Zacks Small-Cap Research

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Titan Pharmaceuticals, Inc. (TTNP-OTCQB)

TTNP: Confirmatory Phase 3 Enrolling Well, Data Expected Mid-2015…

Current Recommendation	**Buy**
Prior Recommendation	N/A
Date of Last Change	06/01/2011
Current Price (11/14/14)	$0.46
Target Price	**$1.00**

UPDATE

On November 14, 2014, Titan Pharmaceuticals reported financial results for the third quarter ending September 30, 2014. The company reported total revenues of $0.9 million in quarter. Revenues reflected the amortization of upfront payments from Probuphine commercialization partner, Braeburn Pharmaceuticals. Importantly, during the third 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 $1.00 price target, which is roughly 120% upside from today's price.

SUMMARY DATA

52-Week High	**$0.95**
52-Week Low	**$0.45**
One-Year Return (%)	**-42.64**
Beta	**1.76**
Average Daily Volume (sh)	**172,136**
Shares Outstanding (mil)	**110**
Market Capitalization ($mil)	**$50**
Short Interest Ratio (days)	**0.25**
Institutional Ownership (%)	**19**
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 A	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	$0.01 A	-$0.01 E	-$0.04 E
2015					-$0.08 E
2016					$0.08 E

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WHAT'S NEW

Financial & Business Update

On November 14, 2014, Titan Pharmaceuticals reported financial results for the third quarter ending September 30, 2014. The company reported total revenues of $0.9 million in quarter. Revenues reflected the amortization of upfront payments from Probuphine commercialization partner, Braeburn Pharmaceuticals. Operating expenses in the quarter totaled $1.6 million, comprised of $0.8 million in both R&D and G&A. The company reported a $1.5 million non-cash gain during the quarter resulting from revaluation of outstanding warrants. This resulted in a net gain in the quarter of $0.7 million, or $0.01 per share.

Net cash burn in the quarter totaled $1.4 million. Titan Pharma exited September 30, 2014 with $7.5 million in cash and investments. On October 8, 2014, Titan closed a public offering of 21.0 units at an offering price of $0.50 per unit, raising net proceeds of approximately $9.6 million. One unit included one share and 0.75 warrants. The warrants are exercisable at $0.60 per share. These funds, together with the cash on hand at September 30, 2014, are sufficient to support Titan's planned operations into the fourth quarter of 2016.

We were a little surprised to see the public offering noted above. We had previously believed that Braeburn Pharmaceuticals would make another equity investment in the company. Prior to the public offering, Braeburn owned 10.9% of the outstanding shares. We believed, incorrectly, that Braeburn would want to keep ownership around the 10% range, and thus not want to see Titan conduct a public offering. This was not the case. Post the offering, Braeburn now owns 8.8% of the basic outstanding shares and 7.0% of the fully-diluted count.

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.

As of the end of the third quarter 2014, enrollment has surpassed the 50% market. Titan expects that fully enrollment will complete in the next few weeks. 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.

…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 upfront cash.

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 ropinirole for the treatment of Parkinson's Disease.

Ropinirole was previously sold as Requip by GlaxoSmithKline for the treatment of Parkinson's Disease (PD) and Restless Leg Syndrome (RLS). GlaxoSmithKline posted peak sales of Requip XL, and extended release formulation of ropinirole, of $250 million in 2010. The goal of the ProNeura formulation is to slowly release, at continuous levels, ropinirole through the process of dissolution. 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.

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 in 2016, 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.

PROJECTED FINANCIALS

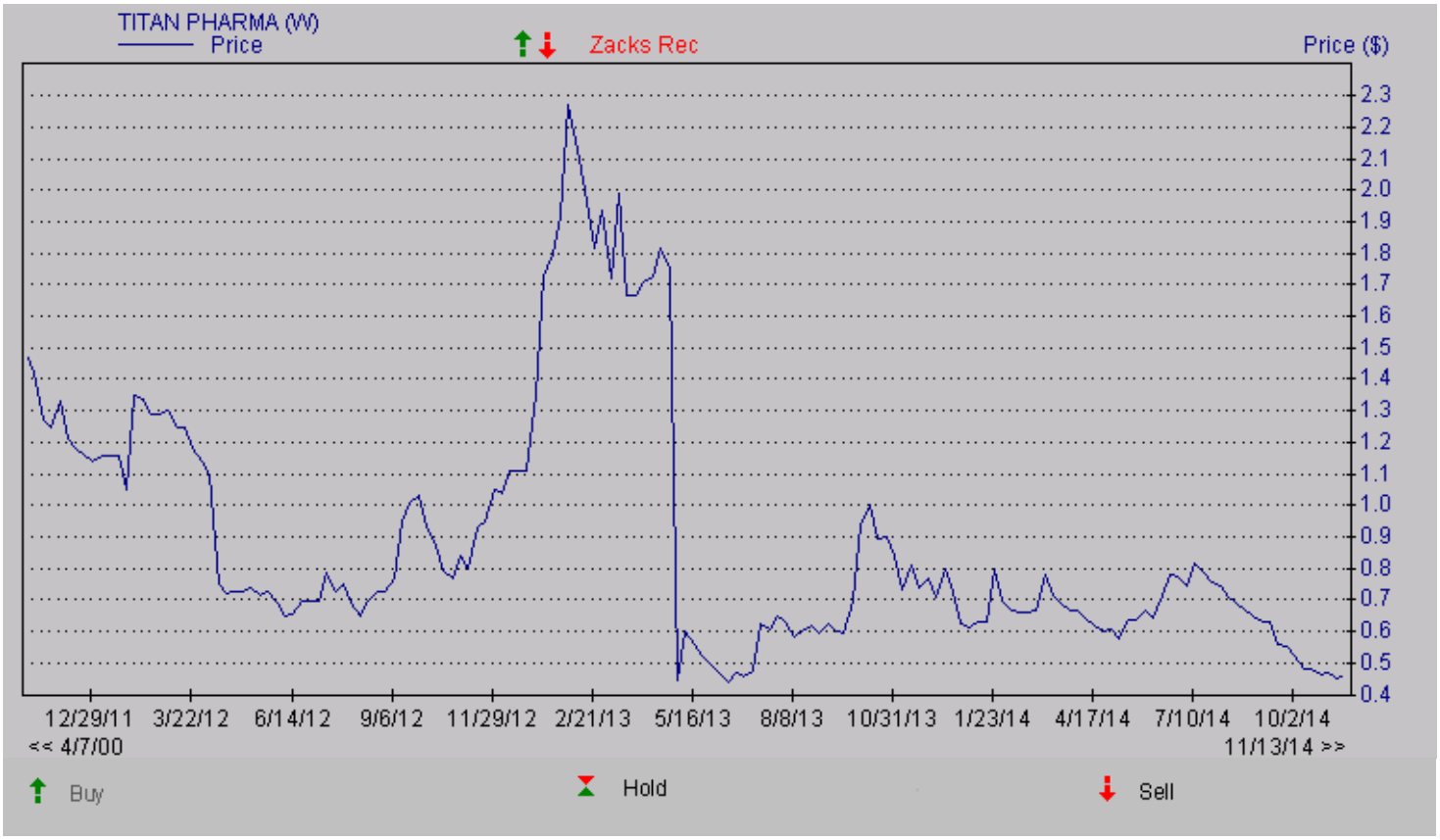
Titan Pharmaceuticals, Inc.
Income Statement

Titan Pharma	2013 A	Q1 A	Q2 A	Q3 A	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	$0.8	$0.9	$3.4	$4.5	$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)	($0.7)	($0.9)	($3.1)	($6.8)	$9.5
Operating Margin	*-8.5%*	-	-	-	-	-	-	-
Total Other Income	$10.6	($0.9)	($0.3)	$1.5	($0.5)	($0.2)	($1.5)	($1.0)
Pre-Tax Income	$9.7	($1.8)	($0.8)	$0.7	($1.4)	($3.3)	($8.3)	$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)	$0.7	($1.4)	($3.3)	($8.3)	$8.5
Net Margin	*92.7%*	-	-	-	-	-	-	-
Reported EPS	**$0.12**	**($0.02)**	**($0.01)**	**$0.01**	**($0.01)**	**($0.04)**	**($0.08)**	**$0.08**
YOY Growth	*-179.2%*	*-129.3%*	*-115.4%*	*-157.8%*	*378.1%*	*-130.0%*	*125.0%*	*-197.5%*
Weight Ave. Shares Out	82.7	88.9	89.0	89.4	110.4	94.4	105.0	110.0

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

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