Zacks Small-Cap Research

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Titan Pharmaceuticals, Inc.

(TTNP-OTCQB)

TTNP: Phase 3 Data Expected Mid-2015…

UPDATE

On April 1, 2015, Titan Pharma reported financial results for the fourth quarter and year ended December 31, 2014. For the full year, Titan reported $3.6 million in total revenues, and net loss of $2.4 million, or $0.03 per share. Revenues reflected the amortization of upfront payments from Probuphine commercialization partner, Braeburn Pharmaceuticals. In November 2014, Titan completed enrollment in its ongoing confirmatory Phase 3 study to support the resubmission of the NDA for Probuphine. We expect data around the middle of the year, with the NDA resubmission to follow in the second half of 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 with a price target of $1.00 per share.

Current Recommendation	**Buy**
Prior Recommendation	N/A
Date of Last Change	06/01/2011
Current Price (04/02/15)	$0.67
Target Price	**$1.00**

SUMMARY DATA

52-Week High	**$0.85**
52-Week Low	**$0.45**
One-Year Return (%)	**2.36**
Beta	**1.81**
Average Daily Volume (sh)	**324,933**
Shares Outstanding (mil)	**110**
Market Capitalization ($mil)	**$76**
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	0.4 E	0.4 E	0.4 E	0.4 E	1.7 E
2016					18.5 E
2017					32.2 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 E	-$0.02 E	$0.02 E	-$0.02 E	-$0.10 E
2016					$0.06 E
2017					$0.10 E

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WHAT'S NEW

Financial & Business Update

On April 1, 2015 Titan Pharmaceuticals reported financial results for the fourth quarter and full year ended December 31, 2014. The company reported total revenues for the year 2014 of $3.6 million compared to $10.5 million in 2013; this was in-line with our projections. Total revenues in the fourth quarter were approximately $0.9 million, and this was approximately the same amount as generated in the fourth quarter of 2013. Revenues reflected the amortization of upfront payments from Probuphine commercialization partner, Braeburn Pharmaceuticals and were consistent throughout all of 2014.

Operating expenses for the year totaled $7.1 million, comprised of $4.1 million in R&D and $3.1 million in G&A, as compared to $11.4 million in 2013, with a breakdown of $8.3 in R&D and $3.1 in G&A. The R&D decrease from 2014 to 2013 was $4.2 million or about 50% and primarily associated with the decrease in external R&D 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. We remind investors that the majority of the costs associated with the current clinical program are borne by Braeburn Pharma, as per the terms of the amended license agreement.

Operating expenses for 2014 were above expectations. R&D expenses were higher than expected particularly in the fourth quarter, with G&A slightly below expectations for the year. The increase in 2014 fourth quarter R&D expenses were related to supporting Probuphine manufacturing and other ProNeura based development programs, such as the expansion of the ProNeura platform for Parkinson's Disease. Total operating expenses for the fourth quarter 2014 were $2.2 million consisting primarily of $1.6 million in R&D and $0.6 million of G&A. The operating expenses for the same period in 2013 were $1.6 million, with $0.9 million in R&D related to the preparation of Probuphine NDA submission and $0.6 million in G&A.

The company reported a $1.1 million non-cash gain for the year resulting primarily on revaluation of outstanding warrants. This compares to net other income of about $10.6 million in 2013, which consisted primarily of $9.0 million in net other income generated by the transactions with Deerfield and $0.17 million of income related to non-cash gains on changes in the fair value of warrants. Net other income for the fourth quarter of 2014 was $0.8 million, compared to net other income of $0.4 million in the fourth quarter of 2013.

Net loss for the full year was approximately $2.4 million, or $0.03 per share, compared to net income of $9.7 million, or $0.12 per share, for 2013. Net loss for the fourth quarter 2014 was $0.5 million, as compared to $0.2 million in the same quarter of 2013.

Net cash burn in the quarter totaled $1.6 million. Titan Pharma exited December 31, 2014 with $15.5 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 the end of 2014, are sufficient to support Titan's planned operations into the fourth quarter of 2016.

Confirmatory Phase 3 Study: Enrollment Complete

On November 20, 2014, Titan announced completion of enrollment in the Phase 3 clinical study 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 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 expect the study to be completed and offer data by the middle of 2015 (best guess is June / July). 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 middle of 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. However, management did state that countries that use buprenorphine, such as Australia, France, Germany, U.K., Italy and some Scandinavian and Asia countries stand out, 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 Ahead With 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 (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 to 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.

In 2015, Titan will continue to aggressively pursue the PD development program. Titan's goal is to complete all the work required and file the IND in time to commence the clinical study in the first half of 2016 following potential approval of Probuphine. 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.

Conclusion

We continue to be positive on the Titan Pharma story. We believe the confirmatory Phase 3 trial proves successful and that the NDA will be back under priority review by the end of 2015. We see the shares worth $1.00 right now, with upside to the $2.00 level after the Phase 3 data comes out.

PROJECTED FINANCIALS

Titan Pharmaceuticals, Inc.
Income Statement

Titan Pharma	2013 A	2014 A	Q1 E	Q2 E	Q3 E	Q4 E	2015 E	2016 E	2017 E
Probuphine Royalty	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$3.5**	**$17.2**
YOY Growth	-	-	-	-	-	-	-	-	-
Fanapt Royalty	**$1.4**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
YOY Growth	*-70.0%*	-	-	-	-	-	-	-	-
Licensing & Grant Revenue	**$9.1**	**$3.6**	**$0.4**	**$0.4**	**$0.4**	**$0.4**	**$1.7**	**$15.0**	**$15.0**
Total Revenues	**$10.5**	**$3.6**	**$0.4**	**$0.4**	**$0.4**	**$0.4**	**$1.7**	**$18.5**	**$32.2**
YOY Growth	*47.3%*	-	-	-	-	-	-	-	-
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	$8.3	$4.1	$1.0	$1.1	$1.2	$1.3	$4.6	$5.0	$6.0
SG&A	$3.1	$3.0	$0.9	$0.9	$1.1	$1.1	$4.0	$4.0	$5.0
Operating Income	($0.9)	($3.5)	($1.5)	($1.6)	($1.9)	($2.0)	($6.9)	$9.5	$21.2
Operating Margin	*-8.5%*	-	-	-	-	-	-	-	-
Total Other Income	$10.6	$1.1	($2.5)	($0.5)	($0.5)	($0.5)	($4.0)	($2.0)	($2.0)
Pre-Tax Income	$9.7	($2.4)	($4.0)	($2.1)	($2.4)	($2.5)	($10.9)	$7.5	$19.2
Taxes & Other	$0	$0	$0	$0	$0	$0	$0	$0	$6.7
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*35%*
Net Income	$9.7	($2.4)	($4.0)	($2.1)	($2.4)	($2.5)	($10.9)	$7.5	$12.5
Net Margin	*92.7%*	-	-	-	-	-	-	-	-
Reported EPS	**$0.12**	**($0.03)**	**($0.04)**	**($0.02)**	**($0.02)**	**($0.02)**	**($0.10)**	**$0.06**	**$0.10**
YOY Growth	*-179.2%*	*-121.8%*	*77.7%*	*98.5%*	*-367.1%*	*406.4%*	*285.2%*	*-163.5%*	*53.7%*
Weight Ave. Shares Out	82.7	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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