Zacks Small-Cap Research

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Titan Pharmaceuticals, Inc.

(TTNP-NASDAQ)

TTNP: Newly NASDAQ-listed Titan Moves Closer to Probuphine® Approval; Announces ProNeura-T3 for Hypothyroidism…

Current Recommendation	**Buy**
Prior Recommendation	N/A
Date of Last Change	06/01/2011
Current Price (11/17/15)	$4.17
Target Price	**$8.25**

UPDATE

On November 16, 2015, Titan Pharmaceuticals, Inc. (TTNP) reported financial results for the third quarter of 2015. Titan reported no revenues, and had a net loss of $1.8 million, or $0.09 per share for the quarter.

On September 28, 2015, Titan announced that the FDA accepted the resubmission of the NDA for Probuphine®. 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, and was recently uplisted to the NASDAQ. Additionally, Titan continues to move forward with the ProNeura in Parkinson's Disease program, and the company announced the addition of an implantable product for hypothyroidism to its pipeline while it continues to evaluate other chronic disease settings for potential 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 maintain our $8.25 price target.

SUMMARY DATA

52-Week High	**$4.90**
52-Week Low	**$2.48**
One-Year Return (%)	**64.81**
Beta	**1.73**
Average Daily Volume (sh)	**31,570**
Shares Outstanding (mil)	**20**
Market Capitalization ($mil)	**$84**
Short Interest Ratio (days)	**13.74**
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 A	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	-$0.09 A	-$0.14 E	-$0.59 E
2016					$0.39 E
2017					$0.39 E

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WHAT'S NEW

Financial & Business Update

On November 17, 2015, Titan Pharmaceuticals, Inc. (TTNP) reported financial results for the third quarter of 2015 ended September 30, 2015. The company reported no revenues in the third quarter of 2015. This was in-line with our expectations.

Operating expenses for the third quarter 2015 totaled $1.8 million, compared with approximately $1.7 million in the same quarter in 2014, and were lower than our expectations. The increase was driven primarily by higher research and development expenses totaling approximately $1.0 million in the third quarter of 2015, compared with approximately $0.8 million in the second quarter of 2014. This increase was associated with external research and development expenses related to the support of Titan's Probuphine® and ProNeura-ropinirole product development programs in addition to other R&D expenses and employee-related costs. General and administrative expenses for the third quarter of 2015 and 2014 were approximately $0.8 million and approximately $0.9 million, respectively. Both R&D and G&A expenses were slightly lower than our expectations.

Net other expenses for the third quarter of 2015 were approximately $5,000 compared with approximately $1.5 million for the same period in 2014, and consisted primarily of non-cash gains and losses on changes in the fair value of warrants. Net loss for the third quarter of 2015 was approximately $1.8 million, or approximately $0.09 per share, compared with net income of approximately $0.7 million, or approximately $0.04 per share in the same quarter in 2014.

Titan exited the third quarter of 2015 with approximately $9.7 million in cash. Net cash burn in the quarter totaled $1.8 million, and was slightly less than the cash burn in the first two quarters of 2015 (approximately $2 million). 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. We also believe that potential licenses outside the U.S. could occur in 2016, thus bringing in more non-dilutive cash to the company. All-in-all, we believe Titan is currently in a strong financial position, especially with the possibility of receiving the $15.0 million milestone payment from Braeburn.

Uplisted to the Nasdaq

On October 12, 2015, Titan's common stock began trading on the NASDAQ Capital Market. As a reminder, on September 28, 2015, Titan announced a 1-for-5.5 reverse stock split which became effective on September 29, 2015 in anticipation of uplisting to the NASDAQ, decreasing the number of common shares outstanding from approximately 110 million to approximately 20 million. The reverse stock split satisfied one of the initial requirements for uplisting to the NASDAQ. We believe the uplisting is an important milestone for the company as it increases liquidity in Titan shares as well as enhances 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 the Phase 3 double-blind, double-dummy study that we have reviewed in previous updates. 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.

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.

With the NDA 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 for Probuphine 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.

Opportunities Outside of the U.S.

Titan continues to pursue and prepare for ex-U.S. approval and commercialization opportunities for Probuphine. The most recent plan is for Titan to meet with a few different European regulatory authorities during the early part of 2016. It sounds like management prefers to wait for the outcome from the FDA regarding Probuphine approval prior to meeting with the regulatory authorities. If Probuphine is approved in the U.S., management believes it would make it a lot easier to achieve commercialization and approvals around the globe. We still believe that Titan is focused on areas such as the U.K., France, and Australia. However, we believe 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. We suspect that Titan may need to conduct new clinical studies prior to filing for Probuphine approval outside of the U.S. We will just have to continue to wait and see what happens along this front. Additionally, Titan continues to contact commercial groups that have expressed interest in the buprenorphine market. Any deal for development or commercialization of Probuphine outside of the Braeburn territory could come with upfront cash, which would be good news for investors.

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.

Introducing ProNeura in Hypothyroidism

On November 16, 2015, Titan announced the addition of an implantable triiodothyronine (T3) product for the treatment of hypothyroidism to its product development pipeline. The goal of ProNeura-T3 is to replicate normal thyroid physiology and could potentially prevent unwanted side effects associated with the current pulsatile-release oral formulation. Management believes that the ProNeura-T3 could potentially offer significant advantages over once-daily oral delivery for patients who require T3 as part of their treatment regimen.

Hypothyroidism, a condition in which the thyroid gland does not produce enough thyroid hormone, affects about 15 million Americans. Women over the age of 60 are more likely to be affected by hypothyroidism. Signs and symptoms of the condition can vary depending on the level of hormone deficiency, but typically include chronic fatigue, weight gain and obesity, dry skin, constipation, cold intolerance, impaired mental activity, and depression. Hypothyroidism is usually diagnosed via thyroid function tests (blood tests), and treatment typically consists of synthetic prohormone thyroxine (T4) given as a once-daily oral medication (Synthroid®, Levoxyl®, and other generics), which in turn is converted to the active T3 in the body. Most of the T3 in the body comes from the conversion of T4. It often takes months or even longer to determine the proper dosage for hypothyroid patients.

Titan believes that up to 15-20% of hypothyroid patients are not adequately treated with T4, which can result in a long-term deficiency of T3. These patients typically also require T3 therapy. Pfizer's Cytomel® is a once-daily synthetic T3 hormone, and is an effective medication for hypothyroidism but can come with potential side effects of headache, nervousness, irritability, sweating, and cardiac arrhythmias due to peak-and-trough blood-level fluctuations of T3 associated with standard oral delivery. This is where Titan believes an implantable T3 product could be helpful as continuous delivery of T3 by the oral or parenteral route is highly desirable, but has been difficult to achieve because of the solubility characteristics of the compound.

Currently, Titan is working on optimizing the formulation of this product. We believe ProNeura-T3 is approximately 6 months behind the ProNeura-PD candidate, and that management will begin regulatory discussions with the FDA regarding the product in mid-2016, and if all goes well, could potentially enter the clinic by mid-2017. We look forward to sharing more details regarding this program as they are made available

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 we were expecting that the company would add at least one additional product candidate to the pipeline by the end of 2015 (ProNeura-T3). 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 to hypothyroidism and other indications 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. Titan continues to work with its contract manufacturer and Braeburn in preparation for product launch. We are not sure how long the final labeling and packaging will ultimately take, but if all goes well and Probuphine gets approved this time around, we could see a product launch as early as mid-2016. We remain optimistic regarding the Titan story, and believe that the uplisting to the NASDAQ should act as a catalyst to further drive institutional awareness.

Titan exited the third quarter of 2015 with approximately $9.7 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.

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 just added an implantable triiodothyronine (T3) product for the treatment of hypothyroidism to its product development pipeline. We are looking forward to learning more about this product and additional pipeline candidates in the future. With both late and early-stage programs utilizing the ProNeura platform under way, we continue to see the shares worth $8.25 right now, with potential upside upon Probuphine approval in 2016. At this point, our model has very little contribution from ProNeura in Parkinson's disease, hypothyroidism 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

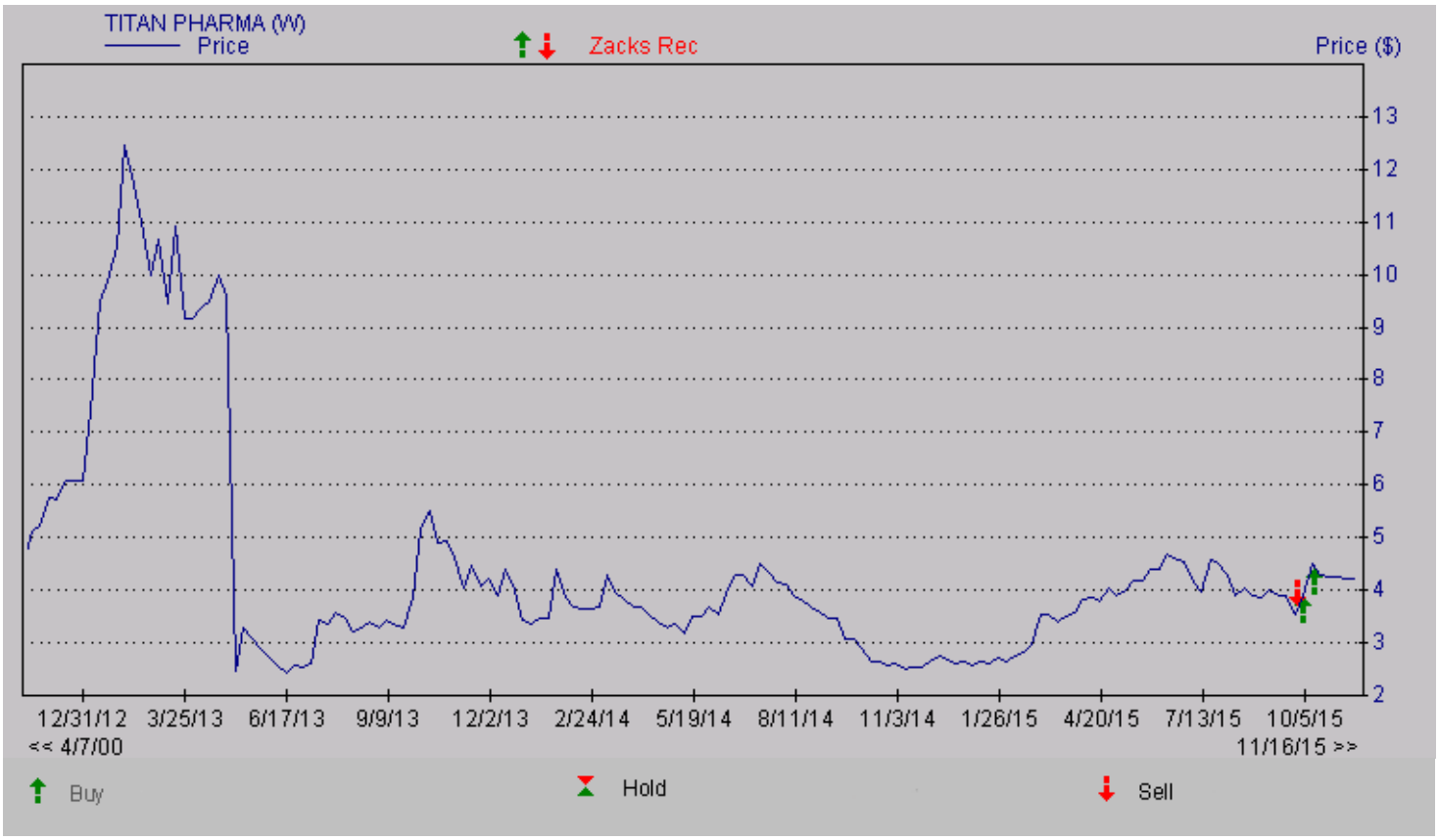
Titan Pharmaceuticals, Inc. - Income Statement

Titan Pharmaceuticals, Inc.	2014 A	Q1 A	Q2 A	Q3 A	Q4 E	2015 E	2016 E	2017 E
Probuphine Royalty	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$4.1**	**$21.3**
YOY Growth	-	-	-	-	-	-	-	-
Licensing & Grant Revenue	**$3.6**	**$0.9**	**$0.8**	**$0.0**	**$0.0**	**$1.7**	**$15.0**	**$0.0**
Total Revenues	**$3.6**	**$0.9**	**$0.8**	**$0.0**	**$0.0**	**$1.7**	**$19.1**	**$21.3**
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	$1.0	$1.3	$4.8	$5.0	$6.0
SG&A	$3.0	$1.1	$0.8	$0.8	$1.1	$3.7	$4.0	$5.0
Operating Income	($3.5)	($1.6)	($1.1)	($1.8)	($2.4)	($6.9)	$10.1	$10.3
Operating Margin	-	-	-	-	-	-	-	-
Total Other Income	$1.1	($3.3)	($1.2)	($0.0)	($0.5)	($5.0)	($2.0)	($2.0)
Pre-Tax Income	($2.4)	($4.9)	($2.3)	($1.8)	($2.9)	($11.9)	$8.1	$8.3
Taxes & Other	$0	$0	$0	$0	$0	$0	$0	$0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	($2.4)	($4.9)	($2.3)	($1.8)	($2.9)	($11.9)	$8.1	$8.3
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($0.14)**	**($0.24)**	**($0.11)**	**($0.09)**	**($0.14)**	**($0.59)**	**$0.39**	**$0.39**
YOY Growth	*-219.8%*	*118.8%*	*118.5%*	*-304.4%*	*502.3%*	*321.1%*	*-165.3%*	*-0.4%*
Weight Ave. Shares Out	17.1	20.1	20.1	20.1	20.1	20.1	21.0	21.5

Source: Company Filing // Zacks Investment Research, Inc. Estimates

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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- 25.5%, Hold/Neutral- 55.2%, Sell/Underperform – 15.5%. Data is as of midnight on the business day immediately prior to this publication.