Zacks Small-Cap Research

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Titan Pharmaceuticals, Inc. (TTNP-NASDAQ)

Progress on Development Programs Overshadowed by Revenue Decline

Based on our DCF model and a 15% discount rate, TTNP is valued at approximately $5.00 per share based on contributions from Probuphine and ropinirole. We currently do not include any contribution from the triiodothyronine programs, other in-development programs or for sales of Probuphine outside the US and Canada. Valuation for pre-clinical programs will be included upon commencement of clinical trials.

Current Price (11/10/17)	$1.60
Valuation	**$5.00**

OUTLOOK

Titan Pharmaceuticals launched its first product, Probuphine, in June 2016 through its partner Braeburn Pharmaceuticals. The company is currently in the process of obtaining approval in Europe and identifying a partner who will commercialize Probuphine outside the US and Canada.

Currently, two other candidates are in or about to enter the clinical phase of 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 benefits from long-duration slow release and controlled substance programs.

Titan's development products include a treatment for Parkinson's Disease (ropinirole) and hypothyroidism (T3). The company is also working on a variety of other implants both in-house and with partners.

SUMMARY DATA

52-Week High	**$4.80**
52-Week Low	**$1.30**
One-Year Return (%)	**-63.6**
Beta	**1.72**
Average Daily Volume (sh)	**215,167**
Shares Outstanding (mil)	**21.2**
Market Capitalization ($mil)	**$33.9**
Short Interest Ratio (days)	**7.17**
Institutional Ownership (%)	**13.1**
Insider Ownership (%)	**13.9**
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	**6.7**
P/E using 2016 Estimate	**N/A**
P/E using 2017 Estimate	**N/A**
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)
2016	$0.0 A	$15.0 A	$0.0 A	$0.0 A	$15.1 A
2017	$0.0 A	$0.1 A	$0.0 A	$0.4 E	$0.6 E
2018					$1.5 E
2019					$3.9 E

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2016	-$0.09 A	$0.55 A	-$0.12 A	-$0.11 A	$0.24*A
2017	-$0.14 A	-$0.16 A	-$0.20 A	-$0.18 E	-$0.68 E
2018					-$0.60 E
2019					-$0.44 E

*Quarterly totals do not sum to annual due to mix of diluted and undiluted shares

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WHAT'S NEW

Titan Reports Third Quarter 2017 Financial and Operational Results

Titan Pharmaceuticals, Inc. (NASDAQ: TTNP) reported third quarter 2017 results on November 9, 2017 in conjunction with the filing of its Form 10-Q. Total revenues, which consisted entirely of Probuphine royalties were $40,000, falling sequentially and below our forecasts of $200,000. This compares to revenues of $26,000 in 3Q:16 and $77,000 in the prior quarter. The weak revenue trend was attributed to the extended delay required to obtain payor approval and reimbursement for the implant. Additionally, the REMS program has erected hurdles that have slowed marketing and uptake of the product. Titan management is making a concerted effort to fully understand the issues that have hampered Probuphine sales and to find a solution for overcoming the impediments. As Titan makes efforts to rectify the problem, they have made significant progress and have expanded their development program. Ropinirole enters the clinic for the first time and preclinical work in a number of new areas including an opioid antagonist in collaboration with Opiant Pharmaceuticals, anti-malarial agents in collaboration with the Reed Army Institute and the Southwest Research Institute, and Liothyronine for hypothyroidism among others are filling the pipeline with future potential. The company has also progressed in its efforts to secure approval in Europe for Probuphine, having just filed a marketing authorization application (MAA) with the EMA on November 6th.

Ropinirole entered Phase I/II trials in October justifying a value to the program. We discuss our assumptions in conjunction with our 2016 full-year update. The addition of the ropinirole program to our company valuation has a positive impact on our target price, offset, unfortunately by a reduction in value related to Probuphine as we reduce our sales estimates to reflect current trends. We are optimistic that Titan will be able help resolve the issues at their partner at some future point and secure sufficient funding to support the valuable programs that are in various stages of development.

As mentioned, revenues fell behind our estimates in the third quarter. R&D expenses of $2.7 million rose 71% over the prior year due to expansion of the ropinirole and other ProNeura development programs. G&A of $1.4 million was up 33% versus the prior year on higher employee related costs and additional fees and expenses. Net loss was ($4.2) million or ($0.20) per share in 3Q:17, compared to net loss of ($2.6) million or ($0.12) per share in 3Q:16.

Cash burn for the third quarter was ($2.5) million, better than the ($2.8) million cash contribution in the third quarter of 2016. Cash balance was $11.7 million at the end of the second quarter, rising sequentially from $8.4 million due to the July loan agreement which added gross proceeds of $7.0 million.

Opiant Pharmaceuticals Collaboration

In early October, Titan announced that it is collaborating with Opiant Pharmaceuticals on an implant to deliver an opioid antagonist. The target population is individuals with opioid use disorder that need treatment to prevent opioid abuse relapse. Initially, the companies will conduct a feasibility study that is expected to be completed in the first half of 2018. Additional financial support from the NIH may also help advance development if initial studies generate favorable results.

Recent and Upcoming Events

- Probuphine
  - EMA confirmed eligibility for review and approval under the centralized procedure
  - EMA provided pediatric indication waiver
  - Target finalizing agreement with EU and ex-US commercialization partners prior to MAA filing
  - Representatives from two Ireland and the UK appointed to report on progress to EMA
  - **November 6, 2017 filing of a Marketing Authorization Application (MAA) in EU**
- Titan granted Small Manufacturing Entity (SME) status in Europe, which provides financial incentives

- Ropinirole
  - IND submitted January 2017
  - Phase I/II PK studies begun 3Q:17
  - Trial will enroll Parkinson's Disease patients receiving adjunctive therapy with oral ropinirole
  - **First patient treated early October 2017**
- Triiodothyronine (T3)
  - Final formulation optimization studies currently in process
  - Completing non-clinical evaluation of its re-formulated implant
  - Pre-IND review with the FDA anticipated
  - Data presented at annual conference of the American Thyroid Association in October 2017
- New Candidates being evaluated for ProNeura
  - **Opioid antagonist collaboration with Opiant Pharmaceuticals**
    - Prevention of opioid relapse and overdose in individuals with opioid use disorder
    - Targeting completion of feasibility assessment in 1H:18
  - Tenofovir and emtricitabine for pre-exposure prophylaxis against HIV acquisition
  - Anti-malarial agents
    - Entered into Cooperative Research and Development Agreement with Reed Army Institute of Research (WRAIR) and Southwest Research Institute (SwRI)
    - Collaboration will evaluate the development of ProNeura-based implants for a long-term regimen in the prevention of malaria
    - Presented Atovaquone data at annual meeting of Tropical Medicine & Hygiene
  - **κ-opioid receptor as non-opioid analgesic for chronic pain**
  - Liraglutide for Type 2 diabetes
  - **Liothyronine (LT3) for treatment of hypothyroidsim**
  - Oxytocin for autism spectrum disorder

Financing

Following the end of the second quarter, Titan entered into a loan agreement with Horizon Technology Finance for up to $10 million in loans over the next four years. $7.0 million of the total was executed in July, yielding net proceeds of $6.8 million. The remaining $3.0 million of borrowing may be accessed upon certain revenue, partnership or market capitalization achievements.

Interest on the loan is LIBOR + 8.4%, with a floor of 9.5%. The loan requires only interest payments until December 18, 2018, after which, interest and principal payments will be made. Early payment and final payment fees and penalties apply, ranging from 2% to 5%. 280,612 warrants were attached to the debt with an exercise price of $1.96, which may be adjusted if new equity financing occurs.

Based on anticipated cash burn rates, Titan will need to raise additional capital prior to August 2018. During the third quarter call, management expressed that they are considering all options to obtain financing for the company which we interpret to mean one of the following approaches:

- Partnership providing upfront payment and coverage of future development expenses
- Licensing of Probuphine outside US and Canada on a regional basis providing upfront payments
- Entering into an M&A transaction for an upfront payment
- Equity issuance
- Debt financing

Management Change at Braeburn

On June 5th, Titan's partner commercializing Probuphine, announced that Behshad Sheldon would step down as CEO and that Mike Derkacz would assume the role. We believe that the slow pace of Probuphine sales may have contributed to the change. Mike's experience has been in launching new products, creating effective teams and focusing organizational leadership at pharmaceutical firms such as Teva, Cephalon and GlaxoSmithKline. Over the last six years, Mike led the strategic development of the CNS and Pain Therapeutic Areas, providing a valuable background to support the development of Probuphine and other products at Braeburn Pharmaceuticals. We believe that his background provides the experience needed to drive growth for Probuphine.

Our Estimates

In an earlier report we constructed our valuation model for Titan's development programs for ropinirole and T3. Our valuation approach does not apply a probability of success until the program has begun Phase I clinical trials. In October Titan launched its Phase I/II trial for the ropinirole implant intended for the treatment of the signs and symptoms of idiopathic Parkinson's disease. We now forecast a 10% probability of revenue generation in the US and Europe for the ropinirole implant which adds ~$0.40 to our per share target price.

Royalty revenues from Braeburn's Probuphine have been well below our initial expectations and changed the dynamic in terms of funding for development programs. With the sequential contraction in third quarter royalties, we shift back our revenue expectations by a year in our model and reduce them expectations in out years to reflect a lower trend. This results in Probuphine royalty revenues of $1.5 million in 2018, rising to $3.9 million in 2019 and $7.3 million in 2020. Steady growth continues to the peak in 2026 of about $50 million which is about 106,000 units. We then assume a terminal decline rate of 5%. The result of this change subtracts approximately $1.30 from our previous target price.

Conclusion

Titan's cash of $12 million at the end of the third quarter is anticipated to provide sufficient capital to fund operations over the next three or four quarters based on company guidance and our estimates. The recent loan agreement with Horizon can provide a small amount of additional capital if needed assuming certain milestones are met.

Now that ropinirole has entered Phase I trials, we now attach value to the program, however, this increase was more than offset by reductions in our estimates for Probuphine. While disappointing, there is cause for optimism in the many new programs in development. Two of these programs are with partners and can potentially be funded through the collaboration, reducing the need for additional capital. However, cash levels are low, and Titan needs to identify sources of additional financing. This may be easier to obtain than feared, given the value of the development portfolio that they hold and the potential for additional partnerships which may provide upfront payments and other sources of capital.

Based on our adjustments to the model we move our price target to $5.00 per share identifying potential upside coming from an improvement in the outlook for Probuphine and the advance of the T3 program into clinical trials.

PROJECTED FINANCIALS

Titan Pharmaceuticals, Inc. - Income Statement

Titan Pharmaceuticals, Inc.	2016 A	Q1 A	Q2 A	Q3 A	Q4 E	2017 E	2018 E	2019 E
Probuphine Royalty	**$0.1**	**$0.0**	**$0.1**	**$0.0**	**$0.4**	**$0.6**	**$1.5**	**$3.9**
YOY Growth	-	-	*1825.0%*	*53.8%*	*1042.9%*	*756.9%*	*163.9%*	*162.5%*
Licensing & Grant Revenue	**$15.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**
Total Revenues	**$15.1**	**$0.0**	**$0.1**	**$0.0**	**$0.4**	**$0.6**	**$1.5**	**$3.9**
YOY Growth	*801.6%*	-	*-99.5%*	*53.8%*	*1042.9%*	*-96.3%*	*163.9%*	*162.5%*
R&D	$6.1	$2.1	$2.5	$2.7	$2.4	$9.7	$8.5	$7.5
G&A	$4.6	$1.4	$1.2	$1.4	$1.4	$5.3	$6.5	$6.8
Operating Income	$4.3	($3.4)	($3.6)	($4.1)	($3.4)	($14.5)	($13.5)	($10.4)
Operating Margin	*28.8%*	-	*-4702.6%*	*-10175.0%*	*-850.0%*	*-2608.3%*	*-920.4%*	*-270.6%*
Total Other Income	$0.8	$0.4	$0.2	($0.1)	$0.9	$0.0	$0.0	$0.0
Pre-Tax Income	$5.1	($3.0)	($3.5)	($4.2)	($3.9)	($14.5)	($13.5)	($10.4)
Taxes & Other	$0	$0	$0	$0	$0	$0	$0	$0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	$5.1	($3.0)	($3.5)	($4.2)	($3.9)	($14.5)	($13.5)	($10.4)
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**$0.24**	**($0.14)**	**($0.16)**	**($0.20)**	**($0.18)**	**($0.68)**	**($0.60)**	**($0.44)**
YOY Growth	*-142.5%*	*55.4%*	*-129.9%*	*59.9%*	*66.8%*	*-384.5%*	*-11.3%*	*-26.4%*
Weight Ave. Shares Out	21.5	21.4	21.2	21.2	21.6	21.3	22.4	23.5

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

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