Zacks Small-Cap Research

August 14, 2014
Jason Napodano, CFA
312-265-9421
jnapodano@zacks.com

scr.zacks.com
10 S. Riverside Plaza, Ste 1600, Chicago, IL 60606

Titan Pharmaceuticals, Inc. (TTNP-OTCQB)

TTNP: Confirmatory Phase 3 Trial Underway, Data Expected Mid-2015…

Current Recommendation	**Buy**
Prior Recommendation	N/A
Date of Last Change	06/01/2011
Current Price (08/14/14)	$0.68
Target Price	**$1.50**

UPDATE

On August 14, 2014, Titan Pharmaceuticals, Inc. announced results for the second quarter of 2014. Revenues were $0.9 million and resulted from the amortization of upfront payments from Braeburn Pharmaceuticals. Net loss for the quarter was $0.8 million, or $0.01 per share.

Importantly, during the second quarter the company initiated the confirmatory Phase 3 study to support the resubmission of the NDA for Probuphine. The study is expected to be completed by mid-2015.

We continue to believe Probuphine will eventually receive U.S. approval, now forecasted to occur during the first half of 2016. We are maintaining our Buy rating and $1.50 price target, which is roughly 125% upside from today's price.

SUMMARY DATA

52-Week High	**$1.16**
52-Week Low	**$0.56**
One-Year Return (%)	**21.95**
Beta	**1.63**
Average Daily Volume (sh)	**95,996**
Shares Outstanding (mil)	**89**
Market Capitalization ($mil)	**$61**
Short Interest Ratio (days)	**0.25**
Institutional Ownership (%)	**1**
Insider Ownership (%)	**15**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
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 2014 Estimate	**N/A**
P/E using 2015 Estimate	**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)
2013	5.2 A	2.2 A	2.2 A	0.9 A	10.5 A
2014	0.9 A	0.9 A	0.9 E	0.9 E	4.6 E
2015					1.7 E
2016					18.5 E

Earnings per Share
(EPS is operating earnings before non-recurring items)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2013	$0.07 A	$0.06 A	-$0.01 A	-$0.00 A	$0.12 A
2014	-$0.02 A	-$0.01 A	-$0.02 E	-$0.02 E	-$0.07 E
2015					-$0.09 E
2016					$0.08 E

© Copyright 2014, Zacks Investment Research. All Rights Reserved.

WHAT'S NEW

Financial & Business Update

On August 14, 2014, Titan Pharmaceuticals reported financial results for the second quarter ending June 30, 2014. The company reported total revenues of $0.9 million in first quarter. Revenues reflected the amortization of upfront payments from Probuphine commercialization partner, Braeburn Pharmaceuticals. By comparison, for the full year 2013, Titan reported total revenues of $10.5 million, comprised of $9.1 million in amortization of upfront payments from Braeburn Pharmaceuticals and $1.4 million in recognized royalties on Fanapt prior to the selling of those royalties to Deerfield management.

Net loss in the second quarter totaled $0.8 million, equating to a loss of $0.01 per share. Net cash burn in the quarter totaled $1.3 million. Titan Pharma exited June 2014 with $8.9 million in cash and investments. We remind investors that the company secured a $5 million equity investment from Braeburn in November 2013 under the duo's revised collaboration agreement. Titan Pharma believes it has cash to fund operations through June 2015.

We continue to expect that Titan is going to need added cash to support operations into 2016 to the tune of around $8-10 million. We continue to believe that Titan will either seek an additional investment from Probuphine partner, Braeburn Pharma, or will look to strike a deal for advancing the ProNeura technology behind Probuphine with a new development partner, potentially one interested in moving forward in Parkinson's disease. We remind investors that Braeburn currently owns around 9.65 million shares, or 10.9% of the outstanding basic shares. We think Braeburn can take its ownership up to 20% without requiring significant maneuvering from either Titan or Braeburn.

Confirmatory Phase 3 Study is Underway

On June 21, 2014, Titan announced enrollment of the first patients in the Phase 3 clinical study to support resubmission of the New Drug Application (NDA) for Probuphine. The clinical study is a randomized, double blind, double dummy design that is expected to enroll approximately 180 patients into two parallel treatment arms. The study population will be clinically stable patients who are receiving maintenance treatment with an approved sublingual formulation containing buprenorphine at a daily dose of 8 mg or less. This is in contrast to the original New Drug Application (NDA) that called for use of Probuphine in opioid addicts that are first starting out on therapy with buprenorphine. Patients will be randomized to receive either four Probuphine implants, or to continue the daily sublingual buprenorphine therapy. The patients will be treated for six months, and the primary analysis will be a non-inferiority comparison of responders in the two arms.

Titan expects that updates on the progress of the study will be provided periodically. We expect the study to complete mid-2015. We remind investors that Braeburn is funding this study, with Titan providing logistical support. If all goes well, we expect to see a refiling of the NDA before the end of 2015. We expect that the FDA will respond to the application in six months, potentially putting a new PDUFA in the second quarter 2016.

In recent conversation with management, we asked about how long patients take to stabilize on Suboxone and they answered, "About 3-4 months." We then asked what percent of patients stabilize at 8 mg versus 12-16 mg, and the conclusion was that it was at least half, maybe higher. So although we believe the FDA's guidance effectively relegates Probuphine to maintenance therapy, it should not have a materially negative impact on sales of the drug. In fact, we think once approved, addiction medicine doc will probably still use Probuphine at a similar rate to how we predicted prior to the complete response letter, or in around 5-10% of all their patients. In essence, we see the narrower label as having only a minor impact on peak sales.

…Titan Looking Ex-U.S….

With the confirmatory Phase 3 study in the U.S. underway, Titan is beginning the process of engaging with key opinion leaders and regulatory consultants outside the U.S. in areas where Probuphine may be an attractive product. These talks are taking place on a country-by-country basis and it is too early to say at this point whether or not any of these countries will recognize the U.S. FDA approval as clearance for sale. It is possible that Titan may need to conduct new clinical studies prior to filing. Nevertheless, it is also possible that Titan secures development and commercialization agreements on a country or regional basis prior to re-filing the U.S. NDA. This is positive new for shareholders because any deal for development or commercialization of Probuphine outside of the

Braeburn territory could come with much needed upfront cash, potentially extending the runway beyond the current guidance of April 2015.

ProNeura In Parkinson's Disease

Probuphine utilizes Titan's ProNeura Technology. ProNeura is a continuous drug delivery system that consists of a small, solid rod made from a mixture of ethylene-vinyl acetate ("EVA") and a drug substance. The drug substance is released slowly, at continuous levels, through the process of dissolution. This results in a stable blood level similar to intravenous administration. In the case of Probuphine, that substance is buprenorphine. However, there are hundreds of drug substances that could be applied to ProNeura for sustained continuous delivery.

Such long-term, linear release characteristics are generally desirable as this avoids peak and trough level dosing that poses problems for many central nervous system and other disease settings. The next indication for which Titan believes ProNeura has utility is the continuous delivery of levodopa for the treatment of Parkinson's disease. In fact, Titan has conducted initial non-clinical studies with long-term delivery of dopamine agonists demonstrating the potential of this product in the treatment of Parkinson's disease in non-clinical models of the disease.

In support of the Parkinson's indication, Titan received a notice of allowance from the U.S. Patent and Trademark Office for a patent application covering the sustained release of dopamine agonists utilizing the ProNeura technology. The patent, titled "Implantable Polymeric Device for Sustained Release of a Dopamine Agonist", provides intellectual property protection of the program for Parkinson's disease and is expected to have an expiration date of at least 2024.

Dopamine Replacement Therapy (DRT) is the most common treatment option for Parkinson's patient. Levodopa (L-DOPA) has been used in the U.S. for more than 30 years. The administration of levodopa temporarily diminishes the motor symptoms associated with the lack dopamine in the substantia nigra of the Parkinson's patient. Unfortunately, levodopa has a relatively short half-life of only 50 minutes. Carbidopa, a dopa decarboxylase inhibitor, is commonly dosed with levodopa to prevent rapid metabolism before it reaches the blood-brain barrier. Co-formulations of levodopa/carbidopa (Sinemet-CR) are available and extend the half-life post administration to 1.5 hours (see package insert).

Because this half-life is still relatively short, Sinemet-CR must be dosed several times a day – frequently every six to eight hours. High doses of Sinemet spike the levodopa concentration in the brain to the point where a serious side effect called dyskinesia (involuntary movements) occurs. As levels return to below normal, the Parkinson's patient experiences a phenomena known as "OFF" time where stiffness, rigidity, or akinesia (lack of movement) occurs. The hefty dosing requirement of levodopa creates compliance issues, especially at night when patients may sleep through their dose schedule. The peaks and troughs associated with Levodopa create significant "ON" and "OFF" treatment times for PD patients.

Early-morning akinesia is often the first motor complication of the PD patient. It primarily occurs after the patient awakes from a nightlong treatment-free period. End of dose wearing off is characterized by declining mobility as the dose period progresses to its end. End of dose wearing off is the most common motor fluctuation in PD and thought to be caused by a reduced duration of action of levodopa. As high as 60% of Parkinson's patients experience these two issues. If Titan can formulate levodopa into ProNeura, they may be able to develop a product that provides around-the-clock stable and consistent levodopa levels in the brain that greatly eliminate or diminish the "ON with dyskinesia" or "OFF" issues noted above.

Titan's goal is to file an investigation new drug (IND) application for ProNeura in the treatment of Parkinson's disease in 2015. The company may need to conduct initial Phase 1 proof-of-concept safety and efficacy studies on their own, but we believe this product – especially if Probuphine gets approved – could bring significant value to shareholders through the signing of a development and commercialization partnership. As of yet, our financial model assumes no contribution from a ProNeura-PD candidate, so this represents upside to our fair value target.

Titan Still Attractive For Long-Term Holders

We remind investors that Braeburn is funding the necessary work to re-file Probuphine. In return, Titan has agreed to reduce its U.S. approval milestone from $45 million to $15 million. We remind investors that the original commercialization agreement signed between Titan and Braeburn back in December 2012 called for up to $50 million in approval milestones based on priority review, for which Probuphine was granted in January 2013. When Titan received a complete response letter on Probuphine in April 2013, this approval milestone was reduced from $50 million to $45 million. The revised agreement reduces the approval milestone to $15 million.

However, the total backend potential milestone consideration from Braeburn to Titan was increased to $165 million from $130 million as part of the restructured agreement. The revised agreement also lowers the sales threshold for Titan to achieve the highest royalty tier on sales of Probuphine. Additionally, the license amendment contains a provision entitling Titan to receive a low single digit royalty on sales by Braeburn, if any, of other mid or long-term continuous delivery treatments for opioid dependence, up to a maximum of $50 million, as well as the right to elect to participate in sales by Braeburn of other products in the addiction market in exchange for a similar reduction in the company's royalties on Probuphine. Therefore, if Braeburn looks to expand its product portfolio beyond Probuphine, Titan is both protected on the downside and can participate in the upside on these future transactions.

We continue to believe Probuphine will eventually receive U.S. approval, now forecasted to occur around the middle of 2016. Plugging in all our assumptions for the opioid dependence market and Probuphine market penetration and pricing, and we arrive at peak sales in the $250 to $300 million range. We note that Titan is in discussion with potential partners about Probuphine outside the U.S. We model a 20% royalty payment on sales at Braeburn, assuming this is the third (and highest) tier for Titan. We apply a 15% discount rate to these cash flows given that Braeburn seems strongly committed to the product and already owns nearly 11% of the company. Thus, we believe Titan shares are fair-valued today at roughly $1.50 per share. That's roughly 125% upside from today's price.

PROJECTED FINANCIALS

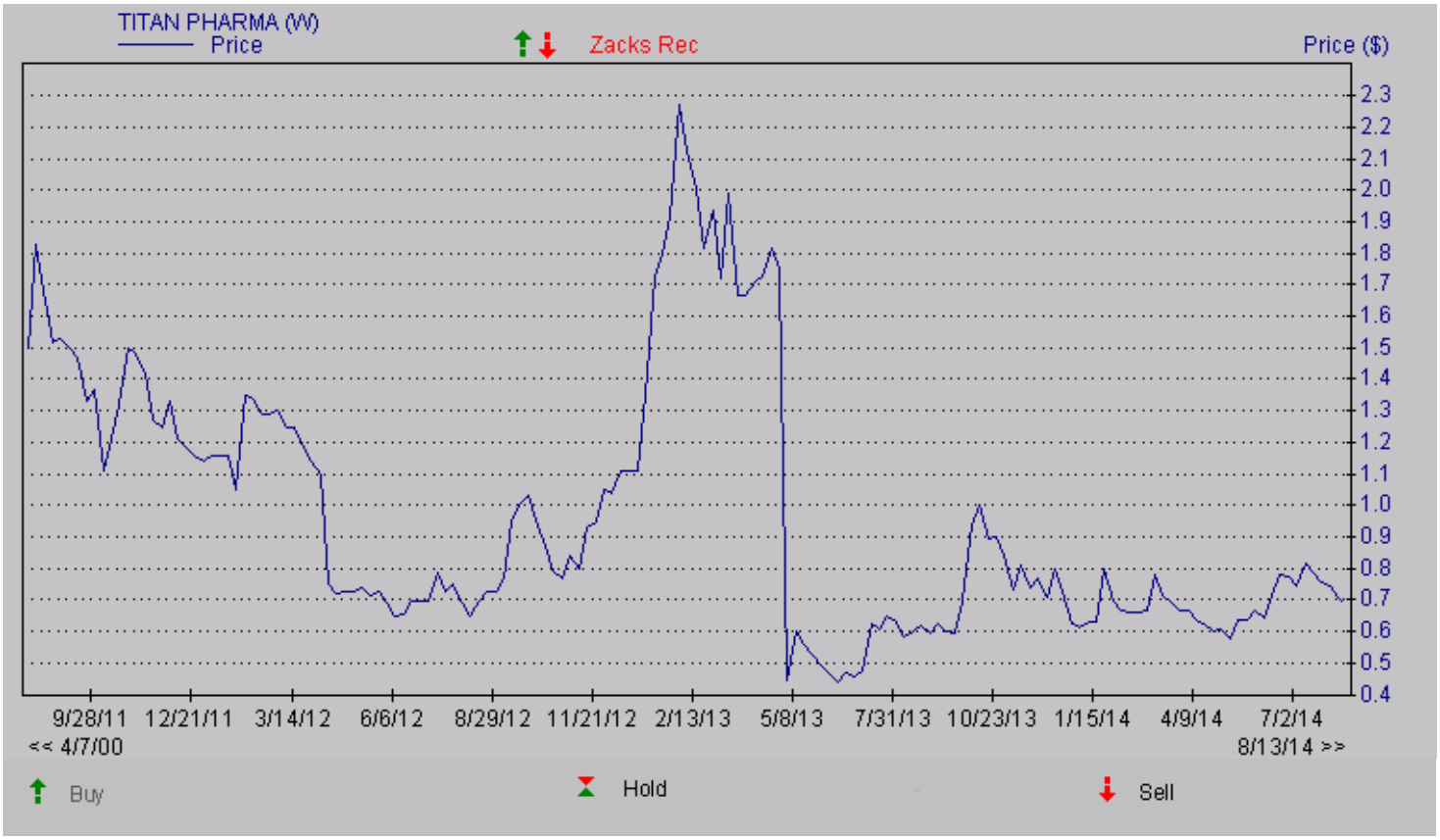
Titan Pharmaceuticals, Inc.
Income Statement

Titan Pharma	2013 A	Q1 A	Q2 A	Q3 E	Q4 E	2014 E	2015 E	2016 E
Probuphine Royalty	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$3.5**
YOY Growth	-	-	-	-	-	-	-	-
Fanapt Royalty	**$1.4**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
YOY Growth	*-70.0%*	-	-	-	-	-	-	-
Licensing & Grant Revenue	**$9.1**	**$0.9**	**$0.9**	**$0.9**	**$0.9**	**$3.6**	**$1.7**	**$15.0**
Total Revenues	**$10.5**	**$0.9**	**$0.9**	**$0.9**	**$0.9**	**$3.6**	**$1.7**	**$18.5**
YOY Growth	*47.3%*	-	-	-	-	-	-	-
CoGS	$0	$0	$0	$0	$0	$0	$0	$0
Product Gross Margin	*100.0%*	*100.0%*	*100.0%*	*100.0%*	*100.0%*	*100.0%*	*100.0%*	*100.0%*
R&D	$8.3	$0.9	$0.7	$1.3	$1.4	$4.4	$6.0	$5.0
SG&A	$3.1	$0.9	$0.7	$0.9	$0.9	$3.4	$4.0	$4.0
Operating Income	($0.9)	($0.9)	($0.6)	($1.3)	($1.4)	($4.2)	($8.3)	$9.5
Operating Margin	*-8.5%*	-	-	-	-	-	-	-
Total Other Income	$10.6	($0.9)	($0.3)	($0.5)	($0.5)	($2.2)	($1.5)	($1.0)
Pre-Tax Income	$9.7	($1.8)	($0.8)	($1.8)	($1.9)	($6.3)	($9.8)	$8.5
Taxes & Other	$0	$0	$0	$0	$0	$0	$0	$0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	$9.7	($1.8)	($0.8)	($1.8)	($1.9)	($6.3)	($9.8)	$8.5
Net Margin	*92.7%*	-	-	-	-	-	-	-
Reported EPS	**$0.12**	**($0.02)**	**($0.01)**	**($0.02)**	**($0.02)**	**($0.07)**	**($0.09)**	**$0.08**
YOY Growth	*-179.2%*	*-129.3%*	*-115.4%*	*45.5%*	*702.8%*	*-160.6%*	*31.3%*	*-182.7%*
Weight Ave. Shares Out	82.7	88.9	89.0	89.2	89.2	89.1	105.0	110.0

Source: Zacks Small-Cap Research, Inc. *Jason Napodano, CFA*

© Copyright 2014, Zacks Investment Research. All Rights Reserved.

HISTORICAL RECOMMENDATIONS



© Copyright 2014, Zacks Investment Research. All Rights Reserved.

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, Jason Napodano, CFA, CFA, hereby certify that the view 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.

INVESMENT BANKING, REFERRALS, AND FEES FOR SERVICE

Zacks SCR does not provide nor has received compensation for investment banking services on the securities covered in this report. Zacks SCR does not expect to receive compensation for investment banking services on the Small-Cap Universe. Zacks SCR may seek to provide referrals for a fee to investment banks. Zacks & Co., a separate legal entity from ZIR, is, among others, one of these investment banks. Referrals may include securities and issuers noted in this report. Zacks & Co. may have paid referral fees to Zacks SCR related to some of the securities and issuers noted in this report. From time to time, Zacks SCR pays investment banks, including Zacks & Co., a referral fee for research coverage.

Zacks SCR has received compensation for non-investment banking services on the Small-Cap Universe, and expects to receive additional compensation for non-investment banking services on the Small-Cap Universe, paid by issuers of securities covered by Zacks SCR Analysts. Non-investment banking services include investor relations services and software, financial database analysis, advertising services, brokerage services, advisory services, equity research, investment management, 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 of services contracted. Fees typically range between ten thousand and fifty thousand USD per annum.

POLICY DISCLOSURES

Zacks SCR Analysts are restricted from holding or trading securities placed on the ZIR, SCR, or Zacks & Co. restricted list, which may include issuers in the Small-Cap Universe. ZIR and Zacks SCR do not make a market in any security nor do they act as dealers in securities. Each Zacks SCR Analyst has full discretion on the rating and price target based on his or her own due diligence. Analysts are paid in part based on the overall profitability of Zacks SCR. Such profitability is derived from a variety of sources and includes payments received from issuers of securities covered by Zacks SCR for services described above. No part of analyst compensation was, is or will be, directly or indirectly, related to the specific recommendations or views expressed in any report or article.

ADDITIONAL INFORMATION

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

ZACKS RATING & RECOMMENDATION

ZIR uses the following rating system for the 1072 companies whose securities it covers, including securities covered by Zacks SCR:
Buy/Outperform: The analyst expects that the subject company will outperform the broader U.S. equity market over the next one to two quarters.
Hold/Neutral: The analyst expects that the company will perform in line with the broader U.S. equity market over the next one to two quarters.
Sell/Underperform: The analyst expects the company will underperform the broader U.S. Equity market over the next one to two quarters.

The current distribution is as follows: Buy/Outperform- 16.7%, Hold/Neutral- 76.0%, Sell/Underperform – 6.3%. Data is as of midnight on the business day immediately prior to this publication.