Zacks Small-Cap Research

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Titan Pharmaceuticals, Inc. (TTNP-OTCQB)

TTNP: Confirmatory Phase 3 Trial To Start Shortly, Offer Data Mid-2015…

Current Recommendation	**Buy**
Prior Recommendation	N/A
Date of Last Change	06/01/2011
Current Price (05/15/14)	$0.65
Target Price	**$1.50**

UPDATE

We continue to believe Probuphine will eventually receive U.S. approval, now forecasted to occur during the first half 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.

SUMMARY DATA

52-Week High	**$1.16**
52-Week Low	**$0.44**
One-Year Return (%)	**25.83**
Beta	**14.26**
Average Daily Volume (sh)	**101,000**
Shares Outstanding (mil)	**83**
Market Capitalization ($mil)	**$53**
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 E	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	-$0.02 E	-$0.02 E	-$0.02 E	-$0.08 E
2015					-$0.09 E
2016					$0.08 E

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WHAT'S NEW

Financial & Business Update

On May 15, 2014, Titan Pharmaceuticals reported financial results for the first quarter ending March 31, 2014. The company reported total revenues of $0.9 million in first quarter. Revenues related to 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 first quarter totaled $1.8 million, equating to a loss of $0.02 per share. Net cash burn in the quarter totaled $1.6 million. Titan Pharma exited March 2014 with $10.2 million in cash and investment. 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 April 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 To Start Shortly

On March 3, 2014, Titan and Braeburn announced they had agreed in principle with the U.S FDA on a path forward for Probuphine, an investigational subdermal implant for the maintenance treatment of opioid dependence. The news comes a few months after Titan and Braeburn attended a face-to-face meeting with the agency in November 2013. The goals of that meeting were to review and discuss existing data, and to better understand the issues of the April 2013 complete response letter.

The agreement includes the design of a clinical study in support of re-filing the NDA for Probuphine. The study, which was submitted for FDA review in mid-March by Braeburn, is expected to begin enrollment by mid-year 2014, and study completion is anticipated by the middle of 2015. 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 are expected to 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.…

While Braeburn is preparing to initiate the confirmatory Phase 3 study in the U.S., 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.

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 E	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	$1.1	$1.3	$1.4	$4.7	$6.0	$5.0
SG&A	$3.1	$0.9	$0.8	$0.9	$0.9	$3.5	$4.0	$4.0
Operating Income	($0.9)	($0.9)	($1.0)	($1.3)	($1.4)	($4.6)	($8.3)	$9.5
Operating Margin	*-8.5%*	-	-	-	-	-	-	-
Total Other Income	$10.6	($0.9)	($0.5)	($0.5)	($0.5)	($2.4)	($1.5)	($1.0)
Pre-Tax Income	$9.7	($1.8)	($1.5)	($1.8)	($1.9)	($7.0)	($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)	($1.5)	($1.8)	($1.9)	($7.0)	($9.8)	$8.5
Net Margin	*92.7%*	-	-	-	-	-	-	-
Reported EPS	**$0.12**	**($0.02)**	**($0.02)**	**($0.02)**	**($0.02)**	**($0.08)**	**($0.09)**	**$0.08**
YOY Growth	*-179.2%*	*-129.3%*	*-127.4%*	*45.5%*	*702.8%*	*-166.9%*	*18.9%*	*-182.8%*
Weight Ave. Shares Out	82.7	88.9	89.1	89.2	89.2	89.1	105.0	110.0

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

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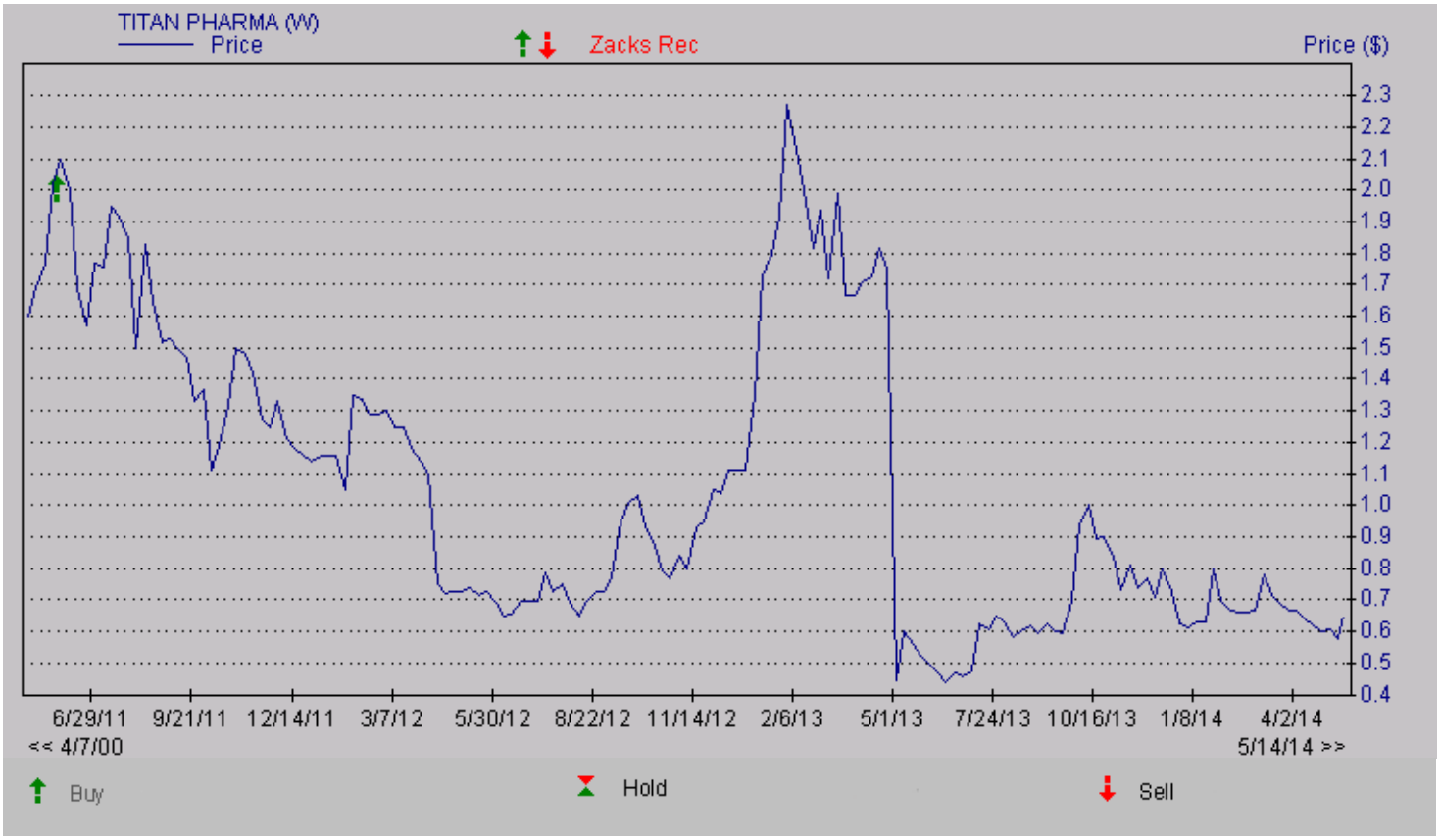

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