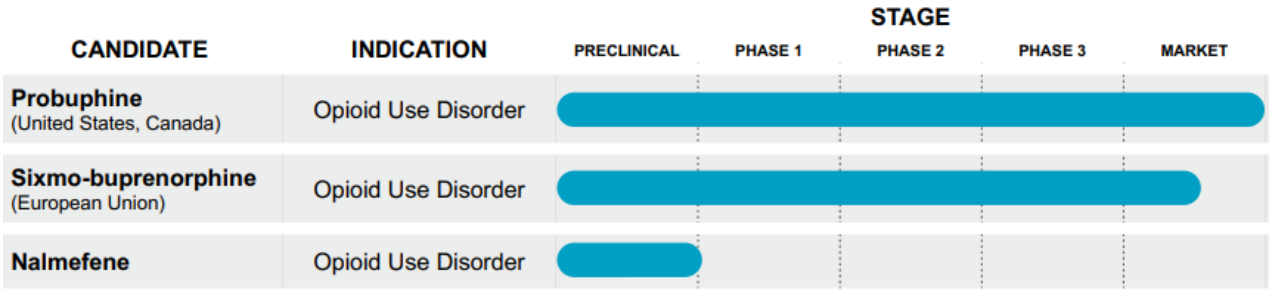
Molteni and the EMA

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 delayed due to the difficulties associated with the coronavirus. In the United States, work is continuing in preparation for the manufacture of Sixmo and the first batch is expected to be produced by the end of June. Management anticipates that first sales will take place in the second half of 2020.

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. No license revenues were received in the first quarter and we believe that sales have been slower than expected.

Exhibit II – Titan Pipeline[3]



Additional Funds

2020 year to date Titan has announced several additional 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 were $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. The company also received $0.7 million in Paycheck Protection Program funds in April 2020 and $0.5 million in warrant proceeds in May 2020. Combined with cash on the balance sheet, the funds obtained are expected to be sufficient to support operations into the third quarter of 2020.

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 adjust our estimates to reflect second quarter actuals, delayed revenues in Europe and slower uptake in Canada. These changes reduce our target price to $0.80.

[3] Source: Titan December 2019 Corporate Presentation.

PROJECTED FINANCIALS

Titan Pharmaceuticals, Inc. - Income Statement[4]

Titan Pharmaceuticals, Inc.	2019 A	Q1 A	Q2 E	Q3 E	Q4 E	2020 E	2021 E	2022 E
Total Revenues	**$3.6**	**$1.3**	**$1.6**	**$1.7**	**$2.8**	**$7.4**	**$6.0**	**$8.4**
YOY Growth	*-45.4%*	*41.4%*	*218.7%*	*79.5%*	*130.1%*	*105.9%*	*-19.3%*	*# DIV/0!*
Cost of Goods Sold	$1.3	$0.2	$0.1	$0.1	$0.1	$0.5	$0.9	$1.0
R&D	$7.2	$2.3	$1.6	$1.6	$1.7	$7.2	$10.0	$15.0
SG&A	$11.9	$3.1	$3.1	$3.1	$3.1	$12.4	$16.0	$11.5
Operating Income	($16.8)	($4.2)	($3.2)	($3.1)	($2.1)	($12.6)	($20.9)	($19.1)
Operating Margin	*-466.5%*	*-316.3%*	*-201.3%*	*-183.5%*	*-74.3%*	*-170.1%*	*-348.0%*	*-227.5%*
Total Other Income	$0.4	($1.4)	$0.0	$0.0	$0.0	($0.6)	$0.0	$1.0
Pre-Tax Income	($16.5)	$5.6	($3.2)	($3.1)	($1.3)	($13.2)	($20.9)	($18.1)
Taxes & Other	$0	$0.0	$0	$0	$0	$0	$0	$1
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*100%*
Net Income	($16.5)	($5.6)	($3.2)	($3.1)	($1.3)	($13.2)	($20.9)	($19.1)
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($0.72)**	**($0.07)**	**($0.03)**	**($0.03)**	**($0.01)**	**($0.13)**	**($0.17)**	**($0.15)**
YOY Growth	*-56.2%*	*-80.2%*	*-91.1%*	*-82.0%*	*-86.2%*	*-81.2%*	*23.8%*	*# DIV/0!*
Weight Ave. Shares Out	23.0	82.6	94.0	96.0	120.0	98.2	125.0	130.0

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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