Zacks Small-Cap Research

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Titan Pharmaceuticals, Inc.

(TTNPD-OTC)

TTNP: FDA Accepts Resubmission of NDA for Probuphine®

Current Recommendation	**Buy**
Prior Recommendation	N/A
Date of Last Change	06/01/2011
Current Price (10/05/15)	$3.90
Target Price	**$8.25**

UPDATE

On September 28, 2015, Titan Pharmaceuticals, Inc. (OTC: TTNP; TTNPD) announced that the FDA accepted the resubmission of the NDA for Probuphine®, which was filed at the end of August 2015. With the PDUFA date set for February 27, 2016, we believe that Probuphine is on track to receive FDA approval this time around. Titan also announced a 1-to-5.5 reverse stock split in preparation for uplisting to the NASDAQ.

Titan continues to move forward with the ProNeura in Parkinson's Disease program, and the company recently reported additional chronic disease states that it is evaluating for the potential for ProNeura platform expansion.

With both late and early-stage programs utilizing the ProNeura platform under way, we continue to remain optimistic regarding the Titan Pharma story and re-iterate our "Buy' rating and $8.25 price target to reflect the recent reverse stock split.

SUMMARY DATA

52-Week High	**$4.90**
52-Week Low	**$2.48**
One-Year Return (%)	**35.05**
Beta	**1.87**
Average Daily Volume (sh)	**30,225**
Shares Outstanding (mil)	**20**
Market Capitalization ($mil)	**$78**
Short Interest Ratio (days)	**0.25**
Institutional Ownership (%)	**0**
Insider Ownership (%)	**6**
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 A	0.0 E	0.0 E	1.7 E
2016					19.1 E
2017					21.3 E

Earnings per Share

(EPS is operating earnings before non-recurring items)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2014	-$0.11 A	-$0.05 A	$0.04 A	-$0.02 A	-$0.14 A
2015	-$0.24 A	-$0.11 A	-$0.14 E	-$0.14 E	-$0.64 E
2016					$0.39 E
2017					$0.39 E

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WHAT'S NEW

Financial and Business Update

Preparing for NASDAQ Uplisting

On September 28, 2015, Titan Pharmaceuticals, Inc. (OTC: TTNP; TTNPD) announced a 1-for-5.5 reverse stock split which became effective on September 29, 2015 in anticipation of uplisting to the NASDAQ. This decreased the number of common shares outstanding from approximately 110 million to approximately 20 million. The reverse stock split satisfies one of the initial requirements for uplisting to the NASDAQ. Titan's application for listing on the NASDAQ has been submitted, and we believe it is in the final stages of the review process. Titan's common stock will temporarily trade under the ticker symbol "TTNPD" under the new CUSIP number 888314 309. If the uplisting is approved, this will be an important milestone for the company as it will both increase liquidity in Titan shares as well as enhance the company's profile among potential investors.

NDA for Probuphine® Accepted for Review

On September 28, 2015, Titan also announced that the U.S. Food and Drug Administration (FDA) accepted the resubmission of the New Drug Application (NDA) for Probuphine® for six-month priority review. We had anticipated this event to occur prior to year end and thus, we are pleased with the results occurring in the third quarter of 2015. With the PDUFA date set for February 27, 2016, we believe that Probuphine is on track to receive FDA approval this time around. Titan announced resubmission of the NDA for Probuphine for the maintenance treatment of opioid addiction by Braeburn Pharmaceuticals to the FDA on August 31, 2015. The Probuphine NDA resubmission included results from a Phase 3 double-blind, double-dummy study that we review below. The study met the pre-specified primary endpoint of non-inferiority in addition to secondary efficacy endpoints. We previously mentioned that we believed that the positive Phase 3 data cleared the way for a re-filing of the U.S. New Drug Application (NDA) in the near term, and are pleased to see that things are moving along as expected.

Titan Goes 3-for-3 in Phase 3

As a reminder to investors, Titan reported positive topline results from a confirmatory Phase 3 study with Probuphine in subjects with opioid addiction on June 8, 2015. This is the third positive Phase 3 trial for the company since 2011.

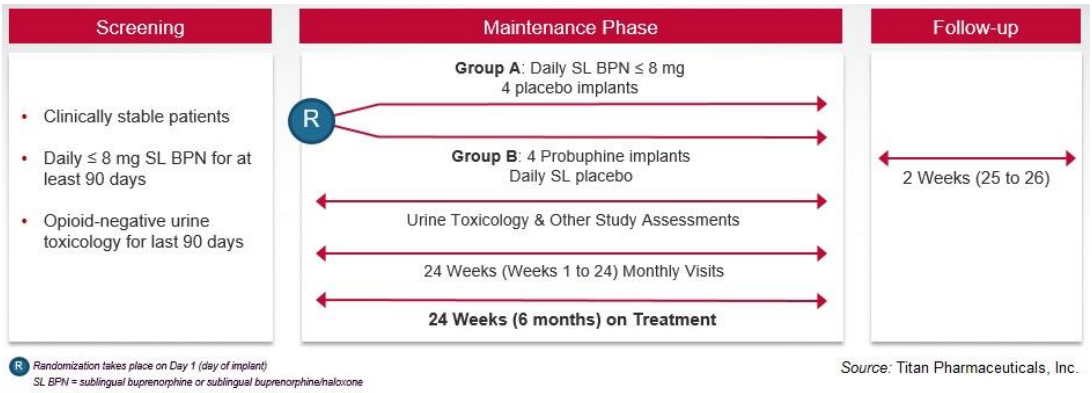
Titan had previously completed two Phase 3 safety and efficacy trials on the drug with both showing superiority over placebo implants and non-inferiority to sublingual buprenorphine/naloxone for the treatment of opioid addiction (1stP3, 2ndP3). The company also conducted two open label long-term treatment safety studies and one relative bioavailability study. Titan filed for U.S. approval in October 2012, and along with commercialization partner, Braeburn Pharmaceuticals, was granted priority review by the agency in January 2013. In March 2013, the FDA's Psychopharmacologic Drugs Advisory Committee (PDAC) voted (10-4) to recommend approval of the product; however, the FDA issued a complete response letter (CRL) in April 2013, requesting additional data on the use of the product in patients stable on lower doses of sublingual buprenorphine/naloxone than previously tested in the first two Phase 3 clinical trials.

The positive topline data from the third Phase 3 trial released in June 2015 only further strengthens the company's claim that Probuphine is a safe and highly effective product for the treatment of opioid addiction. Probuphine is an ethylene-vinyl acetate (EVA) polymer that has been designed to elute buprenorphine over a controlled period of time. The product is extruded into rods roughly the size of a matchstick and implanted in the arms of opioid addicts.



Source: Titan Pharmaceuticals, Inc.

The confirmatory Phase 3 trial (PRO-814) was designed to show that patients currently taking ≤ 8 mg sublingual buprenorphine/naloxone and stable in their absence can be transitioned to Probuphine and maintain absence in a safe and effective manner. The study was a randomized, double blind, double dummy design that enrolled 177 patients into two parallel treatment arms. Patients were randomized to receive either four Probuphine implants, or to continue the daily sublingual buprenorphine therapy. The patients were treated for six months, and the primary analysis was a non-inferiority comparison of responders in the two arms.



In the trial, a responder was defined as having at least four out of six months free of illicit opioids based on urine testing and subject self-report. Analyses conducted according to the pre-planned Statistical Analysis Plan indicated response rates of 96.4% for the Probuphine arm and 87.6% for the sublingual buprenorphine/naloxone arm. The two-sided 95% confidence interval (0.009, 0.167) of the treatment difference (Probuphine - sublingual buprenorphine/naloxone) was well within the pre-defined successful margin for non-inferiority. In fact, sequential analysis showed that Probuphine was clinically superior to sublingual buprenorphine/naloxone ($p < 0.05$).

Titan PRO-814	Probuphine Implants (n=84)	Sublingual Buprenorphine/Naloxone (n=89)
4 of 6 Tests Opioid Free	96.4% [1]	87.6%
6 of 6 Tests Opioid Free	88.1% [2]	71.9%
Implant Site Adverse Event	23.0%	13.5%

1 = $p < 0.005$ (confirmed non-inferior)

2 = $p = 0.008$ (confirmed superior)

No additional data was provided in the press release, as Titan plans to present the full data from the PRO-814 at a medical conference in the near future. However, on the June conference call Titan did note that one patient had an adverse event and needed to have the implant removed. We are not overly concerned with an adverse event rate of +0.6% (1 out of 173 patients that received implants). We note that there was no diversion (authorized implant removal) during the trial, consistent with what has been seen throughout the entire clinical program with Probuphine.

The Probuphine® NDA resubmission included results from the Phase 3 trial that we mentioned above. The NDA is now accepted for priority review by the FDA, and the new action date is set for February 27, 2016. We continue to remain optimistic, and are expecting approval at that time. As a reminder, approval earns Titan a $15.0 million milestone from Braeburn, and we believe that this will help fund the rest of the developmental programs, which we will discuss below.

Titan Continues to Look Ex-U.S.

Titan continues to pursuing ex-U.S. approval and commercialization opportunities for Probuphine. Management is in the process of engaging with key opinion leaders and regulatory consultants outside the U.S. in areas where Probuphine may be an attractive product. We still believe that 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 before U.S. approval. This is positive news for shareholders because any deal for development or commercialization of Probuphine outside of the Braeburn territory could come with upfront cash.

More Attention on the Epidemic of Opioid Dependence

Opioid abuse, addiction and dependence remain major public health and social challenges, especially in the United States. It is estimated that between 26 million and 36 million individuals worldwide abuse opioids (UNODC, World Drug Report 2012) with approximately 2.1 million people in the U.S. suffering from substance use disorders related to prescription opioid pain relievers in 2012, and an estimated 467,000 suffering with heroin addition (National Survey on Drug Use and Health, 2012). Opioid dependence is increasingly being recognized as a global epidemic by various health authorities.

On September 17, 2015, U.S. Health and Human Services Department (HHS) Secretary Sylvia Burwell announced that HHS plans to revise the regulations surrounding the prescribing of buprenorphine to allow for expanded access to medication-assisted treatment (MAT) for the treatment of opioid dependence. Currently, there is a limit to the number of patients that can be treated with buprenorphine products by certified physicians. This cap restricts availability to these important and often life-saving medication-assisted therapies. The HHS revision aims to "provide a balance between expanding the supply of this important treatment, encouraging use of evidence-based MAT, and minimizing the risk of drug diversion." We see this as good news for Titan and Probuphine, as federal officials are aiming to address the opioid epidemic in an effort to offer greater access to safe and effective treatment options for opioid maintenance. If approved, we see the potential for Probuphine to help address the nation's opioid abuse epidemic, which is consistent with HHS's objectives.

Moving Forward with ProNeura in Parkinson's Disease

With Titan advancing its development plans for ProNeura-ropinirole product for Parkinson's disease, we believe that the company remains on track to submit briefing material to the FDA in the fourth quarter of 2015 to support a pre-IND meeting. Titan plans to complete non-clinical safety and pharmacological 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.

The product is similar to Probuphine, only instead of the EVA rods eluting buprenorphine, they are eluting ropinirole. Ropinirole was previously sold as Requip by GlaxoSmithKline for the treatment of Parkinson's disease and Restless Leg Syndrome (RLS). 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 design an appropriate proof-of-concept clinical study.

On June 17, 2015, Titan presented non-clinical data in the form of a poster titled "Continuous Delivery of Ropinirole by Subdermal ProNeura™ Implants," at the 19th International Congress of Parkinson's Disease and Movement Disorders. The dose-escalating study in Parkinsonian primates showed that motor function could be improved with no onset of dyskinesias (involuntary movements), following the continuous, non-fluctuating release of ropinirole with the ProNeura platform. Management stated that there were no observed signs of irritation, inflammation or fibrotic capsule formation at the site of implantation, with continuous, non-fluctuating release of ropinirole being observed for a period of several months following implantation. We believe that these early stage results of ProNeura with ropinirole are encouraging, and although it is still quite early, we are interested in watching the story unfold and seeing if the ProNeura-ropinirole product can indeed provide continuous, non-fluctuating therapeutic drug levels for several months from one treatment in human trials.

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.

Potential ProNeura Expansion to Other Chronic Disease States

As mentioned in previous updates, Titan had been looking for additional product opportunities, and to expand the use of its ProNeura platform. At the Rodman & Renshaw 17th Annual Global Investment Conference that took place in September 2015, Titan mentioned the potential for ProNeura expansion for the treatment of select chronic diseases for which low-dose, long-term delivery and stable drug levels may offer advantages over oral administration. Titan is currently evaluating additional compounds in other chronic disease settings such as hormonal deficiencies, type 2 diabetes, attention deficit hyperactivity disorder (ADHD), benign prostatic hyperplasia (BPH), and pre-exposure prophylaxis therapy for HIV-1 prevention. We believe Titan is conducting early feasibility studies with potential ProNeura compounds and that at least one additional product candidate will be added to the pipeline by the end of 2015. Although it is early, we do see upside in ProNeura expansion to select chronic disease settings, especially if Probuphine gets approved, and believe that this may present Titan with additional opportunities such as joint development projects and/or potential licensing of the ProNeura platform to other companies. We look forward to hearing more about the ProNeura expansion in the near future.

Conclusion

With positive Phase 3 data in place, the Probuphine NDA back under priority review with the FDA, and a new PDUFA date set for February 27, 2016, we see a clear path to approval this time around. We remain optimistic regarding the Titan story and also believe a NASDAQ uplisting is forthcoming. We believe uplisting to the NASDAQ will act as a catalyst to further drive institutional awareness to the Titan story.

Titan exited the second quarter of 2015 with approximately $11.5 million in cash. We believe that these funds are sufficient to support Titan's planned operations into the fourth quarter of 2016. By that time, we expect U.S. approval of Probuphine, which will net Titan a $15.0 million milestone payment from Braeburn, and additional potential sales milestones of up to $165 million and a tiered royalty based on a percentage of net sales from the mid-teens to the low twenties. We also believe that potential licenses outside the U.S. could occur in 2016, thus bringing in more non-dilutive cash to the company. Overall, we believe Titan is currently in a strong financial position, especially with the possibility of receiving the $15.0 million milestone payment from Braeburn.

We would also like to point out that Titan has also made progress in evaluating additional compounds that can be delivered in the ProNeura implant, and the company expects to add another product to the development pipeline by the end of 2015. We are looking forward to learning more about this product. With both late and early-stage programs utilizing the ProNeura platform under way, we see the shares worth $8.25 right now which reflect the recent reverse stock split, with potential upside upon Probuphine approval in early 2016. At this point, our model has very little contribution from ProNeura in Parkinson's disease or other chronic indications or in value for Probuphine outside the U.S. We believe these situations may also present additional upside to our financial model.

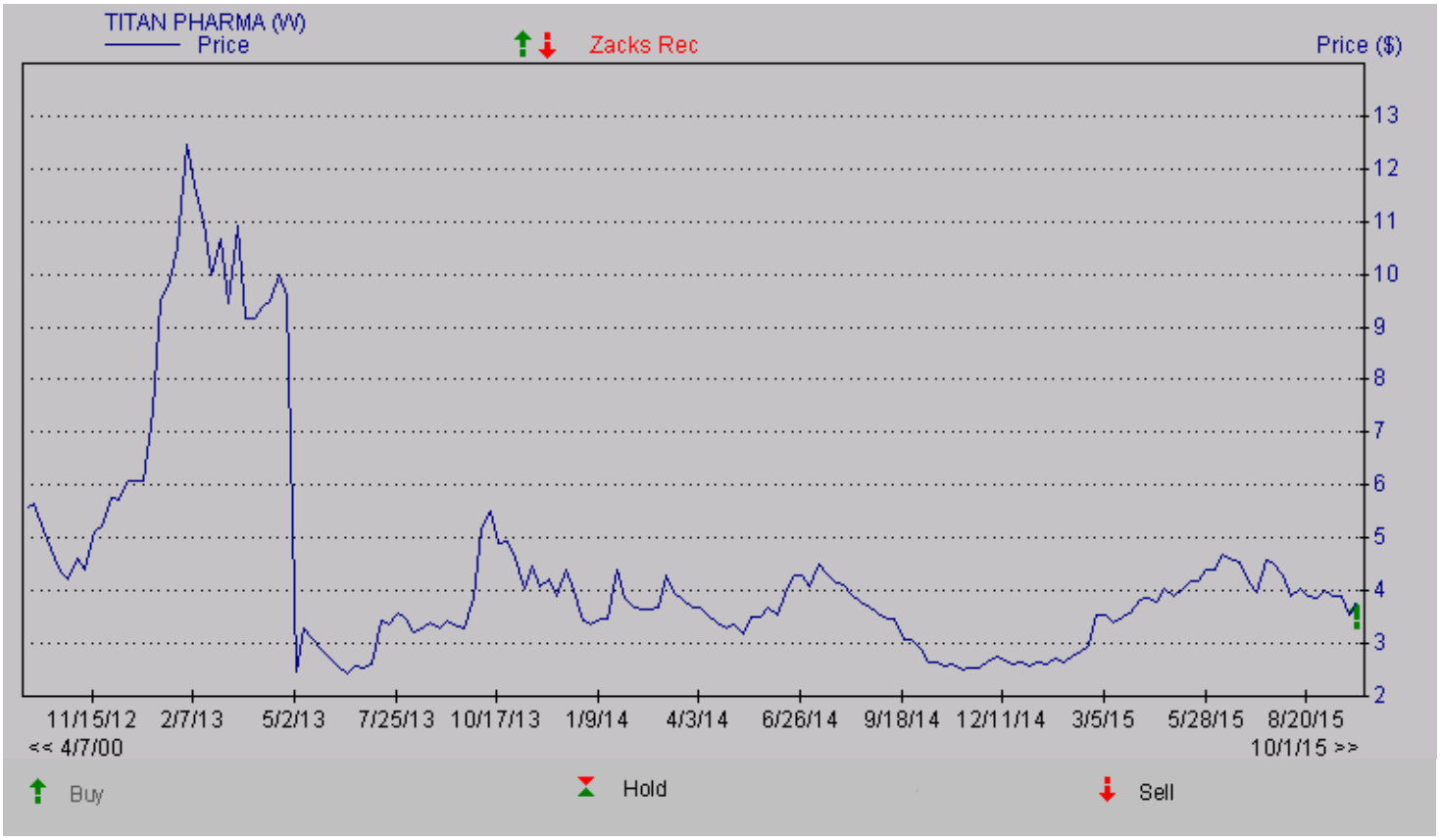
PROJECTED FINANCIALS

Titan Pharmaceuticals, Inc.
Income Statement

Titan Pharmaceuticals, Inc.	2014 A	Q1 A	Q2 A	Q3 E	Q4 E	2015 E	2016 E	2017 E	2018 E
Probuphine Royalty	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$4.1**	**$21.3**	**$37.2**
YOY Growth	-	-	-	-	-	-	-	-	-
Licensing & Grant Revenue	**$3.6**	**$0.9**	**$0.8**	**$0.0**	**$0.0**	**$1.7**	**$15.0**	**$0.0**	**$10.0**
Total Revenues	**$3.6**	**$0.9**	**$0.8**	**$0.0**	**$0.0**	**$1.7**	**$19.1**	**$21.3**	**$47.2**
YOY Growth	-	-	-	-	-	-	-	-	-
CoGS	$0	$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%*	*100.0%*
R&D	$4.1	$1.4	$1.1	$1.2	$1.3	$5.0	$5.0	$6.0	$6.0
SG&A	$3.0	$1.1	$0.8	$1.1	$1.1	$4.0	$4.0	$5.0	$6.0
Operating Income	($3.5)	($1.6)	($1.1)	($2.3)	($2.4)	($7.4)	$10.1	$10.3	$35.2
Operating Margin	-	-	-	-	-	-	-	-	-
Total Other Income	$1.1	($3.3)	($1.2)	($0.5)	($0.5)	($5.5)	($2.0)	($2.0)	($2.0)
Pre-Tax Income	($2.4)	($4.9)	($2.3)	($2.8)	($2.9)	($12.9)	$8.1	$8.3	$33.2
Taxes & Other	$0	$0	$0	$0	$0	$0	$0	$0	$0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	($2.4)	($4.9)	($2.3)	($2.8)	($2.9)	($12.9)	$8.1	$8.3	$33.2
Net Margin	-	-	-	-	-	-	-	-	-
Reported EPS	**($0.14)**	**($0.24)**	**($0.11)**	**($0.14)**	**($0.14)**	**($0.64)**	**$0.39**	**$0.39**	**$1.51**
YOY Growth	*-219.8%*	*118.8%*	*118.5%*	*-414.9%*	*493.3%*	*353.8%*	*-160.6%*	*-0.4%*	*290.9%*
Weight Ave. Shares Out	17.1	20.1	20.1	20.2	20.4	20.2	21.0	21.5	22.0

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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- 27.1%, Hold/Neutral- 55.0%, Sell/Underperform – 14.8%. Data is as of midnight on the business day immediately prior to this publication.