Zacks Small-Cap Research

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Titan Pharmaceuticals, Inc.

(TTNP-OTCQB)

TTNP: Phase 3 Nears Completion; Still On Track for Probuphine NDA Re-File for the 2nd Half of 2015

Current Recommendation	**Buy**
Prior Recommendation	N/A
Date of Last Change	06/01/2011
Current Price (05/14/15)	$0.73
Target Price	**$1.00**

UPDATE

Titan is still on track to complete the confirmatory Phase 3 study of Probuphine by mid-2015, and we expect to see data from the trial shortly thereafter. If all goes well, the refiling of the NDA will occur before the end of 2015. We think that the FDA will respond to the application within six months, potentially putting a new PDUFA date for the Probuphine NDA in the first half of 2016. We continue to believe that Probuphine will eventually receive U.S. approval, forecasted to occur during the first half of 2016. Additionally, Titan plans to complete non-clinical studies to enable timely submission of the IND in the first half of 2016, and commence a proof-of-concept clinical study in the second half of 2016 for its ProNeura Parkinson's Disease Program. We remain positive on the Titan Pharma story and are maintaining our "Buy' rating with a price target of $1.00 per share.

SUMMARY DATA

52-Week High	**$0.85**
52-Week Low	**$0.45**
One-Year Return (%)	**14.51**
Beta	**1.82**
Average Daily Volume (sh)	**263,538**
Shares Outstanding (mil)	**110**
Market Capitalization ($mil)	**$82**
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 2015 Estimate	**N/A**
P/E using 2016 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)
2014	0.9 A	0.9 A	0.9 A	0.9 A	3.6 A
2015	0.9 A	0.8 E	0.0 E	0.0 E	1.7 E
2016					17.8 E
2017					14.7 E

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

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2014	-$0.02 A	-$0.01 A	$0.01 A	$0.00 A	-$0.03 A
2015	-$0.04 A	-$0.02 E	-$0.03 E	-$0.03 E	-$0.11 E
2016					$0.06 E
2017					$0.01 E

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WHAT'S NEW

Financial & Business Update

On May 13, 2015, Titan Pharmaceuticals reported financial results for the first quarter of 2015. The company reported total revenues of $0.9 million, which was consistent with all four quarters in 2014. Revenues reflected the amortization of upfront payments from Probuphine commercialization partner, Braeburn Pharmaceuticals in December 2012. This was slightly above our expectations as were assuming that the remaining $1.7 million left to be paid by Braeburn would be split evenly over all four quarters in 2015, and so we are now projecting that the remaining $0.8 million will all be reflected in the second quarter of 2015.

Operating expenses for the first quarter totaled $2.5 million, comprised of $1.4 million in R&D and $1.1 million in G&A, and were above our expectations. R&D costs were higher than expected due to increases in external expenses associated with the completion of the Probuphine® product development program, and the preparation and review of the Probuphine® NDA prior to the receipt of the complete response letter (CRL) in April 2013, as well as the ProNeura product development program. The increases in G&A expenses in the first quarter were due to higher non-cash stock compensation, and employee-related costs. We remind investors that the majority of the costs associated with the current clinical program are borne by Braeburn Pharmaceuticals, as per the terms of the amended license agreement.

Net other expense for the first quarter of 2015 was $3.3 million, compared with $0.9 million for the same period in 2014, and consisted of non-cash losses on changes in the fair value of warrants. Net loss for the first quarter 2015 was $4.9 million, or $0.04 per share, compared to $1.8 million, or $0.02 per share in the same quarter in 2014.

Net cash burn in the quarter totaled $2 million. Titan exited the first quarter of 2015 with approximately $13.4 million in cash. As a reminder, 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. We believe that these funds, together with the cash on hand at the end of the first quarter, are sufficient to support Titan's planned operations into the fourth quarter of 2016.

Phase 3 Study Nearing Completion with Data Still Expected in Mid-2015



Source: Titan Pharmaceuticals, Inc.

On November 20, 2014, Titan announced completion of enrollment in the Phase 3 clinical study (PRO-814) to support resubmission of the New Drug Application (NDA) for Probuphine. Enrollment of the study was completed in little over four months, almost two months ahead of Titan's schedule. The study is designed to address key questions that were posed by the FDA and its complete response letter (CRL) in 2013 after the review of the original NDA.

The PRO-814 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. Patients will be randomized to receive either four Probuphine implants, or to continue the daily sublingual buprenorphine therapy. 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. The patients will be treated for six months, and the primary analysis will be a non-inferiority comparison of responders in the two arms.



We still expect the study to be completed by mid-2015, and that results will be available shortly thereafter, as soon as June 2015. We remind investors that Braeburn is funding this study, with Titan continuing to provide logistical support. During the quarter, Titan continued to support Braeburn in the clinical and CMC regulatory preparation activities of the Probuphine platform including the manufacturing activities associated with the validation of the manufacturing process. If all goes well and the Phase 3 results are positive, we expect to see a refiling of the NDA before the end of 2015. We think that the FDA will respond to the application within six months, potentially putting a new PDUFA date for the Probuphine NDA in the first half of 2016.

…Titan Still Looking Ex-U.S….

With the confirmatory Phase 3 study nearing completion, 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. Management plans on initiating regulatory discussions outside of the U.S. following release of PRO-814 Phase 3 clinical data later in the year. Furthermore, management expects to have some meetings scheduled before the end of the year with at least two or three different local health authorities in Europe. 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. However, management did state that countries that use buprenorphine stand out, such as Australia, France, Germany, U.K., Italy and some Scandinavian and Asian countries, and that there is early interest in these markets. We suspect 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.

Moving Forward With ProNeura In Parkinson's Disease

Titan's ProNeura technology 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 (PD). Titan brought on two new board members in November 2014 to assist with the expanding product pipeline.

Ropinirole was previously sold as Requip by GlaxoSmithKline for the treatment of Parkinson's Disease 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 and has commenced work on optimizing an implant formulation of ropinirole. This work, along with input from key scientific and regulatory advisors, is helping Titan plan the non-clinical studies and an appropriate proof-of-concept clinical study.

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. In addition to the U.S., Titan has similar issued patents in Europe, Japan, Australia, Canada, South Korea, Mexico, New Zealand, South Africa, and Hong Kong, while prosecution of patent applications continues in the U.S., Israel, India, and China.

Titan will continue to aggressively pursue its ProNeura Parkinson's Disease program throughout 2015 and 2016. Titan plans to complete non-clinical studies to enable timely submission of the IND in the first half of 2016, and commence a Phase 1 proof-of-concept safety and efficacy clinical study in the second half of 2016, following potential approval of Probuphine. As per management, the plan is to possibly meet with the FDA for a pre-IND meeting by the end of 2015. 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.

The Potential for ProNeura Expansion to Other Indications in the Near Future

It's also worth mentioning that Titan continues to look for additional product opportunities, and to expand the use of its ProNeura platform. Although Probuphine, and the ProNeura Parkinson's Disease program continue to remain of highest priority for Titan, the company has also been looking at delivering additional peptides, small molecules, and different types of compounds through the ProNeura drug delivery platform system. The funding generated from the Probuphine milestones is allowing Titan to explore these additional programs. Management noted that there a wide variety of compounds that have been evaluated to date, and the company is now in the process of narrowing down areas that it feels a chronic treatment would make the most sense to further explore. Later this year, we may get more details about an additional product that Titan is evaluating. This is a product that management believes may get into the clinic two or three quarters behind ropinirole. We look forward to hearing more details regarding expansion of the ProNeura drug delivery system in the upcoming quarters.

Conclusion

We continue to be positive on the Titan Pharma story, and are looking forward to seeing results from the Phase 3 Probuphine trial. We believe that if this confirmatory Phase 3 trial proves successful, the NDA will be back under priority review by the end of 2015, with a potential new PDUFA date for the first half of 2016. We still see the shares worth $1.00 right now, with upside to the $2.00 level after the Phase 3 data comes out in mid-2015.

PROJECTED FINANCIALS

Titan Pharmaceuticals, Inc.
Income Statement

Titan Pharma	2014 A	Q1 A	Q2 E	Q3 E	Q4 E	2015 E	2016 E	2017 E
Probuphine Royalty	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$2.8**	**$14.7**
YOY Growth	-	-	-	-	-	-	-	-
Licensing & Grant Revenue	**$3.6**	**$0.9**	**$0.8**	**$0.0**	**$0.0**	**$1.7**	**$15.0**	**$0**
Total Revenues	**$3.6**	**$0.9**	**$0.8**	**$0.0**	**$0.0**	**$1.7**	**$17.8**	**$14.7**
YOY Growth	-	-	-	-	-	-	-	-
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	$4.1	$1.4	$1.1	$1.2	$1.3	$5.0	$5.0	$6.0
SG&A	$3.0	$1.1	$0.9	$1.1	$1.1	$4.2	$4.0	$5.0
Operating Income	($3.5)	($1.6)	($1.2)	($2.3)	($2.4)	($7.5)	$8.8	$3.7
Operating Margin	-	-	-	-	-	-	-	-
Total Other Income	$1.1	($3.3)	($0.5)	($0.5)	($0.5)	($4.8)	($2.0)	($2.0)
Pre-Tax Income	($2.4)	($4.9)	($1.7)	($2.8)	($2.9)	($12.3)	$6.8	$1.7
Taxes & Other	$0	$0	$0	$0	$0	$0	$0	$0.6
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*35%*
Net Income	($2.4)	($4.9)	($1.7)	($2.8)	($2.9)	($12.3)	$6.8	$1.1
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($0.03)**	**($0.04)**	**($0.02)**	**($0.03)**	**($0.03)**	**($0.11)**	**$0.06**	**$0.01**
YOY Growth	*-121.8%*	*118.8%*	*63.7%*	*-414.9%*	*493.3%*	*333.2%*	*-151.4%*	*-85.3%*
Weight Ave. Shares Out	93.8	110.3	110.5	111.0	112.0	111.0	120.0	130.0

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

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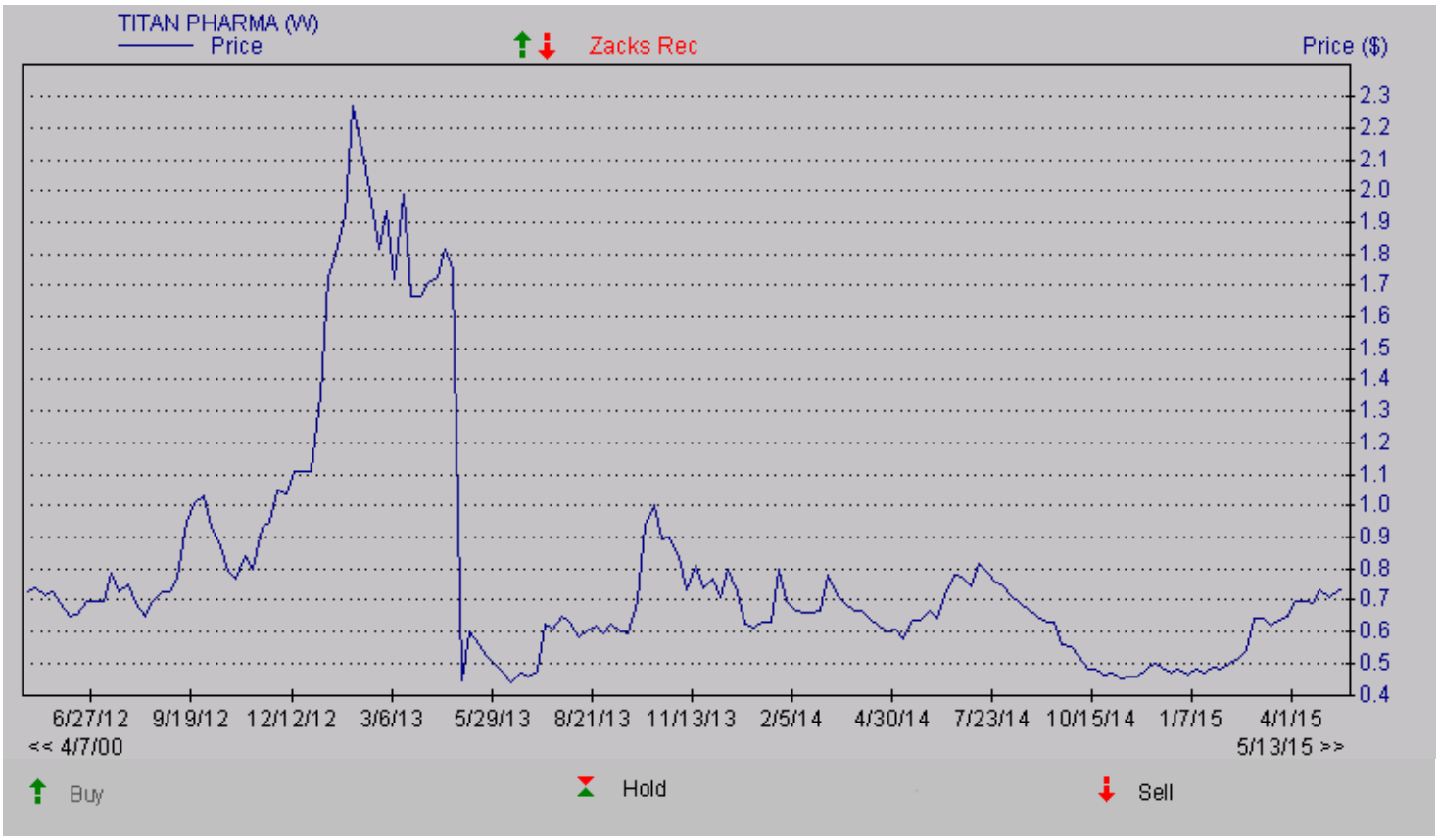

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