Zacks Small-Cap Research

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Titan Pharmaceuticals, Inc. (TTNP-NASDAQ)

3Q:16 Report: Training Providers and Securing Payors, Target Price Steady at $12.00.

Based on our DCF model and a 15% discount rate, TTNP is valued at approximately $12.00 per share. We currently do not include any contribution from the ropinirole or triiodothyronine programs or for sales of Probuphine outside the US and Canada.

OUTLOOK

Titan Pharmaceuticals launched its first product, Probuphine, in June 2016 through its partner Braeburn Pharmaceuticals.

Currently, two other candidates are in the development pipeline which use Titan's proprietary ProNeura drug delivery system. Consisting of ethylene-vinyl acetate and a drug substance, ProNeura is a novel approach to drug delivery that benefit from long-duration slow release and controlled substance programs.

Titan's development products include a treatment for Parkinson's Disease (ropinirole) and hypothyroidism (T3) which are currently undergoing pre-clinical studies prior to an IND meeting with the FDA.

We maintain our price target of $12.00 per share.

Current Price (11/11/16)	$4.50
Valuation	**$12.00**

SUMMARY DATA

52-Week High	**$8.74**
52-Week Low	**$2.57**
One-Year Return (%)	**7.91**
Beta	**1.24**
Average Daily Volume (sh)	**152,690**
Shares Outstanding (mil)	**21.2**
Market Capitalization ($mil)	**$95.4**
Short Interest Ratio (days)	**9.53**
Institutional Ownership (%)	**0.3**
Insider Ownership (%)	**22.5**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.0**
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 2016 Estimate	**17.3**
P/E using 2017 Estimate	**7.1**
Zacks Rank	**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)
2015	$0.9 A	$0.8 A	$0.0 A	$0.0 A	$1.7 A
2016	$0.0 A	$15.0 A	$0.0 A	$1.1 E	$16.1 E
2017					$25.0 E
2018					$43.4 E

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2015	-$0.24 A	-$0.11 A	-$0.09 A	-$0.11 A	-$0.56 A
2016	-$0.09 A	$0.55 A	-$0.12 A	-$0.08 E	$0.26 E
2017					$0.63 E
2018					$1.40 E

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WHAT'S NEW

Titan Reports Third Quarter 2016 Financial and Operational Results

Titan Pharmaceuticals, Inc. (NASDAQ: TTNP) reported 3Q:16 results on November 9, 2016. Total revenues, which consisted entirely of Probuphine royalties were $26,000, which compares to royalty revenues of $4,000 in the prior quarter and $0 in 3Q:15. The result was behind our estimates of $350,000. Titan cited paperwork and administrative burden as a primary reason for the slower than expected ramp up in sales. Loss per share was ($0.12) compared to our estimate of ($0.11) and third quarter 2015 loss per share of ($0.09). Our estimate and actual earnings per share varied due to lower than expected revenues and higher R&D costs partially offset by lower G&A expense.

Research and development expenditures were $1.6 million for the quarter, up from $1.0 million in the prior year and above our estimate of $1.4 million. Higher R&D was attributable to greater external R&D expenses related to ProNeura development and employee expenses. Reimbursement from partner Braeburn reduced the amount by $0.4 million. General and administrative expenditures were $1.1 million, up $0.3 million compared to last year's spend. This was lower than our $1.2 million estimate. The year over year increase was related to higher non-cash stock compensation of $0.1 million and professional fees of $0.2 million. Net other expense of $4,000 consisted primarily of non-cash gains and losses on changes in the fair value of warrants.

Titan generated net cash from operations for the first nine months of 2016 of $8.7 million due to the milestone payment from Braeburn offset by operating costs. As of September 30, 2016, the cash and equivalents balance was $16.5 million.

As we have previously discussed, Titan has many opportunities outside the United States and Canada and is expected to develop partnerships in many of the areas where new treatments for addiction are needed, especially in the European Economic Area. Currently, the company is preparing materials to present to the European Medicines Agency (EMA) to identify the approval pathway in Europe. Dr. Beebe, the Chief Development Officer, has a meeting scheduled in December which will help define the required approval pathway for Probuphine. The company has also conducted talks with key opinion leaders and regional pharmaceutical companies in areas where buprenorphine is used for addiction and these entities are conducting due diligence on Titan and Probuphine.

Our Forecasts

In the third quarter of 2016, Titan recognized twenty-six thousand dollars of royalty revenue from the sale of Probuphine. We anticipate that this amount will continue to rise in the fourth quarter and beyond as training continues and as third party payors are added. As of the date of the 3Q:16 report, over 2,400 providers have been trained in the specialties of general practice, psychiatry, neurology and physiology among others. As for payors, several large and regional insurance companies as well as Medicare, Medicaid and the Veterans' Administration have been added. In 2017, as key providers are trained, identify appropriate patients for the therapy, and become more comfortable with the product and implantation, we anticipate growth to $17 million in Probuphine revenues. As partner Braeburn has taken over the operational costs of launching Probuphine, operating expenditures for Titan are focused on the company's emerging programs for Parkinson's Disease (ropinirole) and hypothyroidism (triiodothyronine). We anticipate that R&D in the coming quarters will increase as these programs dominate the company's focus.

Sales are expected to accelerate sharply in 2017 and 2018 as Braeburn passes on royalties from the sale of Probuphine in the high teens range. We anticipate 2% to 3% penetration into a market that is between one and two million patients in size. By 2018 we see revenues of almost $30 million for Titan and earnings of over a dollar per share. At this point, we do not include any contribution from sales outside the US and Canada. Our model and estimates are provided at the end of this report.

Ropinirole Development Plan

Titan has completed the manufacture and release of ropinirole implants for good laboratory practice (GLP) toxicity studies. The company has also completed pharmacokinetic and dose ranging studies in non-human primates, some of the required local toxicity studies, and a 13-week chronic toxicity study in non-human primates. These studies are part of the package that the company is developing to take to the FDA to support an IND application late

in the fourth quarter or in January 2017. Assuming the IND is cleared, TTNP will begin clinical trials in humans in support of the 505(b)(2) filing.

As background, Titan presented a plan to the FDA in December 2015 regarding the development of a ropinirole hydrochloride (HCL) implant for Parkinson's Disease. On March 7, the FDA responded to Titan's initial development plan for submission of an investigational new drug (IND) application with sufficient feedback for the company to begin the required non-clinical studies in support of a fourth quarter 2016 IND application. As with the process for Probuphine, Titan is pursuing 505(b)(2) registration for the product, which relies on existing clinical data to support an improved method of drug delivery.

The ropinirole implant is designed for the long-term, continuous delivery of ropinirole HCL for the treatment of signs and symptoms of Parkinson's disease (PD), including stiffness, tremors, muscle spasms, and poor muscle control. Ropinirole is a dopamine agonist provided in an oral format and currently sold as a generic by Glaxo Smith Kline, Dr. Reddy's Laboratories and Sun Pharma for the treatment of Parkinson's disease symptoms and restless leg syndrome. The U.S. patent for the ProNeura form of the drug was issued in March 8, 2016 as patent number 9,278,163.

According to the Parkinson's Disease Foundation, almost one million Americans and ten million people worldwide suffer from the disease, a number that is expected to grow dramatically in coming years. Current treatment for PD is with an oral dose of dopamine replacement therapy (DRT). However, given the uneven distribution of the dopamine agonist to the brain via oral administration, DRT is often associated with the pulsatile stimulation of dopamine receptors which can eventually result in motor complications and dyskinesias. Titan expects to show that the subdermal ProNeura drug delivery system is able to provide a continuous, non-fluctuating dose of ropinirole that may prevent or delay the onset of the motor complications and dyskinesias. Current treatments that offer continuous delivery of medication providing non-pulsatile stimulation of dopamine receptors in the brain appear to be more effective in controlling motor complications, but are surgically invasive and with potential risk of serious adverse effects.

Hypothyroidism Development Plan

Titan is currently testing the current formulation of triiodothyronine in animal models generating data for a pre-IND meeting with the FDA, which they anticipate will take place in 4Q:16. As with Probuphine and ropinirole program, this project will also use the ProNeura system to administer the active drug, triiodothyronine (T3), which is a thyroid hormone used to treat patients with hypothyroidism. Currently the drug is approved as an oral formulation under the brand name Cytomel manufactured by King Pharmaceuticals. The company submitted briefing material to the FDA in December in preparation for a pre-IND meeting and the FDA responded with comments on the company's development plans. If the pre-IND meeting is successful, we anticipate a proof-of-concept study by the second half of 2017.

As background, hypothyroidsim is a deficiency of thyroid hormone triiodothyronine (T3) and thyroxine (T4), which are tyrosine-based hormones secreted by the thyroid gland. Underproduction of these hormones slows the body's metabolism. The condition can result in poor ability to tolerate cold, a feeling of tiredness, constipation, depression, and weight gain. Thyroid hormones maintain the rate at which the body uses fats and carbohydrates, help control the body's temperature, influence heart rate, and help regulate the production of proteins. Of the two hormones secreted by the thyroid, T4 only has a slight effect on metabolism and is converted to more potent T3 inside cells through enzymatic action.

Probuphine

The FDA approved Probuphine in May 2016 and will be marketed by partner Braeburn Pharmaceuticals in the United States and Canada. Braeburn and will pay Titan a average royalty rate in the 15% to low-20% range of sales and will also pay up to $165 million in sales milestones and $35 million in regulatory milestones over the life of the agreement. This limited license for Braeburn allows the additional opportunity for marketing the product outside of North America by Titan and currently the company is exploring approval in Europe, working through the EMA and local regulatory agencies. Titan is also considering commercial partners for marketing the drug in the EU. Our model currently does not reflect sales from these geographies, and this represents upside from our current estimates.

Titan's North American marketing partner, Braeburn, has an aggressive training program in place that seeks to certify 4,000 providers by the end of the year. As of early November 2016, over 2,400 providers had been trained and certified to implant Probuphine in patients, up from 2,342 three months earlier. We attribute the deceleration in

training rate to a greater focus on select groups of large centers rather than the broad approach used in the first weeks after launch. If Braeburn is able to achieve its certification targets for the year, the vast majority of prescribers of opioid addiction treatment will be able to offer the product. For reference, Braeburn estimates that the top 6,000 prescribers write 92% of the prescriptions in the space. If they are able to achieve its year-end target of 4,000 providers, we believe that Titan's partner will be on track to achieve this 6,000 hurdle by mid-2017.

Braeburn continues to meet with providers and has since added to the formularies of several regional and other insurance companies as well as Medicare, Medicaid and the Veteran's Administration. Third party coverage will support a higher level of penetration for the implant and to date, Titan's partner has met with 40 different plans and has received positive responses.

Other development plans include a push into rural areas with the training program for providers and meetings with managed care companies to negotiate reimbursement and formulary inclusion.

The training program is a four hour process that requires review of relevant literature for prescribing and implantation and also attendance at live training programs. We outline the details of the program for providers that prescribe, insert and remove the implants:

- Review the Prescribing Information for Probuphine.
- Attest to performing a sterile procedure in the three months immediately preceding enrollment in the Probuphine REMS Program.
- Complete the Probuphine REMS Program Live Training: Lecture and Practicum, which includes training on the proper removal procedure for Probuphine.
- Successfully complete the Probuphine REMS Program Knowledge Assessment and meet the Probuphine REMS Program Criteria for Procedural Competency.
- Enroll in the Probuphine REMS Program by completing the Probuphine REMS Program Healthcare Provider Dual Enrollment Form.
- Obtain recertification annually to continue functioning as an inserter of Probuphine.

From a provider standpoint, the program appears to be attractive. While the provider will need to maintain the implants in inventory (just as with any pharmaceutical that is kept in the office), reimbursement for the surgical procedure is estimated to be from $200 to $250 for insertion and from $300 to $400 for removal depending on the reimbursement program the patient falls under. The provider will also receive compensation from the office visit, and the patient is required to follow-up monthly with the provider which is also classified as an office visit.

Probuphine Approval and Background

The Food and Drug Administration (FDA) issued a press release on May 26, 2016 announcing the agency's approval of the first buprenorphine implant for treatment of opioid dependence. The approval reflects the demand for new tools to address the problem of opioid use and addiction and addresses several shortcomings in other delivery methods. Probuphine is an implantable device that allows for slow release of buprenorphine, which was previously only available in pill or as a sublingual film.

There have been a number of favorable trends in recent months supportive of approval and additional usage of this novel approach to treating opioid addiction including a push for additional Federal funds to be allocated towards addressing the problem of opioid addiction and increases in prescribing limits for physicians. We feel that this supportive environment will drive increased penetration of opioid addiction treatment and favor treatments such as implants that have a number of favorable characteristics when compared with pills, tablets or films.

Probuphine was initially delayed by the FDA in part due to concerns about the removal of the implant and the safety and training related to this process. As a result of this concern, the FDA has included a black box warning that probuphine may carry the risk of implant migration, protrusion, expulsion and nerve damage resulting from the procedure. All physicians who are able to prescribe probuphine are required to complete training on proper insertion and withdrawal of the implant. We believe that the black box warning is in line with expectations given the content of the discussions at the Psychopharmacologic Drugs Advisory Committee (PDAC) meeting in January 2016.

The product label limits usage to patients "who have achieved and sustained prolonged clinical stability on transmucosal buprenorphine." While this restriction may reduce the potential peak sales for probuphine and steer usage towards those already on treatment, our forecast model reflects penetration levels in-line with this limitation. We do believe that there is a strong argument to favor the use of the subdermal implant in place of a pill or sublingual film given the potential risks from diversion, accidental usage by children or other adults, and improper (excessive) or missed dosing. We expect that implants will also improve relapse rates given the passive delivery of buprenorphine.

Conclusion

With over $16 million of cash on the balance sheet, Titan appears to have sufficient capital resources to fund its current ropinirole and T3 programs. Additionally, we anticipate that growing royalty revenues from Titan's partner will generate sufficient cash flow to avoid any capital raise in the foreseeable future. Based on our conversations with management, we believe a capital raise will only be required if the company plans to accelerate development programs or new products. We do not anticipate any such activity over the next year or two.

We maintain our favorable view of Titan following the additional detail provided on the call and see the trend in provider training as a strong indication of future revenues. Our forecasts call for a sharp ramp up in 2017 as the REMS provider community becomes more familiar with the therapy and takes advantage of this novel approach to opioid addiction treatment. We maintain our $12 per share price target and note that this does not include any contribution from Probuphine sales outside North America or future contributions from development programs.

PROJECTED FINANCIALS

Titan Pharmaceuticals, Inc. - Income Statement

Titan Pharmaceuticals, Inc.	2015 A	Q1 A	Q2 A	Q3 A	Q4 E	2016 E	2017 E	2018 E
Probuphine Royalty	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$1.1**	**$1.1**	**$17.0**	**$32.4**
YOY Growth	-	-	-	-	-	-	*1472.5%*	*90.0%*
Licensing & Grant Revenue	**$1.7**	**$0.0**	**$15.0**	**$0.0**	**$0.0**	**$15.0**	**$8.0**	**$11.0**
Total Revenues	**$1.7**	**$0.0**	**$15.0**	**$0.0**	**$1.1**	**$16.1**	**$25.0**	**$43.4**
YOY Growth	-	*-100.0%*	*1874.2%*	-	-	*862.5%*	*55.6%*	*73.2%*
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	$4.7	$0.7	$1.7	$1.6	$1.5	$5.5	$6.0	$6.0
G&A	$3.8	$1.1	$1.2	$1.1	$1.2	$4.6	$5.0	$6.0
Operating Income	($6.8)	($1.8)	$12.0	($2.6)	($1.6)	$6.0	$14.0	$31.4
Operating Margin	-	-	*80.3%*	*-10061.5%*	*-156.4%*	*37.0%*	*56.1%*	*72.3%*
Total Other Income	($4.5)	($0.0)	($0.1)	($0.0)	$0.0	($0.1)	$0.0	$0.0
Pre-Tax Income	($11.3)	($1.8)	$11.9	($2.6)	($1.6)	$5.8	$14.0	$31.4
Taxes & Other	$0	$0	$0	$0	$0	$0	$0	$0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	($11.3)	($1.8)	$11.9	($2.6)	($1.6)	$5.8	$14.0	$31.4
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($0.56)**	**($0.09)**	**$0.55**	**($0.12)**	**($0.08)**	**$0.26**	**$0.63**	**$1.40**
YOY Growth	*299.7%*	*-62.9%*	*-579.5%*	*37.2%*	*-32.1%*	*-147.0%*	*139.1%*	*121.5%*
Weight Ave. Shares Out	20.1	20.4	21.9	21.2	21.2	22.0	22.2	22.4

Source: Company Filing // Zacks Investment Research, Inc. Estimates

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