Zacks Small-Cap Research

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Titan Pharmaceuticals, Inc. (TTNP-OTC)

TTNP: Management Hopes To Have A Deal, "Substantially Before" The End Of The Year…

Current Recommendation	**Outperform**
Prior Recommendation	N/A
Date of Last Change	06/01/2011
Current Price (11/13/12)	$0.75
Target Price	**$2.50**

UPDATE

Titan Pharmaceuticals should be in store for an interesting next few weeks. The NDA for Probuphine was filed on October 28, 2012. Titan is seeking a Priority Review from the U.S. FDA. We are expecting to hear back on the NDA acceptance and fate of the Priority Review around the first of the year.

Meanwhile, Titan remains in active discussion, and collaboration, with its potential licensee partner on Probuphine. The exclusivity option period expires December 31, 2012. Management noted on its third quarter call that they expect to have a deal done "substantially before" that time. That could mean as soon as a few weeks.

With a decent level of cash, a pending deal potentially anytime and the FDA set to accept the NDA and rule on Priority Review at the end of the year, we think Titan stock may finally be headed for better times. We see fair-value as $2.50 per share.

SUMMARY DATA

52-Week High	**$1.42**
52-Week Low	**$0.65**
One-Year Return (%)	**-46.48**
Beta	**9.95**
Average Daily Volume (sh)	**123,642**
Shares Outstanding (mil)	**66**
Market Capitalization ($mil)	**$50**
Short Interest Ratio (days)	**0.25**
Institutional Ownership (%)	**0**
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 2012 Estimate	**N/A**
P/E using 2013 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)
2011	0.9 A	0.7 A	1.0 A	1.4 A	4.1 A
2012	1.3 A	1.4 A	1.2 A	1.3 E	5.2 E
2013					30.0 E
2014					17.5 E

Earnings per Share

(EPS is operating earnings before non-recurring items)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2011	-$0.08 A	-$0.12 A	-$0.01 A	-$0.05 A	-$0.26 A
2012	-$0.09 A	-$0.03 A	-$0.12 A	-$0.02 E	-$0.16 E
2013					$0.19 E
2014					$0.05 E

Zacks Projected EPS Growth Rate - Next 4 Years % **N/A**

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WHAT'S NEW

Financial Results

On November 13, 2012, Titan Pharmaceuticals reported financial results for the third quarter ended September 30, 2012. Total revenues in the quarter were $1.2 million, and consisted entirely of royalty revenues on sales of Fanapt at Novartis. Fanapt sales at Novartis were $16 million in the third quarter 2012, essentially in-line with our estimate. As a reminder, Titan is eligible to receive 8-10% royalties on Fanapt sales (8% below $100 million), of which Titan pays substantially all to Deerfield Management relating to the company's agreement with Deerfield in November 2011 where management sold these royalties in exchange for $5 million in cash and $10 million in debt forgiveness on a previous loan facility.

Net loss for the third quarter 2012 was $8.0 million, or 12 cents per share. This was significantly worse than expected. However, we note that the net loss includes approximately $5.4 million in non-cash expense associated with the increase in fair-value of the outstanding warrant liability. Titan recorded $3.0 million in R&D and $0.9 million in G&A expense during the quarter. These numbers were in-line with our forecasts. Net burn from operations and investing was only $2.5 million during the third quarter. For the first nine months of 2012, Titan burned approximately $8.7 million from operating and investing activities.

Titan exited the third quarter ended September 30, 2012 with $5.1 million in cash and investments. We remind investors that in September 2012, the company secured $4.25 million in cash through a stock purchase and option agreement with a larger pharmaceutical company for the potential license of Probuphine. As part of the transaction, Titan sold 3.4 million shares of common stock to the potential partner at a price of $1.25 per share, netting proceeds to Titan of $4.25 million.

Also during September 2012, Series B warrants to purchase just over 1.13 million shares of common stock were exercised resulting in gross proceeds to Titan of $0.96 million. Subsequent to the closing of the quarter, in October 2012, Series B warrants to purchase another 4.63 million shares of common stock were exercised resulting in gross proceeds of $3.93 million to Titan. Factoring in a burn of $2.5 million in cash for the fourth quarter, we model that Titan will exit 2012 with roughly $6.5 million in cash and investments. We find this to be sufficient to fund operations into April 2013, including a scheduled installment payment to Deerfield of approximately $2.5 million in early April 2013.

Titan Enters Exclusive Talks For Probuphine

On September 14, 2012, Titan Pharmaceuticals announced it had entered into a stock purchase and option agreement with a larger pharmaceutical company for the potential license of Probuphine. As part of the transaction, Titan sold 3.4 million shares of common stock to the potential partner at a price of $1.25 per share, netting proceeds to Titan of $4.25 million.

Given that Titan's stock was trading at $0.72 before the announcement, we interpret the transaction as roughly $2.5 million in a straight stock purchase transaction and $1.75 million in an exclusivity option for talks on Probuphine. The exclusivity period has recently been mutually extended to December 31, 2012. However, on the third quarter conference call held on November 13, 2012, Titan's Executive Chairman, Marc Rubin, M.D., stated that the company's goal is to have a deal done "substantially before" December 31, 2012. Dr. Rubin noted later in the call that they were confident in that guidance.

We do not know what Dr. Rubin considers to be "substantially before" December 31, 2012. Given that December 31, 2012 is only seven weeks away, it is possible a deal could be announced between now and Christmas. That being said, we question the timeframe given that the Probuphine NDA was only just filed on October 28, 2012, and 60 days for FDA acceptance and the granting of priority review would be on December 28, 2012. If the partner is waiting for NDA acceptance and a decision on priority review, investors may have to wait until December 29th or 30th. That's clearly not "substantially before" the 31st. And if the FDA deems the application not worthy of priority review, a decision we put as a toss-up, we may not hear back on NDA acceptance until the first week of January 2013.

Clearly just because the exclusivity period expires does not mean talks have ceased and the deal fell through. All it means is that the pharmaceutical company interested in Probuphine no longer has an exclusive right to negotiate for the drug. However, on the third quarter call, Titan management noted that the extension of the exclusivity period to December 31, 2012 had little to do with the NDA acceptance and priority review. Instead, management notes in the company's 10Q the potential partner is in the middle of completing "certain internal structural tasks." We can only guess as what these are.

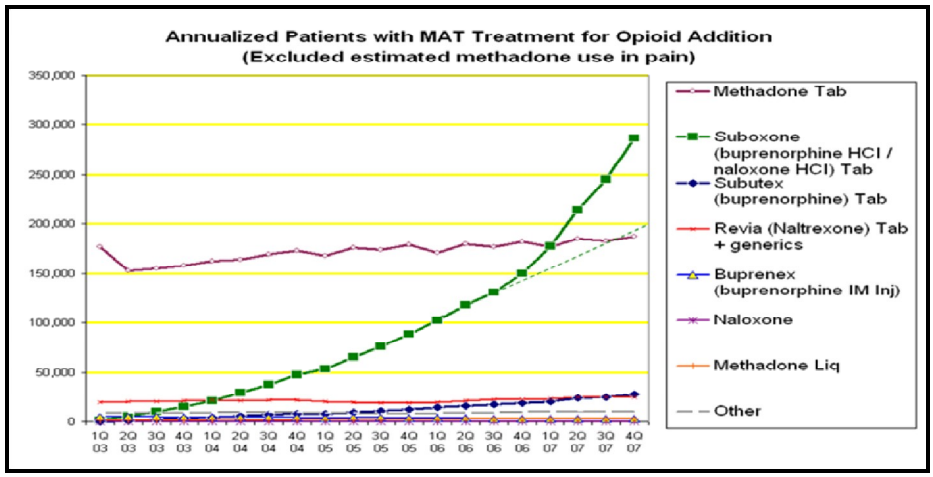
Titan says that it is operating under the assumption they get priority review. This includes pushing forward with manufacturing inspections and pre-launch activities. Titan reports that its potential partner has been very active in assisting with these activities. It even sounded like the partner was providing some financial and logistical support. If this is true, than investors probably can assume a deal is just around the corner. We've said in the past, we think Probuphine has peak sales in the area of $300 million. We expect that the deal will include an upfront payment, backend milestones, and royalties on future sales. Titan should be able to obtain upfront cash in the area of $15 million, a similar approval milestone in mid-2013, backend milestone totaling $100 million, and a ~20% royalty on sales.

Under this scenario, we see the net present value (NPV) of Titan's cash from a deal, risk-adjusted backend milestones, and royalties on sales worth $200 million, or around $2.50 per diluted share.

INVESTMENT THESIS

Large Market Opportunity

Sublingual buprenorphine sales are just over $1 billion in the U.S., with another $250 million outside the U.S.



Probuphine has several key advantages over Suboxone. On Titan's second quarter update call, management hosted two of the lead investigators in the PRO-806 phase 3 study. They were Dr. Walter Ling, M.D., Professor of Psychiatry and Director, Integrated Substance Abuse Programs at the David Geffen School of Medicine at UCLA and Dr. Richard N. Rosenthal, M.D., Chairman of Psychiatry at St. Luke's-Roosevelt Hospital Center, a teaching hospital of Columbia University, past president of the American Academy of Addiction Psychiatry. Both doctors expressed their enthusiasm for Probuphine and why they believe it will see meaningful commercial uptake.

We do not see the implant procedure as greatly limiting uptake for Probuphine. Management full acknowledges that there will be some patients adverse to an implantable drug, but we suspect that it will be only a small percent of the patients seeking treatment. In our view, and the views of Dr. Ling and Dr. Rosenthal, Probuphine improves compliance greatly over the once daily oral medication, as well as eliminates the risk for diversion or misuse.

It eliminates the need for monthly visits to the clinic or the need for the physician to actively monitor the patient to make sure dosing is on schedule. Once Probuphine is implanted, the drug goes to work unencumbered for six months. Dr. Rosenthal called Probuphine, "The right drug with the right delivery system."

Opioid addiction is a major health and social issue, especially in the U.S. An estimated 5+ million people worldwide, nearly 4 million of which are in the U.S., are abusing or addicted to opioids. In the U.S. alone, opioid abuse has increased 140% from 1992 to 2003. It's a $10+ billion burden to the U.S. healthcare market.

The World Health Organization estimates that between 4.6 and 5.2 million individuals in the U.S. and Europe use illicit opioids such as heroin, and more than 2.0 million individuals in the U.S. alone are addicted to prescription opioid medications. It is estimated that more than 1.0 million people in the U.S. and Europe currently receive pharmacological treatment for opioid addiction. A six month prescription of Suboxone costs roughly $2,000, with patients averaging duration between 8 and 10 months. At a parity price of $2,000 per implant, if Probuphine can capture 20% market share, the drug is a $300 million opportunity for Titan.

- Suboxone does 500,000+ Rx per month…
  - 20% try Probuphine (six month implant)…
    - Probuphine costs $2,000 per implant…
      - Average patient gets 1.4 implants…
        - 0.5 million * 20% * $2,000 per implant * 1.4 implants ~ $300 million

PROJECTED FINANCIALS

Titan Pharmaceuticals, Inc.
Income Statement

	2010 E	2011 A	Q1 A	Q2 A	Q3 A	Q4 E	2012 E	2013 E	2014 E
Probuphine Royalty	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$4.7**	**$12.1**
YOY Growth	-	-	-	-	-	-	-	-	*155.0%*
Fanapt Royalty	**$2.5**	**$3.6**	**$1.2**	**$1.4**	**$1.2**	**$1.3**	**$5.1**	**$5.3**	**$5.4**
YOY Growth	-	*42.7%*	*71.5%*	*125.9%*	*26.2%*	*0.5%*	*42.7%*	*3.6%*	*1.9%*
Licensing & Grant Revenue	**$7.6**	**$0.5**	**$0.0**	**$0**	**$0**	**$0**	**$0.0**	**$20.0**	**$0**
Total Revenues	**$10.1**	**$4.1**	**$1.3**	**$1.4**	**$1.2**	**$1.3**	**$5.2**	**$30.0**	**$17.5**
YOY Growth	-	*-59.7%*	-	-	-	-	*26.8%*	*482.3%*	*-41.8%*
CoGS	$0	$0	$0	$0	$0	$0	$0	$0	$0
Product Gross Margin	*100.0%*	*100.0%*	-	-	-	-	*100.0%*	*100.0%*	*100.0%*
R&D	$12.9	$11.2	$3.1	$2.0	$3.0	$1.5	$9.5	$5.0	$6.0
% R&D	*127.4%*	*275.5%*	-	-	-	-	*184.9%*	*16.6%*	*34.3%*
SG&A	$3.3	$3.4	$1.7	$1.1	$0.9	$1.1	$4.8	$6.0	$7.0
% SG&A	*32.3%*	*82.8%*	-	-	-	-	*94.0%*	*20.0%*	*40.1%*
Operating Income	($6.0)	($10.5)	($3.5)	($1.7)	($2.7)	($1.3)	($9.2)	$19.0	$4.5
Operating Margin	*0.0%*	*-258.3%*	-	-	-	-	*-178.9%*	*63.4%*	*25.6%*
Total Other Income	($0.8)	($4.7)	($1.6)	$0.0	($5.4)	($0.4)	($1.5)	($1.0)	$1.0
Pre-Tax Income	($6.8)	($15.2)	($5.2)	($1.7)	($8.0)	($1.7)	($10.7)	$18.0	$5.5
Taxes & Other	($1.2)	$0	$0	$0	$0	$0	$0	$2.7	$1.6
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*5%*	*15%*	*30%*
Net Income	($5.6)	($15.2)	($5.2)	($1.7)	($8.0)	($1.7)	($10.7)	$15.3	$3.8
Net Margin	*0.0%*	*-373.7%*	-	-	-	-	*-208.0%*	*51.0%*	*21.9%*
Reported EPS	**($0.09)**	**($0.26)**	**($0.09)**	**($0.03)**	**($0.12)**	**($0.02)**	**($0.16)**	**$0.19**	**$0.05**
YOY Growth	*-6.2%*	*171.5%*	-	-	-	-	*-36.5%*	*-217.7%*	*-76.5%*
Weight Ave. Shares Out	59.2	59.3	59.4	65.0	66.8	72.5	65.9	80.0	85.0

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

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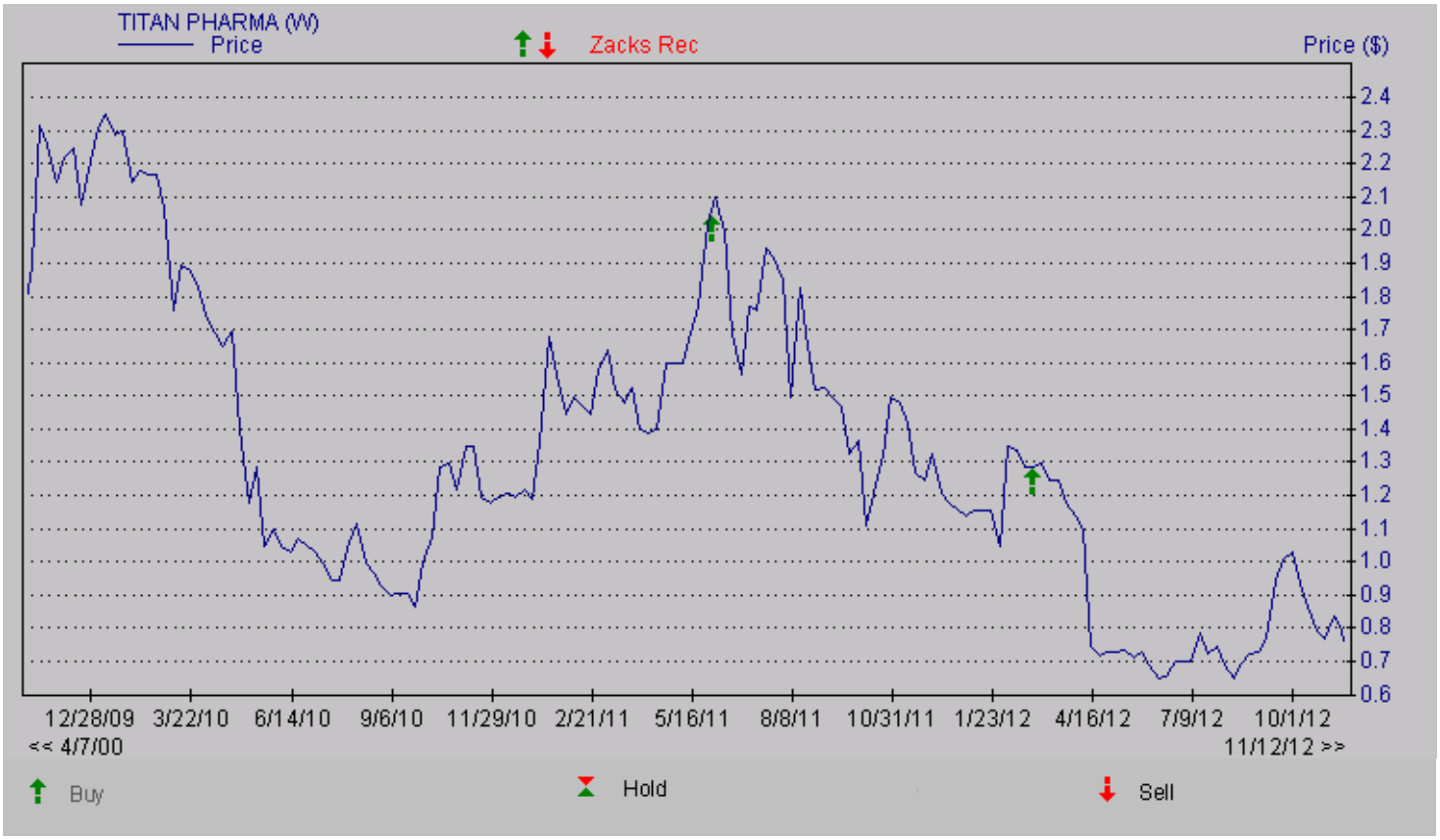

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