Zacks Small-Cap Research

November 15, 2013
Jason Napodano, CFA
312-265-9421
jnapodano@zacks.com

scr.zacks.com
111 North Canal Street, Chicago, IL 60606

Titan Pharmaceuticals, Inc. (TTNP-OTCQB)

TTNP: Braeburn Furthers Commitment To Titan, FDA Meeting Next Week Is The Major Event…

Current Recommendation	**Buy**
Prior Recommendation	N/A
Date of Last Change	06/01/2011
Current Price (11/15/13)	$0.82
Target Price	**$1.50**

UPDATE

On November 13, 2013, Titan Pharmaceuticals (TTNP) announced a restructuring of the Probuphine commercialization agreement with Braeburn Pharmaceuticals Sprl whereby Braeburn will make an additional equity investment in Titan Pharma, reduce the U.S. FDA approval milestone for Probuphine, and restructure the total milestone potential payable to Titan.

We believe Titan shares are fair-valued today at roughly $1.50 per share. The catalyst for driving the stock to this price will be confirmation by management that the Probuphine NDA will be re-filed during the first half of 2014.

SUMMARY DATA

52-Week High	**$2.48**
52-Week Low	**$0.43**
One-Year Return (%)	**-11.67**
Beta	**11.07**
Average Daily Volume (sh)	**326,040**
Shares Outstanding (mil)	**83**
Market Capitalization ($mil)	**$66**
Short Interest Ratio (days)	**0.25**
Institutional Ownership (%)	**1**
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 2013 Estimate	**N/A**
P/E using 2014 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)
2012	1.3 A	1.4 A	1.2 A	3.3 A	7.1 A
2013	5.2 A	2.2 A	2.2 A	2.2 E	11.8 E
2014					0 E
2015					27.9 E

Earnings per Share
(EPS is operating earnings before non-recurring items)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2012	-$0.09 A	-$0.03 A	-$0.12 A	-$0.01 A	-$0.15 A
2013	$0.07 A	$0.06 A	-$0.01 A	-$0.02 E	$0.10 E
2014					-$0.14 E
2015					$0.14 E

© Copyright 2013, Zacks Investment Research. All Rights Reserved.

WHAT'S NEW

Braeburn Solidifies Commitment To Probuphine, Titan Pharma

On November 13, 2013, Titan Pharmaceuticals (TTNP) announced a restructuring of the Probuphine commercialization agreement with Braeburn Pharmaceuticals Sprl whereby Braeburn will make an additional equity investment in Titan Pharma, reduce the U.S. FDA approval milestone for Probuphine, and restructure the total milestone potential payable to Titan. Below we highlight the key points of the revised agreement:

- Braeburn will make a new $5.0 million equity investment in Titan Pharmaceuticals by acquiring 6.25 million shares of common stock at $0.80 per share. We remind investors that Braeburn already owned 3.40 million shares of stock prior to this transaction dating back to the exclusivity option and stock purchase agreement in September 2012. In total, Braeburn now owns 9.650 million shares of common stock at with a cost basis of approximately $0.96 per share. Based on an estimated basic share count of 88.8 million shares of common stock, Braeburn owns approximately 10.9% of Titan Pharmaceuticals.

- Titan has agreed to a reduce U.S. approval milestone on Probuphine 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 last week reduces the approval milestone to $15 million.

- 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. Information on the sales milestones, additional indication milestones, and royalty rates has been redacted from the Form 8K SEC filing on the revised agreement. However, below we provide a brief history on the Braeburn-Titan relationship and the schedule for future payments and royalties.

Milestone	Amount	Date
Equity investment for "exclusivity talks"	$4.25 million (3.4 million shares at $1.25 per)	September 2012
Upfront payment for Probuphine	$15.75 million	December 2012
Equity investment for continued relationship	$5.00 million	November 2013
Probuphine FDA Approval (opioid addiction)	$15.00 million	TBD
sNDA for chronic pain	$?	TBD
Probuphine FDA Approval (chronic pain)	$?	TBD
sNDA for additional new indication	$?	TBD
Probuphine FDA approval (new indication)	$?	TBD
Probuphine sales threshold # 1	$?	TBD
Probuphine sales threshold # 2	$?	TBD
Probuphine sales threshold # 3	$?	TBD
Probuphine sales threshold # 4	$?	TBD
Probuphine sales threshold # 5	$?	TBD
TOTAL MILESTONE POTENTIAL	$165 million	
Royalty Tier # 1 (sales ≤ $ X)	? %	
Royalty Tier # 2 (between $ X & $ Y)	? %	
Royalty Tier # 3 (sales ≥ $ Z)	? %	

- Braeburn has agreed to assume responsibility for all third party expenses relating to the Probuphine regulatory process. This includes the additional analysis and consultants the companies have hired to help analyze the FDA's complete response letter and prepare for the upcoming FDA meeting on November 19, 2013. 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.

From a cash standpoint, the equity investment by Braeburn goes a long way to help securing the financial position at Titan Pharma. Titan exited the third quarter ended September 30, 2013 with approximately $9.0 million in cash on hand. Operating burn in the third quarter totaled $2.2 million. Titan has done a very good job since the complete response letter earlier in the year to reduce costs and minimize burn. If we assume operating burn in the fourth quarter will equal $2.5 million and add in the $5.0 million from Braeburn from the above transaction, we estimate that Titan will exit 2013 with approximately $11.5 million in cash on the books. We believe this is enough cash to fund operations into January 2015 (current management guidance).

Whether or not Probuphine will be approved by January 2015 remains to be seen. The goals of the FDA meeting on November 19th are two-fold:

1. For Titan to better understand the issues raised in the complete response letter, and
2. Review and discuss the existing and new data analysis so Titan and Braeburn can gain clarity on the regulatory path for re-filing the Probuphine NDA.

The best case scenario for Titan and Braeburn is that the existing and new data to be presented to the FDA on the 19th is deemed sufficient enough to re-file the application. If Titan and Braeburn are going to present this data to the agency in a face-to-face meeting, and the FDA agrees it is sufficient enough to re-file, then we can assume (with risk of course) that the FDA is blessing the data and the odds of approval in six-months is high. After all, the FDA already asked its Psychopharmacologic Drugs Advisory Committee (PDAC) to review the application and the members voted to recommend approval of the product in March 2013. If Titan and Braeburn can get this re-filed during the first half of the year, the new review date will come before the company runs out of cash in January 2015. The $15 million approval milestone will come late 2014, and it will be one heck of a turn-around for Titan.

If Titan and Braeburn have to do additional clinical studies, obviously the delay will be longer. We note that Braeburn is responsible for paying for all third-party expenses associated with the application. That said, we think it is highly unlikely that all this can be accomplished by July 2014, meaning that Titan will need to raise cash again in late 2014. For a detailed overview of the history of Probuphine, the clinical data, and the issues raised in the complete response letter from April 2013, we encourage investors to view our August 2013 Zacks report.

Conclusion

We think the U.S. FDA should have approved Probuphine back in April 2013, or at the very least, notified Titan of a three-month delay in the review cycle to enhance and implement the new REMS. Some of the issues noted in the CRL, specifically the questions on opioid receptor blocking or blood plasma levels seem to ask the company above-and-beyond what should be necessary for a 505(b)(2) application. Titan conducted two successful pivotal registration studies on Probuphine. The data has been presented and published for peer-review. The company followed-up these studies with two open-label safety extension studies, provided the FDA with adequate minimum patient data, adequate manufacturing and controls information, and seemed clearly amenable to the proposed changes to the REMS outlined in late March 2013. The goal-post for approval was moved.

That being said, what's done is done. Titan has to figure out a way to move forward based on the guidance that the U.S. FDA provides. We are optimistic that a path forward can eventually be found for Probuphine, but how long and at what cost remains to be seen. Greater clarity will emerge following the face-to-face meeting between Titan, Braeburn, and the FDA on November 19, 2013. That being said, the balance sheet has been strengthened and with Braeburn now owing over 10% of the company, we think downside seems limited.

Several investors have asked us why Titan and Braeburn have taken so long before responding to the FDA. The complete response letter was issued in April 2013 and it is seven months later before they duo are finally meeting with the FDA. However, Titan has said in the past, they want the response to be, "full and formal". The goal is to go into that meeting armed with enough information that they can re-file quickly after the meeting. If Titan and Braeburn can pull that off, this is stock that will be significantly higher in a year.

Valuation

In the past we've stated we believe Probuphine is a $250 million product, or perhaps a little more with minor price increases post-launch. Below we provide a hypothetic ramp of Probuphine sales at Braeburn and estimated milestones and royalties to Titan Pharma. We model Approval in 2015 (note the $15 million milestone payment), and receipt of approximately $70 million of the $165 million backend potential. Our model assumes no additional milestones for new indications with Probuphine, such as chronic pain. 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. The catalyst for driving the stock to this price will be confirmation by management that the Probuphine NDA will be re-filed during the first half of 2014. Ultimate upside for investors comes if Braeburn, an 11% owner in Titan, decides to use Titan as a vehicle to come public at some point in 2015 or 2016. Given the revised agreement noted above, it seems obvious Braeburn would like to build a portfolio of opioid dependence and chronic pain drugs. The best way to accomplish this goal would be as a public company.

Titan Pharmaceuticals	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023
Adults in the U.S. (Millions)	237	239	241	244	246	249	251	254	256	259	261
Percent with Opioid Addiction	*1%*	*1%*	*1%*	*1%*	*1%*	*1%*	*1%*	*1%*	*1%*	*1%*	*1%*
Percent Seeking Treatment	*40%*	*40%*	*40%*	*40%*	*40%*	*40%*	*40%*	*40%*	*40%*	*40%*	*40%*
Probuphine Target Market	0.9	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0
Market Share	*0%*	*0%*	*2.5%*	*4.0%*	*6.0%*	*7.5%*	*7.5%*	*7.5%*	*7.5%*	*7.5%*	*7.5%*
Active Probuphine Users	0.000	0.000	0.024	0.039	0.059	0.075	0.075	0.076	0.077	0.078	0.078
Price Per Implant ($1,500)	*$0*	*$0*	*$1,750*	*$1,838*	*$1,929*	*$2,026*	*$2,026*	*$2,026*	*$2,026*	*$2,026*	*$2,026*
Procedures per Year	*0*	*0*	*1.75*	*1.75*	*1.75*	*1.75*	*1.75*	*1.75*	*1.75*	*1.75*	*1.75*
Probuphine Sales at Partner	$0	$0	$73.9	$125.5	$199.6	$264.5	$267.2	$269.9	$272.6	$275.3	$278.0
YoY Growth	-	-	-	*70%*	*59%*	*33%*	*1%*	*1%*	*1%*	*1%*	*1%*
Royalty on Probuphine (15-20%)	$0	$0	$12.9	$22.6	$39.9	$52.9	$53.4	$54.0	$54.5	$55.1	$55.6
YoY Growth	-	-	-	*75%*	*77%*	*33%*	*1%*	*1%*	*1%*	*1%*	*1%*
Licensing & Milestones	$0	$0	$15.0	$0	$10.0	$10.0	$10.0	$10.0	$10.0	$10.0	$10.0
Cash Revenues (in Millions)	**$0**	**$0**	**$27.9**	**$22.6**	**$49.9**	**$62.9**	**$63.4**	**$64.0**	**$64.5**	**$65.1**	**$65.6**
Cash Operating Expenses	$10.0	$10.0	$10.0	$10.0	$10.0	$10.0	$10.0	$10.0	$10.0	$10.0	$10.0
Cash Taxes	$0	$0	$0	$0	$17.5	$22.0	$22.2	$22.4	$22.6	$22.8	$23.0
Net Cash Flow (in Millions)	**($10.0)**	**($10.0)**	**$17.9**	**$12.6**	**$22.4**	**$30.9**	**$31.2**	**$31.6**	**$31.9**	**$32.3**	**$32.6**

Assumptions	
Discount Rate:	**15.0%**
Terminal Growth:	2.0%

Valuation	
10-Year Model:	$94.4
Terminal Value:	$54.0
Net Cash at YE'13:	$6.2
Firm Value:	**$154.6**

Price Target	
Basic Outstanding:	88.8
Options / Warrants:	12.4
Fully Diluted:	101.2
Target	**$1.53**

Source: Zacks Investment Research, Inc. *Jason Napodano, CFA*

PROJECTED FINANCIALS

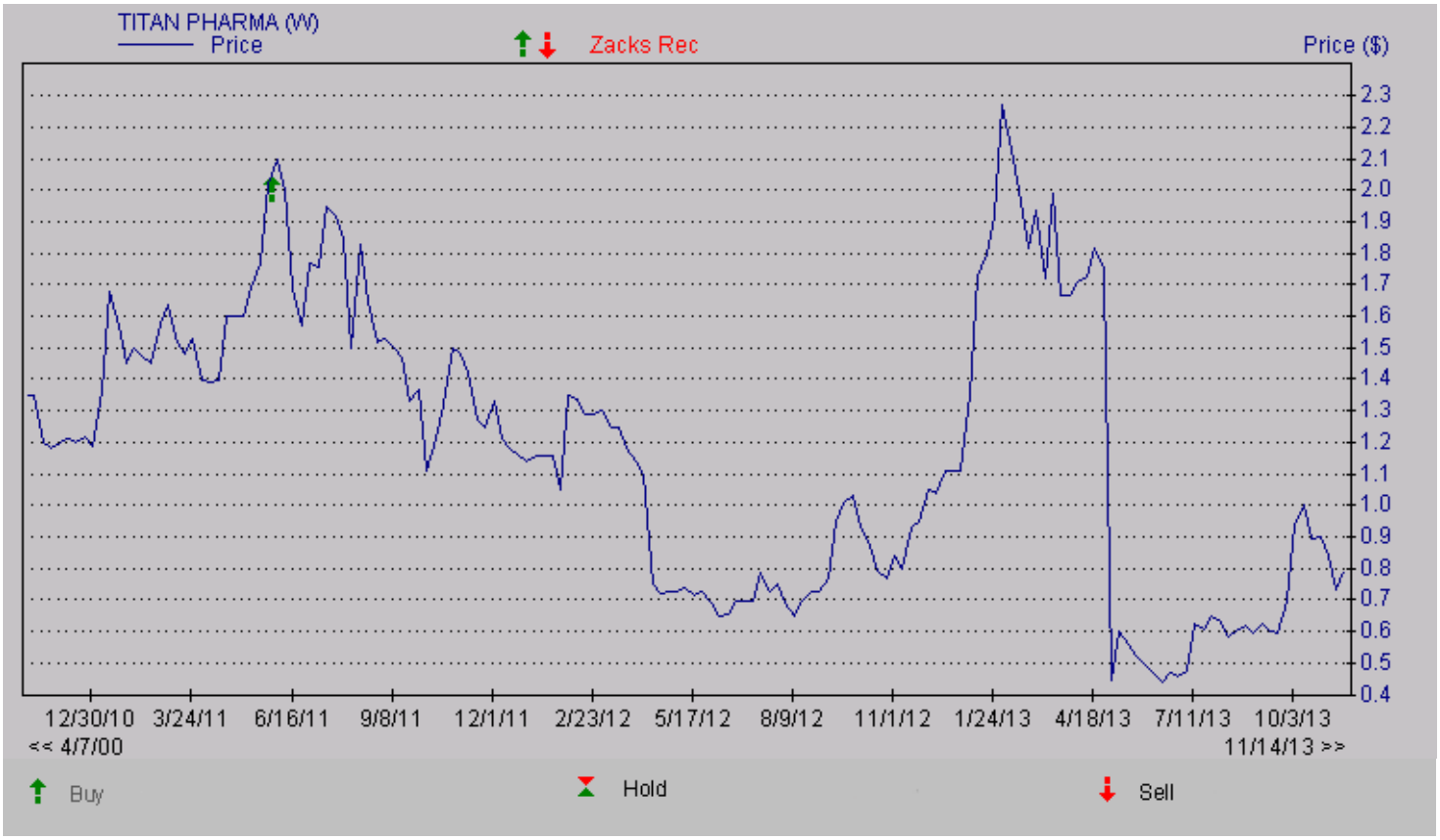
Titan Pharmaceuticals, Inc.
Income Statement

Titan Pharma	2012 A	Q1 A	Q2 A	Q3 A	Q4 E	2013 E	2014 E	2015 E
Probuphine Royalty	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$12.9**
YOY Growth	-	-	-	-	-	-	-	-
Fanapt Royalty	**$4.8**	**$1.4**	**$0**	**$0**	**$0.0**	**$1.4**	**$0**	**$0**
YOY Growth	*32.5%*	*16.0%*	*-100.0%*	*-100.0%*	*-100.0%*	*-70.0%*	-	-
Licensing & Grant Revenue	**$2.4**	**$3.8**	**$2.2**	**$2.2**	**$2.2**	**$10.3**	**$0**	**$15.0**
Total Revenues	**$7.1**	**$5.2**	**$2.2**	**$2.2**	**$2.2**	**$11.8**	**$0**	**$27.9**
YOY Growth	*75.0%*	-	-	-	-	*65.4%*	-	-
CoGS	$0	$0	$0	$0	$0	$0	$0	$0
Product Gross Margin	*100.0%*	-	-	-	-	*100.0%*	*100.0%*	*100.0%*
R&D	$10.6	$3.9	$1.8	$1.7	$3.0	$10.4	$10.0	$7.5
% R&D	*149.1%*	-	-	-	-	*88.2%*	*#DIV/0!*	*26.8%*
SG&A	$4.9	$1.1	$0.7	$0.6	$1.3	$3.7	$5.2	$5.5
% SG&A	*68.5%*	-	-	-	-	*31.8%*	*#DIV/0!*	*19.7%*
Operating Income	($8.4)	$0.2	($0.3)	($0.1)	($2.1)	($2.3)	($15.2)	$14.9
Operating Margin	*-117.6%*	-	-	-	-	*-20.0%*	*#DIV/0!*	*53.5%*
Total Other Income	($1.5)	$5.8	$5.4	($1.0)	$0.4	$10.6	$1.0	$1.0
Pre-Tax Income	($9.9)	$6.0	$5.1	($1.1)	($1.7)	$8.2	($14.2)	$15.9
Taxes & Other	$0	$0	$0	$0	$0	$0	$0	$0
Tax Rate	*5%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	($9.9)	$6.0	$5.1	($1.1)	($1.7)	$8.2	($14.2)	$15.9
Net Margin	*-138.7%*	-	-	-	-	*69.8%*	*#DIV/0!*	*57.0%*
Reported EPS	**($0.15)**	**$0.07**	**$0.06**	**($0.01)**	**($0.02)**	**$0.10**	**($0.14)**	**$0.14**
YOY Growth	*-42.1%*	-	-	-	-	*-165.0%*	*-247.2%*	*-202.0%*
Weight Ave. Shares Out	66.5	86.8	82.6	82.5	89.0	85.2	100.0	110.0

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

© Copyright 2013, Zacks Investment Research. All Rights Reserved.

HISTORICAL RECOMMENDATIONS



DISCLOSURES

The following disclosures relate to relationships between Zacks Investment Research ("ZIR"), Zacks & Company (ZCO") and Zacks Small-Cap Research ("Zacks SCR") and the issuers covered by the Zacks SCR analysts in the Small-Cap Universe.

ZIR or Zacks SCR Analysts do not hold or trade securities in the issuers which they cover. Each analyst has full discretion on the rating and price target based on their own due diligence. Analysts are paid in part based on the overall profitability of Zacks SCR. Such profitability is derived from a variety of sources and includes payments received from issuers of securities covered by Zacks SCR for non-investment banking services. No part of analyst compensation was, is or will be, directly or indirectly, related to the specific recommendations or views expressed in any report or blog.

ZIR and Zacks SCR do not make a market in any security nor do they act as dealers in securities. Zacks SCR has never received compensation for investment banking services on the small-cap universe. Zacks SCR does not expect received compensation for investment banking services on the small-cap universe. Zacks SCR has received compensation for non-investment banking services on the small-cap universe, and expects to receive additional compensation for non-investment banking services on the small-cap universe, paid by issuers of securities covered by Zacks SCR. Non-investment banking services include investor relations services and software, financial database analysis, advertising services, brokerage services, advisory services, investment research, and investment management.

Additional information is available upon request. Zacks SCR reports are based on data obtained from sources we believe to be reliable, but is not guaranteed as to accuracy and does not purport to be complete. Because of individual objectives, the report should not be construed as advice designed to meet the particular investment needs of any investor. Any opinions expressed by Zacks SCR Analysts are subject to change. Reports are not to be construed as an offer or the solicitation of an offer to buy or sell the securities herein mentioned.

ZCO and Zacks SCR are separate legal entities. ZCO is U.S. broker-dealer registered with the U.S. Securities and Exchange Commission and a member of the Financial Industry Regulatory Authority and the Securities Investor Protection Corp. This report is for your information only and is not an offer to sell, or a solicitation of an offer to buy, the securities or instruments through ZCO.

Zacks SCR uses the following rating system for the securities it covers. Buy/Outperform: The analyst expects that the subject company will outperform the broader U.S. equity market over the next one to two quarters. Hold/Neutral: The analyst expects that the company will perform in line with the broader U.S. equity market over the next one to two quarters. 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 of Zacks Ratings is as follows on the 1028 companies covered: Buy/Outperform- 15.5%, Hold/Neutral- 77.1%, Sell/Underperform – 6.2%. Data is as of midnight on the business day immediately prior to this publication.

© Copyright 2013, Zacks Investment Research. All Rights Reserved.