Zacks Small-Cap Research

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Titan Pharmaceuticals, Inc. (TTNP-OTCQB)

TTNP: Titan and Braeburn Pushing Forward with Probuphine…

Current Recommendation	**Buy**
Prior Recommendation	N/A
Date of Last Change	06/01/2011
Current Price (04/01/14)	$0.67
Target Price	**$1.50**

UPDATE

We continue to believe Probuphine will eventually receive U.S. approval, now forecasted to occur in early 2017. Plugging in all our assumptions for the opioid dependence market and Probuphine market penetration and pricing, and we arrive at peak sales in the $250 to $300 million range. We note that Titan is in discussion with potential partners about Probuphine outside the U.S. We model a 20% royalty payment on sales at Braeburn, assuming this is the third (and highest) tier for Titan. We apply a 15% discount rate to these cash flows given that Braeburn seems strongly committed to the product and already owns nearly 11% of the company. Thus, we believe Titan shares are fair-valued today at roughly $1.50 per share. That's roughly 125% upside from today's price.

SUMMARY DATA

52-Week High	**$1.95**
52-Week Low	**$0.43**
One-Year Return (%)	**-58.64**
Beta	**13.38**
Average Daily Volume (sh)	**235,948**
Shares Outstanding (mil)	**83**
Market Capitalization ($mil)	**$55**
Short Interest Ratio (days)	**0.25**
Institutional Ownership (%)	**12**
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 E	0.9 E	0.9 E	0.9 E	4.6 E
2015					1.7 E
2016					0 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	-$0.00 E	-$0.01 E	-$0.01 E	-$0.01 E	-$0.03 E
2015					-$0.07 E
2016					-$0.08 E

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WHAT'S NEW

Financial & Business Update

On March 31, 2014, Titan Pharmaceuticals reported financial results for the fourth quarter and full year ending December 2013. The company reported total revenues of $0.9 million in fourth quarter. Revenues related to amortization of upfront payments from Probuphine commercialization partner, Braeburn Pharmaceuticals. For the full year 2013, Titan reported total revenues of $10.5 million, comprised of $9.1 million in amortization of upfront payments from Braeburn Pharmaceuticals and $1.4 million in recognized royalties on Fanapt prior to the selling of those royalties to Deerfield management.

Net loss in the fourth quarter totaled $0.2 million, equating to $0.00 per share. Net income for the full year totaled $9.7 million, or a gain of $0.12 per share. Amortization of the Probuphine upfront payment from Braeburn is non-cash revenues, so net cash burn in the fourth quarter 2013 totaled $2.1 million. Burn for the full year totaled $10.1 million. Titan Pharma exited 2013 with $11.8 million in cash and investment. The cash position was recently bolstered by a $5 million equity investment from Braeburn in November 2013 under the duo's revised collaboration agreement. Titan Pharma believes it has cash to fund operations through April 2015.

We continue to expect that Titan is going to need added cash to support operations into 2016 to the tune of around $8-10 million. That being said, we think there is almost no chance that Braeburn lets Titan run out of cash, or at the very least, raise capital in the open market. Instead, we think Braeburn will double-down on its investment in Titan, seeking to bring its ownership level closer to 20% by the end of 2014. For Titan investors, this is the most shareholder friendly path forward, and we think could be a prelude to an outright acquisition of Titan by Braeburn following Probuphine's final approval in about two years. We remind investors that Braeburn currently owns around 9.65 million shares, or 10.9% of the outstanding basic shares.

…Agreement In Principle With FDA…

On March 3, 2014, Titan and Braeburn announced they had agreed in principle with the U.S FDA on a path forward for Probuphine, an investigational subdermal implant for the maintenance treatment of opioid dependence. The news comes a few months after Titan and Braeburn attended a face-to-face meeting with the agency in November 2013. The goals of that meeting were to review and discuss existing data, and to better understand the issues of the April 2013 complete response letter. The pathway forward agreed to with the FDA centers around testing Probuphine in experienced sublingual buprenorphine patients that are "stable" on 8 mg of drug daily. 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 agreement includes the design of a clinical study in support of re-filing the NDA for Probuphine. Although final details of the required clinical study are yet to be finalized, Titan and Braeburn note they expect to conduct a randomized, double blind and double dummy design clinical study comparing four Probuphine implants to treatment with 8 mg or less of Suboxone, an approved daily dosed sublingual formulation of buprenorphine. The "double dummy" design incorporates an implant and oral tablet, with patient randomized to receive Probuphine plus a placebo tablet or Suboxone plus a placebo implant. The primary goal of the study is to provide information for a non-inferiority analysis of patient outcomes at six months. The FDA is currently reviewing the design protocol submitted by Braeburn. We expect to hear back publicly from Titan in the next month or two on things like patient enrollment numbers and the data analysis plan.

In recent conversation with management, we asked about how long patients take to stabilize on Suboxone and they answered, "About 3-4 months." We then asked what percent of patients stabilize at 8 mg versus 12-16 mg, and the conclusion was that it was at least half, maybe higher. So although we believe the FDA's guidance effectively relegates Probuphine to maintenance therapy, it should not have a materially negative impact on sales of the drug. In fact, we think once approved, addiction medicine doc will probably still use Probuphine at a similar rate to how we predicted prior to the complete response letter, or in around 5-10% of all their patients. In essence, we see the narrower label as having only a minor impact on peak sales.

Titan Still Attractive For Long-Term Holders

We remind investors that Braeburn is funding the necessary work to re-file Probuphine. In return, Titan has agreed to reduce its U.S. approval milestone from $45 million to $15 million. We remind investors that the original commercialization agreement signed between Titan and Braeburn back in December 2012 called for up to $50 million in approval milestones based on priority review, for which Probuphine was granted in January 2013. When Titan received a complete response letter on Probuphine in April 2013, this approval milestone was reduced from $50 million to $45 million. The revised agreement reduces the approval milestone to $15 million.

However, the total backend potential milestone consideration from Braeburn to Titan was increased to $165 million from $130 million as part of the restructured agreement. The revised agreement also lowers the sales threshold for Titan to achieve the highest royalty tier on sales of Probuphine. Additionally, the license amendment contains a provision entitling Titan to receive a low single digit royalty on sales by Braeburn, if any, of other mid or long-term continuous delivery treatments for opioid dependence, up to a maximum of $50 million, as well as the right to elect to participate in sales by Braeburn of other products in the addiction market in exchange for a similar reduction in the company's royalties on Probuphine. Therefore, if Braeburn looks to expand its product portfolio beyond Probuphine, Titan is both protected on the downside and can participate in the upside on these future transactions.

We continue to believe Probuphine will eventually receive U.S. approval, now forecasted to occur in early 2017. Plugging in all our assumptions for the opioid dependence market and Probuphine market penetration and pricing, and we arrive at peak sales in the $250 to $300 million range. We note that Titan is in discussion with potential partners about Probuphine outside the U.S. We model a 20% royalty payment on sales at Braeburn, assuming this is the third (and highest) tier for Titan. We apply a 15% discount rate to these cash flows given that Braeburn seems strongly committed to the product and already owns nearly 11% of the company. Thus, we believe Titan shares are fair-valued today at roughly $1.50 per share. That's roughly 125% upside from today's price.

PROJECTED FINANCIALS

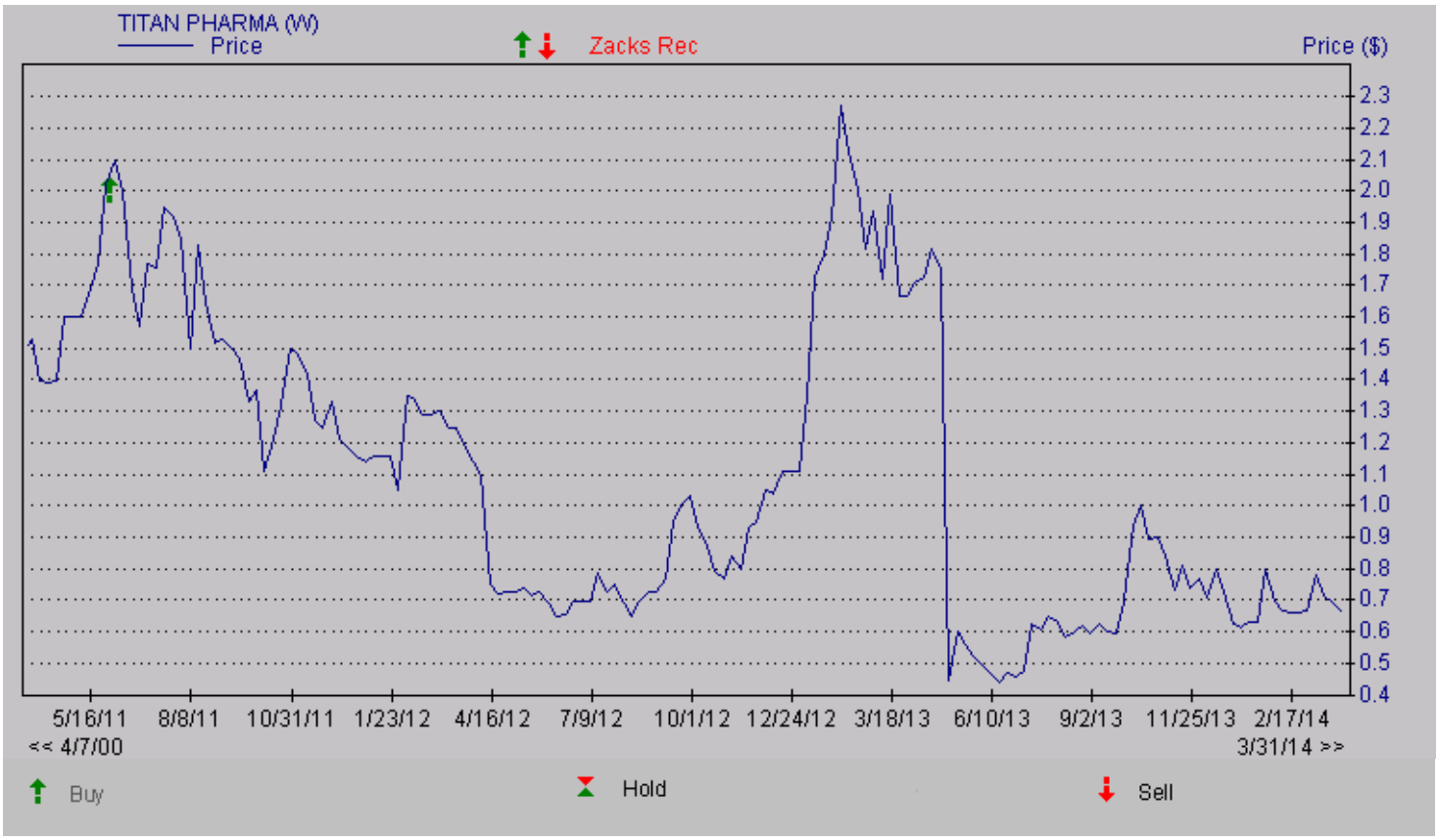
Titan Pharmaceuticals, Inc.
Income Statement

Titan Pharma	2013 A	Q1 E	Q2 E	Q3 E	Q4 E	2014 E	2015 E	2016 E
Probuphine Royalty	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
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**	**$0**
Total Revenues	**$10.5**	**$0.9**	**$0.9**	**$0.9**	**$0.9**	**$3.6**	**$1.7**	**$0.0**
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	$1.0	$1.2	$1.3	$1.4	$4.9	$6.0	$5.0
SG&A	$3.1	$0.6	$0.6	$0.7	$0.7	$2.6	$4.0	$4.0
Operating Income	($0.9)	($0.7)	($0.9)	($1.1)	($1.2)	($3.9)	($8.3)	($9.0)
Operating Margin	*-8.5%*	-	-	-	-	-	-	-
Total Other Income	$10.6	$0.3	$0.3	$0.3	$0.3	$1.2	$1.0	$1.0
Pre-Tax Income	$9.7	($0.4)	($0.6)	($0.8)	($0.9)	($2.7)	($7.3)	($8.0)
Taxes & Other	$0	$0	$0	$0	$0	$0	$0	$0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	$9.7	($0.4)	($0.6)	($0.8)	($0.9)	($2.7)	($7.3)	($8.0)
Net Margin	*92.7%*	-	-	-	-	-	-	-
Reported EPS	**$0.12**	**($0.00)**	**($0.01)**	**($0.01)**	**($0.01)**	**($0.03)**	**($0.07)**	**($0.07)**
YOY Growth	*-179.2%*	*-107.1%*	*-111.7%*	*-38.6%*	*271.8%*	*-126.0%*	*127.9%*	*4.6%*
Weight Ave. Shares Out	82.7	89.1	89.1	89.2	89.2	89.2	105.0	110.0

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

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