Zacks Small-Cap Research

Sponsored – Impartial - Comprehensive

August 17, 2020
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)

Indegene to Advance Probuphine Commercialization

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 (8/14/20)	$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 2021. A co-promotion partnership was signed with healthcare solutions company Indegene to engage health care providers and support prescribing Probuphine.

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	**$0.59**
52-Week Low	**$0.14**
One-Year Return (%)	**-99.0**
Beta	**0.9**
Average Daily Volume (sh)	**11,283,940**
Shares Outstanding (mil)	**97.2**
Market Capitalization ($mil)	**$27.2**
Short Interest Ratio (days)	**1.12**
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 2020 Estimate	**N/A**
P/E using 2021 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	$1.3 A	$1.4 E	$2.7 E	$6.8 E
2021					$6.0 E
2022					$8.4 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	-$0.05 A	-$0.04 E	-$0.01 E	-$0.15 E
2021					-$0.13 E
2022					-$0.14 E

© Copyright 2020, Zacks Investment Research. All Rights Reserved.

WHAT'S NEW

Second Quarter 2020 Financial and Operational Results

Titan Pharmaceuticals, Inc. (NASDAQ: TTNP) has continued its efforts to commercialize Probuphine; however, coronavirus related headwinds have slowed domestic product sales and delayed the shipment of product to Molteni. To reinvigorate the sales effort in the US, Titan signed an agreement with Indegene, a global healthcare solutions company that employs multichannel marketing to help companies commercialize their product. To adapt to the pandemic environment, the company was able to secure approval for a virtual risk evaluation and mitigation strategy (REMS) training program to qualify additional providers to implant Probuphine. According to commentary on the earnings call, the third quarter has recovered to pre-COVID-19 levels of activity.

In the second quarter, revenues were $1.3 million, with a majority of the amount sourced from the nalmefene grant. Results from the reporting period are summarized in Titan's earnings release, Form 10-Q and conference call presented to investors on August 14, 2020. Management rescheduled a special meeting of shareholders in order to obtain a majority of affirmative votes to authorize additional shares. The meeting will take place August 31, 2020.

Total revenues the second quarter were $1.3 million compared to $502 thousand in the prior year period. License revenues in 1Q:20 were $6,000 compared with $0 in 2Q:19; product revenue fell to $115,000 from $304,000 and grant revenue rose to $1.2 million from $198,000. Gross margin turned negative as cost of goods sold exceeded product revenues; however, sales remain on a very small base with the proportion of fixed costs distorting the potential for this line item. Research and development expenditures totaled $2.0 million, increasing from $1.9 million the year before as Titan increased its activities related to the NIDA grant. General and administrative spend rose to $3.5 million, up from $3.2 million in 2Q:19. Total operating expenses were $5.5 million, up 7% from the second quarter last year. Net loss was ($4.6) million or ($0.05) per share compared to a net loss of ($5.2) million and ($0.38) per share.[1]

Probuphine Commercialization

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. In late June 2020, the company added Indegene Inc. to help in the co-promotion of Probuphine. The effort will use multichannel marketing tools, predictive analytics, webinars and social media campaigns to expand awareness of Probuphine. The strategic imperatives for the collaboration include:

- Drive Probuphine discussion at the point of care
- Accelerate and drive REMS certification
- Focus on established business and adjacent areas to drive further penetration
- Identify and partner with state initiatives

Following a coronavirus pandemic-induced slowdown, management noted a pickup in enrollments and activity in July and August and anticipates that the fourth quarter will produce the fruits of the partnerships and efforts that the team has made.

Milestones

- Websites established for both patients and providers - 2019
- Benefits verification duration reduced from over 90 days to 24 hours – 2019/2020
- Targeted training of providers with a focus on the most productive
- Co-promotion partnership with Indegene – June 2020
- FDA approval of virtual training for providers – June 2020
- Sales activities moved online or to the phone

[1] Note that share count increased materially from 2019 to 2020.

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 2021.

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. Product was initially expected to be shipped to Molteni by the end of 2Q:20; however, facilities modifications and testing protocols required by the EU were delayed due to restrictions related to the coronavirus which in turn led to the delay in product shipment. The Sixmo consignment is now expected to ship by the end of 3Q:20. Combined with delays in Europe also related to the coronavirus, we anticipate that first sales will take place early in 2021.

Additional Funds

During 2020 and year to date, Titan has announced several additional capital inflows. The first, on January 7th, 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. Titan is currently seeking shareholder approval to increase authorized shares in order to raise additional capital required to fund Probuphine commercialization. We anticipate that new capital will be required in the next few months to support this effort.

Summary

Titan continues to develop infrastructure in its efforts to expand sales and has added another collaborator to co-promote Probuphine. Sales have been slow to expand and the impact from the coronavirus retarded the trend even further. However, management noted that enrollment levels had reached pre-COVID levels in July and requests were increased for in-person healthcare provider visits in August. With the addition of Indegene to the mix, we are hopeful to see a rise in sales in the second half of 2020. We maintain our target price to $0.80.

PROJECTED FINANCIALS

Titan Pharmaceuticals, Inc. - Income Statement[2]

Titan Pharmaceuticals, Inc.	2019 A	Q1 A	Q2 A	Q3 E	Q4 E	2020 E	2021 E	2022 E
Total Revenues	**$3.6**	**$1.3**	**$1.3**	**$1.4**	**$2.7**	**$6.8**	**$6.0**	**$8.4**
YOY Growth	*-45.4%*	*41.4%*	*163.9%*	*47.8%*	*121.9%*	*87.2%*	*-11.3%*	*# DIV/0!*
Cost of Goods Sold	$1.3	$0.2	$0.2	$0.1	$0.1	$0.5	$0.9	$1.0
R&D	$7.2	$2.3	$2.0	$1.6	$1.7	$7.6	$10.0	$15.0
SG&A	$11.9	$3.1	$3.5	$3.1	$3.1	$12.8	$13.0	$13.0
Operating Income	($16.8)	($4.2)	($4.4)	($3.4)	($2.2)	($14.2)	($17.9)	($20.6)
Operating Margin	*-466.5%*	*-316.3%*	*-330.9%*	*-241.1%*	*-80.4%*	*-209.4%*	*-298.0%*	*-245.3%*
Total Other Income	$0.4	($1.4)	($0.3)	$0.0	$0.0	($0.6)	$0.0	$1.0
Pre-Tax Income	($16.5)	($5.6)	($4.6)	($3.4)	($1.2)	($14.8)	($17.9)	($19.6)
Taxes & Other	$0	$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)	($4.6)	($3.4)	($1.2)	($14.8)	($17.9)	($20.6)
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($0.72)**	**($0.07)**	**($0.05)**	**($0.04)**	**($0.01)**	**($0.15)**	**($0.13)**	**($0.14)**
YOY Growth	*-56.2%*	*-80.2%*	*-87.2%*	*-80.5%*	*-88.0%*	*-79.1%*	*-11.7%*	*# DIV/0!*
Weight Ave. Shares Out	23.0	82.6	94.9	96.0	120.0	98.4	135.0	150.0

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

[2] Note: 2021 revenue decline represents the end of nalmefene grant revenues.

© Copyright 2020, Zacks Investment Research. All Rights Reserved.

HISTORICAL STOCK PRICE

Titan Pharmaceuticals, Inc. – Share Price Chart



DISCLOSURES

The following disclosures relate to relationships between Zacks Small-Cap Research ("Zacks SCR"), a division of Zacks Investment Research ("ZIR"), and the issuers covered by the Zacks SCR Analysts in the Small-Cap Universe.

ANALYST DISCLOSURES

I, John Vandermosten, hereby certify that the views expressed in this research report accurately reflect my personal views about the subject securities and issuers. I also certify that no part of my compensation was, is, or will be, directly or indirectly, related to the recommendations or views expressed in this research report. I believe the information used for the creation of this report has been obtained from sources I considered to be reliable, but I can neither guarantee nor represent the completeness or accuracy of the information herewith. Such information and the opinions expressed are subject to change without notice.

INVESTMENT BANKING AND FEES FOR SERVICES

Zacks SCR does not provide investment banking services nor has it received compensation for investment banking services from the issuers of the securities covered in this report or article.
Zacks SCR has received compensation from the issuer directly, from an investment manager, or from an investor relations consulting firm engaged by the issuer for providing non-investment banking services to this issuer and expects to receive additional compensation for such non-investment banking services provided to this issuer. The non-investment banking services provided to the issuer includes the preparation of this report, investor relations services, investment software, financial database analysis, organization of non-deal road shows, and attendance fees for conferences sponsored or co-sponsored by Zacks SCR. The fees for these services vary on a per-client basis and are subject to the number and types of services contracted. Fees typically range between ten thousand and fifty thousand dollars per annum. Details of fees paid by this issuer are available upon request.

POLICY DISCLOSURES

This report provides an objective valuation of the issuer today and expected valuations of the issuer at various future dates based on applying standard investment valuation methodologies to the revenue and EPS forecasts made by the SCR Analyst of the issuer's business.
SCR Analysts are restricted from holding or trading securities in the issuers that they cover. ZIR and Zacks SCR do not make a market in any security followed by SCR nor do they act as dealers in these securities. Each Zacks SCR Analyst has full discretion over the valuation of the issuer included in this report based on his or her own due diligence. SCR Analysts are paid based on the number of companies they cover. SCR Analyst compensation is not, was not, nor will be, directly or indirectly, related to the specific valuations or views expressed in any report or article.

ADDITIONAL INFORMATION

Additional information is available upon request. Zacks SCR reports and articles are based on data obtained from sources that it believes to be reliable, but are not guaranteed to be accurate nor do they purport to be complete. Because of individual financial or investment objectives and/or financial circumstances, this report or article should not be construed as advice designed to meet the particular investment needs of any investor. Investing involves risk. Any opinions expressed by Zacks SCR Analysts are subject to change without notice. Reports or articles or tweets are not to be construed as an offer or solicitation of an offer to buy or sell the securities herein mentioned.

© Copyright 2020, Zacks Investment Research. All Rights Reserved.