Zacks Small-Cap Research

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

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

Titan Pharmaceuticals, Inc. (TTNP-OTC)

TTNP: Titan Licenses Probuphine To Braeburn Pharmaceuticals…

Current Recommendation	**Outperform**
Prior Recommendation	N/A
Date of Last Change	06/01/2011
Current Price (12/18/12)	$1.23
Target Price	**$2.50**

UPDATE

On December 17, 2012, Titan Pharma announced the signing of a license agreement with Braeburn Pharmaceuticals Sprl, wholly owned by Apple Tree Partners. As per terms of the agreement, the license grants Braeburn exclusive commercialization rights to Probuphine in the U.S. and Canada. In return, Titan has received $15.75 million in an up-front payment and will receive up to $50 million upon the approval of Probuphine by the FDA for the treatment of opioid dependence. Additionally, is eligible to receive up to $130 million upon achievement of sales milestones and up to $35 million in regulatory milestones for additional contemplated indications, including chronic pain. Finally, Titan will receive tiered, double digit percentage royalties on net sales of Probuphine in the U.S. and Canada.

SUMMARY DATA

52-Week High	**$1.40**
52-Week Low	**$0.65**
One-Year Return (%)	**-5.93**
Beta	**9.92**
Average Daily Volume (sh)	**144,908**
Shares Outstanding (mil)	**75**
Market Capitalization ($mil)	**$83**
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	17.1 E	20.9 E
2013					60.0 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	$0.19 E	$0.08 E
2013					$0.51 E
2014					$0.05 E

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

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WHAT'S NEW

Titan Licenses Probuphine To Braeburn Pharma

On December 17, 2012, Titan Pharma announced the signing of a license agreement with Braeburn Pharmaceuticals Sprl, wholly owned by Apple Tree Partners. As per terms of the agreement, the license grants Braeburn exclusive commercialization rights to Probuphine in the U.S. and Canada. In return, Titan has received $15.75 million in an up-front payment and will receive up to $50 million upon the approval of Probuphine by the FDA for the treatment of opioid dependence. Additionally, is eligible to receive up to $130 million upon achievement of sales milestones and up to $35 million in regulatory milestones for additional contemplated indications, including chronic pain. Finally, Titan will receive tiered, double digit percentage royalties on net sales of Probuphine in the U.S. and Canada.

Terms of the deal exceeded our expectations. In October 2012, we wrote: "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."

	Our Expectations	Actual Braeburn Deal
Upfront Payment	$15 million	$15.75 million
Approval Milestone	$15 – 20 million	"Up to $50 million"
Sales Milestones	$100 million	$130 million
New Indications	-	$35 million
Royalties	~20%	"Tiered Double-Digit"

We note the approval milestone is listed as "up to $50 million" and suspect that the milestone may be reduced modestly if Probuphine is granted a standard review from the U.S. FDA vs. the priority review management is seeking, and the milestone may be further reduced if Titan receives a complete response letter in 2013 and needs to re-submit the application at a later date.

In addition to the potential milestone payments, Apple Tree Partners has allocated in excess of $75 million to launch, commercialize and continue the development of Probuphine. We remind investors that in September 2012, Titan announced it had entered into a stock purchase and option agreement with a 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. Thus, in-total, Titan has received $20 million to date from Braeburn / Apple Tree.

Background on Apple Tree Partners

According to its website, Apple Tree Partners is a venture capital firm specializing in startup, early venture, and growth capital investments. The firm may also invest in assets at all stages of development. It seeks to invest in proprietary products and technologies with a focus on drug development, drug discovery, and medical device companies. The firm prefers to take a board seat. It prefers to co-invest and leverage its capital through syndication with larger venture firms, corporate partnering, and innovative financing approaches. Apple Tree Partners was founded in 1999 and is based in New York, New York.

Apple Tree Partners has founded and built Aileron Therapeutics, Gloucester Pharmaceutical, HeartWare International (NASDAQ:HTWR) and Tokai Pharmaceuticals. We note that Gloucester Pharmaceuticals was acquired by Celgene Corp. in December 2009 for $640 million, only five months after the company Apple Tree participated in a $29 million Series D funding in August 2009. HeartWare, which traded below $1 per share at the end of 2008, currently trades over $80 per share with a market capitalization of $1.2 billion. In the past, Apple Tree has participated in venture funding on SGX Pharmaceuticals, which was acquired by Eli Lilly & Co. in July 2008 for $64 million and Coelacanth Corp., which was acquired by Lexicon Genetics in June 2001 for $32 million.

Braeburn Pharmaceuticals is a start-up venture that will launch Probuphine as its flagship product. The company will be headed up by Rosemary A. Crane and Garry Neil, MD. Ms. Crane was a former Group Chair OTC, Specialty and Nutritionals at Johnson & Johnson and President, Primary Care at Bristol Myers Squibb. Dr. Neil was a former Group President Pharmaceutical R&D at Johnson & Johnson. We expect that Braeburn will hire small specialty sales force, perhaps of around 50 reps, to promote Probuphine should the drug be approved mid-2013.

On a conference call held on December 17, 2012, Marc Rubin, MD, Titan's Executive Chairman noted that the newly formed Braeburn shares in the company's vision and expectations for Probuphine. Dr. Rubin believes that Braeburn has the necessary resources, experience, commitment, and conviction to see Probuphine a success.

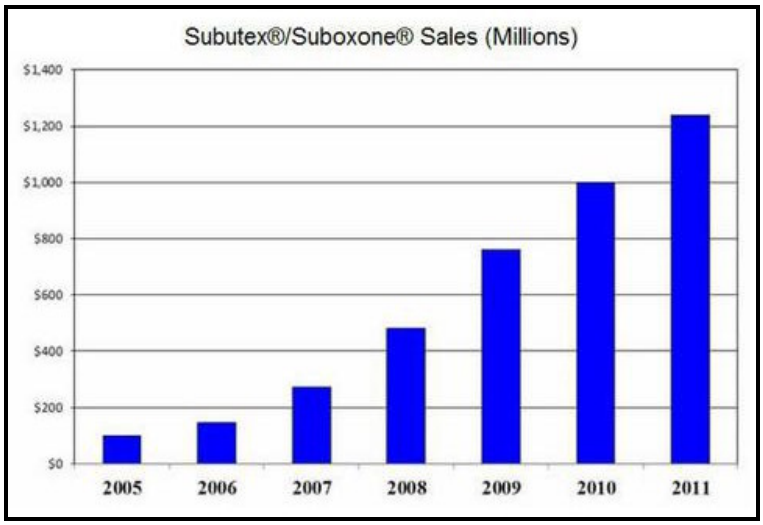
Probuphine NDA Under Review

Titan filed the new drug application (NDA) on Probuphine on October 29, 2012, seeking Priority Review. The NDA has been submitted under Section 505(b)(2) of the Food, Drug and Cosmetic Act and references the approved sublingual tablet formulations of buprenorphine. If granted, the Priority Review would accelerate the FDA's decision on Probuphine from the standard ten month review for a 505(b)(2) application, to six months. Investors should hear back from the FDA on the status of the application on December 28, 2012 if priority review, or the first week of January 2013 if a standard review is granted.

Titan says that it is operating under the assumption they get priority review. This includes pushing forward with manufacturing inspections and pre-launch activities. In November 2012, Titan told investors that its yet unnamed partner had been very active in assisting with these activities, which even included providing some financial and logistical support. We suspect that Braeburn would like to be in position to launch the drug shortly after approved.

Meaningful Market Opportunity

We see a meaningful market opportunity for Probuphine. The market is currently dominated by Suboxone, a combination buprenorphine and naloxone tablet, indicated for the maintenance treatment of opioid dependence. The drug is most commonly used by heroin addicts looking to kick their habit. Between Suboxone tablets and Suboxone sublingual film, Reckitt took in over $1.2 billion in sales from the franchise in 2011.



Recently, the Reckitt Benckiser announced they were voluntarily discontinuing sales of the sublingual formulation of Suboxone to focus solely on the film version. We think this opens a meaningful door for Titan. Regardless, 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. According to Titan management, there are 2.3 million opioid addicts in the U.S., approximately 20% of which are addicted to illicit opioids, such as heroin, and the other 80% to prescription drugs, such as OxyContin, methadone, and codeine. Until recently, medication-assisted therapies for opioid addiction had been sanctioned to a limited number of facilities in the U.S. Today, physicians can be certified to prescribe certain opioid addiction medications in an office setting, which has greatly expanded patient access to opioid addiction pharmaceutical therapies. As a result, it is estimated that there are approximately 750,000 people in the U.S. receiving medicinal treatment for opioid addiction.

We expect that Braeburn will launch Probuphine at a slight premium price to Suboxone, or at around $2,500 for the course of the six month implant. Suboxone does an estimated 500,000 prescriptions per month. If Braeburn can transition 20% of the market to Probuphine, the drug has peak sales around $300 million in opioid addiction alone.

We remind investors that Probuphine is patent protected into 2024, which should provide great impetus to develop the drug in chronic pain. Buprenorphine has several advantages over other opioids use for chronic pain – namely safety, longer half-life, and minimal potential for addiction / euphoric effect. Buprenorphine transdermal patches that are applied for 3 to 7 days are approved in the U.S., such as Purdue's BuTrans. Management believes that longer-term effect pain control can be achieved by the implant of Probuphine. Purdue launched BuTrans in January 2011 and booked an estimated $300 million in sales during the first year. Developing Probuphine for chronic pain has the potential to double our peak sales forecast.

A Whole New Ballgame For Titan

Titan exited the third quarter ended September 30, 2012 with $5.1 million in cash and investments. 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 modeled that Titan will exit 2012 with roughly $6.5 million in cash and investments.

Assuming Titan receives the cash from Braeburn before the end of the year, we now forecast that Titan will exit 2012 with roughly $22 million in cash. We note that Titan has a $2.5 million scheduled installment payment to Deerfield in early April 2013. However, if Probuphine is approved, either in late April 2013 or late August 2013, Titan will receive up to $50 million from Braeburn Pharmaceuticals. This would be a transformational event for the company, and allow management to continue to expand upon the novel delivery of the ProNeura technology platform. We remind investors that Titan is seeking to generate proof-of-concept data using the ProNeura delivery platform and levodopa / carbidopa for the treatment of Parkinson's disease.

We think Titan's stock has some meaningful upside left given the recent licensing deal with Braeburn that solidifies the company's financial position and provides for significant upside potential upon approval. Over the near-term, the market will be focusing on the NDA acceptance, potentially with Priority Review to come on December 28, 2012. Titan plans to seek regulatory filings in Europe as well, which could allow for additional out-licensing opportunities in the coming quarters. Our target remains $2.50 per share based on DCF.

PROJECTED FINANCIALS

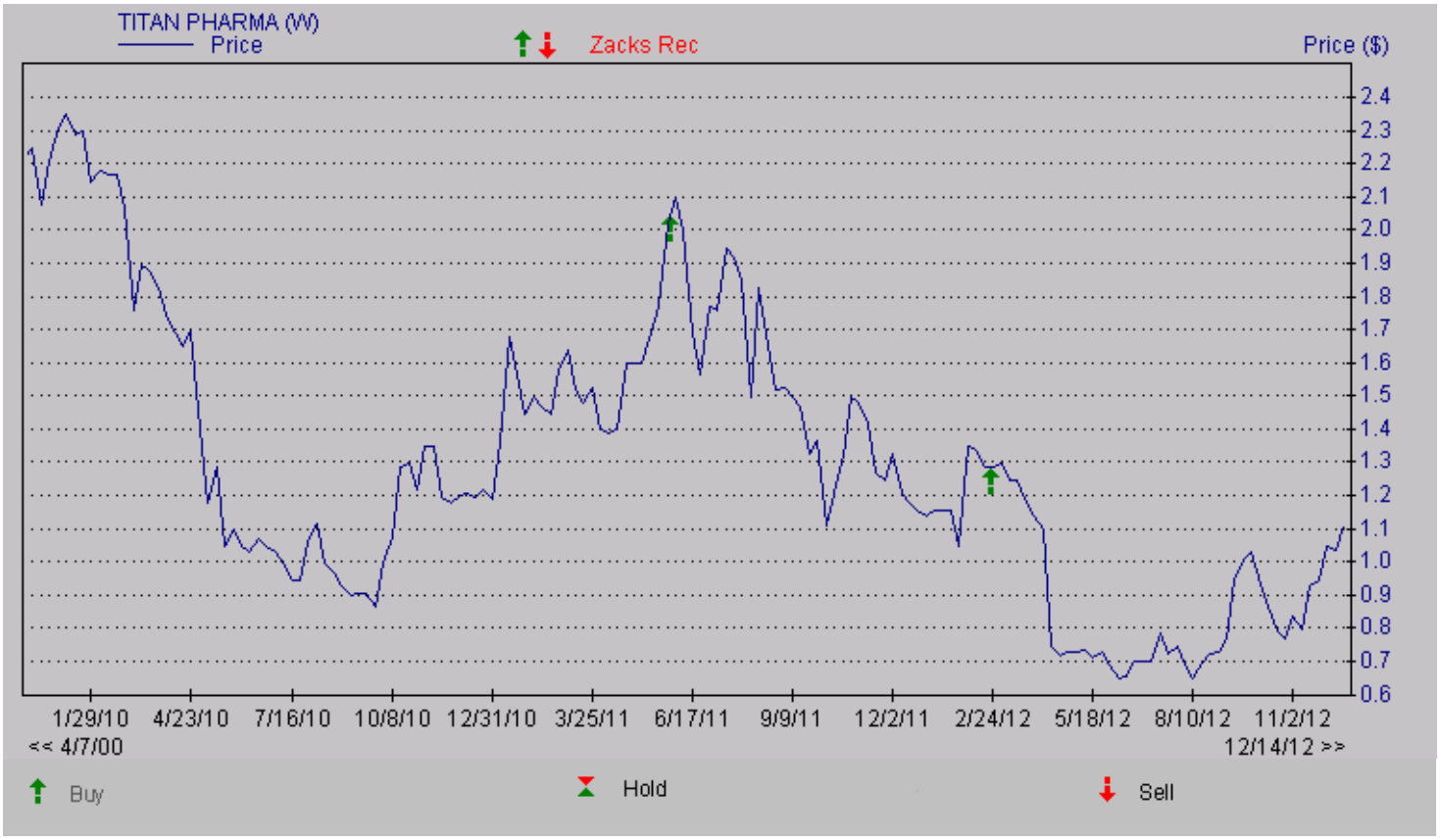
Titan Pharmaceuticals, Inc.
Income Statement

	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**	**$15.8**	**$15.8**	**$50.0**	**$0**
Total Revenues	**$10.1**	**$4.1**	**$1.3**	**$1.4**	**$1.2**	**$17.1**	**$20.9**	**$60.0**	**$17.5**
YOY Growth	-	*-59.7%*	-	-	-	-	*414.0%*	*187.1%*	*-70.9%*
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%*	-	-	-	-	*45.6%*	*8.3%*	*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%*	-	-	-	-	*23.2%*	*10.0%*	*40.1%*
Operating Income	($6.0)	($10.5)	($3.5)	($1.7)	($2.7)	$14.5	$6.5	$49.0	$4.5
Operating Margin	*0.0%*	*-258.3%*	-	-	-	-	*31.2%*	*81.7%*	*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)	$14.1	$5.0	$48.0	$5.5
Taxes & Other	($1.2)	$0	$0	$0	$0	$0	$0	$7.2	$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)	$14.1	$5.0	$40.8	$3.8
Net Margin	*0.0%*	*-373.7%*	-	-	-	-	*24.0%*	*68.0%*	*21.9%*
Reported EPS	**($0.09)**	**($0.26)**	**($0.09)**	**($0.03)**	**($0.12)**	**$0.19**	**$0.08**	**$0.51**	**$0.05**
YOY Growth	*-6.2%*	*171.5%*	-	-	-	-	*-129.7%*	*570.0%*	*-91.2%*
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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