

Titan Pharmaceuticals, Inc. (TTNP-NASDAQ)

Molteni Investment Relieves the Pressure

Based on our DCF model and a 15% discount rate, TTNP is valued at approximately \$8.50 per share based on contributions from Probuphine and ropinirole in the US/EU. We currently do not include any contribution from the triiodothyronine or other in-development programs. Valuation for pre-clinical programs will be added upon commencement of clinical trials.

Current Price (4/6/18) **\$1.02**
Valuation \$8.50

OUTLOOK

Titan Pharmaceuticals launched its first product, Probuphine, with Braeburn Pharmaceuticals; however, Titan is currently negotiating to find another partner. The company is also in the process of obtaining approval in Europe and has partnered to commercialize Probuphine in the EU and other regions.

Ropinirole is in clinical trials and several other candidates are about to enter the clinical phase of the development pipeline. All products 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 has characteristics beneficial to 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 **\$3.25**
 52-Week Low **\$0.94**
 One-Year Return (%) **-68.1**
 Beta **1.49**
 Average Daily Volume (sh) **114,503**

Shares Outstanding (mil) **21.2**
 Market Capitalization (\$mil) **\$21.6**
 Short Interest Ratio (days) **4.06**
 Institutional Ownership (%) **7.1**
 Insider Ownership (%) **12.0**

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 2017 Estimate **N/A**
 P/E using 2018 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 | \$0.1 A | \$0.2 A |
| 2018 | | | | | \$0.4 E |
| 2019 | | | | | \$9.5 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 | -\$0.17 A | -\$0.68 A |
| 2018 | | | | | -\$0.59 E |
| 2019 | | | | | -\$0.19 E |

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

WHAT'S NEW

Summary of 2017 and Year to Date Highlights

Titan Pharmaceuticals, Inc. (NASDAQ: TTNP) [reported](#) fourth quarter and full year 2017 results in its April 2 release. The update caps a year with Probuphine revenues well below expectations. To address the weak sales by partner Braeburn, Titan began discussions to return commercialization rights. However, since the parties are in the negotiation process, the eventual outcome is unknown.

Due to the slow ramp of sales from Probuphine in the summer of 2017, Titan secured a debt facility from Horizon Technology Finance in July to fund the development programs in the pipeline. Titan made substantial headway in development, launching its ropinirole program and enrolling its first patient, developing new collaborations with Opiant Pharmaceuticals (NASDAQ: OPNT) and Walter Reed Army Institute as well as new initiatives for a κ -opioid receptor and diabetes medicine liraglutide. The company also had its MAA accepted by the EMA for Probuphine in Europe.

However, continued weak sales of domestic Probuphine after borrowed funds were received forced an amendment to the Horizon loan agreement in January 2018 and immediate repayment of \$3 million of the amount outstanding. After several weeks of uncertainty, new partner Molteni stepped up and paid its promised upfront for European Probuphine development rights and assumed \$2.4 million of Horizon's debt. The receipt of cash along with Molteni's strategic investment allowed the extension of the interest only and forbearance periods to be extended to December 31, 2019, providing some breathing room for Titan to get Probuphine back on track.

2017 Financial Results

For 2017 Titan reported total revenues of \$215 thousand increasing from \$65 thousand in 2016. Full year research and development costs totaled \$9.6 million, rising 57%. The expansion was due to external research and development expenses related to the ProNeura development programs, including the costs associated with the IND and clinical study of the ropinirole implant. Higher costs also stemmed from the preparation of the Probuphine MAA for submission to the EMA and employee related expenses. General and administrative expenses rose 10% to \$5.1 million, as non-cash stock-based compensation and other compensation increased partially offset by the reduction in headcount by one.

Cash and equivalents at year end 2017 were \$7.5 million, compared to \$14.0 million at the end of 2016. Debt was \$6.6 million, however, following the end of the reporting period, \$3 million in debt was paid down and \$2.4 million in cash was received from Molteni's upfront payment. Cash burn was (\$13.2) million in 2017 compared to a cash contribution of \$6.1 million in 2016 which arose due to the \$15 million upfront payment upon FDA approval from Braeburn for Probuphine.

Return of Probuphine

Titan [announced](#) on January 22 that it is in discussions with Probuphine license holder Braeburn regarding the disposition of Probuphine. Sales of the implant have been disappointing since the 2Q:16 launch of the product as Braeburn has been working through payor, reimbursement, and Risk Evaluation and Mitigation Strategy (REMS) requirements among other complexities since first sales. Just prior to Titan's announcement, the FDA issued a Complete Response Letter (CRL) for CAM2038, Braeburn's lead development candidate for the treatment of adults with opioid abuse disorder. Due to the shift of Braeburn management's attention toward addressing the CRL, a transfer of the development license from Braeburn has emerged as the most efficient path forward.

As per the agreement between Titan and Braeburn, the latter is required to make commercially reasonable efforts to sell Probuphine. More specifically this means that the company must use its skill, effort, expertise and resources to commercialize the drug.¹ As Braeburn reduced the size of its sales force in the face of poor sales, the requirement to fully commercialize the drug appears to be violated and Titan has begun the process to transfer commercialization rights from Braeburn to Titan. While we initially considered that a legal fight might be possible, it appears that the parties are in negotiations to return the rights and based on commentary from management, the costs of the transition are likely to be borne by partners. Additionally, it appears that all of the inventory, equipment and provider relationships will smoothly transfer from Braeburn to the entity that eventually commercializes.

¹ https://www.sec.gov/Archives/edgar/data/910267/000114420413061109/v360394_ex10-2.htm

Braeburn had sublicensed Probuphine to Knight Therapeutics (TSE: GUD) who has filed a new drug submission (NDS) to Health Canada. A response from the regulatory agency is expected this summer. It is unclear if Knight will maintain the distribution role to the North and this will be part of the negotiation.

There is still no clear timeline for the transfer; however, Titan will share the details of the final agreement as they become available. We anticipate that it will take one or two quarters to work through the transition of Probuphine rights away from Braeburn and to find a new partner. We believe that Titan can obtain an upfront payment from another partner after rights are returned.

Braeburn is required to continue support for the patients that are already using Probuphine and there should be a small stream of royalty income continuing from product sales in the interim prior to a new partner assuming the licenses.

Pipeline and Marketed Products

- Probuphine North America
 - Titan and Braeburn negotiating for return of commercialization rights
 - Transition period expected
 - Transition costs and new commercial rollout will be assumed by partners
- Probuphine Europe
 - November 6, 2017 filing of MAA
 - Molteni asset purchase, supply and support agreement with Titan – November 2017
 - Addressing questions from the EMA with response submission expected in Fall 2018
 - Notice of Allowance from European Patent office for methods of use providing protection until 2023
- 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)
 - 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
 - Walter Reed pursuing funding opportunities for the program
 - κ -opioid receptor as non-opioid analgesic for chronic pain
 - Liraglutide for Type 2 diabetes
 - Liothyronine (LT3) for treatment of hypothyroidism
 - Oxytocin for autism spectrum disorder

Other Achievements

- New Members Added to Board of Directors
 - Scott Smith, formerly COO of Celgene
 - Dr. Rajinder Kumar, CEO of MeRaD Pharmaceutical Ltd

Valuation Update

We adjust our valuation to reflect the corporate tax reduction signed into law in December 2017 and the advancement of our NPV model forward by one year. We also reduce 2018 Probuphine forecasted revenues in 2018 due to uncertainty over the transition of the license. The net of these changes has increased our target price to \$8.50 per share.

Conclusion

While Probuphine has consistently fallen behind our estimates due to a variety of difficulties which have been discussed in our reports, we see it as a positive that rights are transferring back to Titan. The potential for finding a new partner that can address these issues is a positive as is the opportunity for a cash infusion from an upfront payment; however, there is little detail on how this may eventually be resolved. In a worst case scenario, the transfer of the licenses gets tied up for an extended duration; while in a best case scenario an effective partner provides an upfront payment and is immediately able to effectively build off of the work Braeburn has done to provide a rapid ramp up in sales.

While there was concern over the repayment of the Horizon debt, we believe that the risk related to this has been addressed through the participation of Molteni. Interest only and forbearance periods have been extended to December 2019, providing some breathing room for Titan to revive Probuphine sales with another partner. We anticipate that details of the transition of Probuphine will be provided following the conclusion of negotiations.

We adjust our previous estimates for Probuphine sales down for 2018 to reflect the transition of the license back to Titan, reduce future tax rates and advance our NPV model ahead by one year. The net result of these changes increases our target to \$8.50 per share.

PROJECTED FINANCIALS

Titan Pharmaceuticals, Inc. - Income Statement

| Titan Pharmaceuticals, Inc. | 2016 A | Q1 A | Q2 A | Q3 A | Q4 A | 2017 A | 2018 E | 2019 E |
|-----------------------------|---------------|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|
| Total Revenues | \$15.1 | \$0.0 | \$0.1 | \$0.0 | \$0.1 | \$0.2 | \$0.4 | \$9.5 |
| <i>YOY Growth</i> | 801.6% | - | -99.5% | 53.8% | 65.7% | -98.6% | 82.3% | 2311.9% |
| R&D | \$6.1 | \$2.1 | \$2.5 | \$2.7 | \$2.3 | \$9.6 | \$9.4 | \$9.0 |
| G&A | \$4.6 | \$1.4 | \$1.2 | \$1.4 | \$1.1 | \$5.1 | \$6.5 | \$6.8 |
| Operating Income | \$4.3 | (\$3.4) | (\$3.6) | (\$4.1) | (\$3.4) | (\$14.5) | (\$15.5) | (\$6.3) |
| <i>Operating Margin</i> | 28.8% | - | -4702.6% | -10175.0% | -5817.2% | -6745.1% | -3957.7% | -67.1% |
| Total Other Income | \$0.8 | \$0.4 | \$0.2 | (\$0.1) | (\$0.3) | \$0.0 | \$0.0 | \$0.0 |
| Pre-Tax Income | \$5.1 | (\$3.0) | (\$3.5) | (\$4.2) | (\$3.7) | (\$14.5) | (\$15.5) | (\$6.3) |
| Taxes & Other | \$0 | \$0 | \$0 | \$0 | \$0 | \$0 | \$0 | \$0 |
| <i>Tax Rate</i> | 0% | 0% | 0% | 0% | 0% | 0% | 0% | 0% |
| Net Income | \$5.1 | (\$3.0) | (\$3.5) | (\$4.2) | (\$3.7) | (\$14.5) | (\$15.5) | (\$6.3) |
| <i>Net Margin</i> | - | - | - | - | - | - | - | - |
| Reported EPS | \$0.24 | (\$0.14) | (\$0.16) | (\$0.20) | (\$0.17) | (\$0.68) | (\$0.59) | (\$0.19) |
| <i>YOY Growth</i> | -142.5% | 55.4% | -129.9% | 59.9% | 60.0% | -385.8% | -13.5% | -67.5% |
| Weight Ave. Shares Out | 21.5 | 21.4 | 21.2 | 21.2 | 21.2 | 21.2 | 26.2 | 33.0 |

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

HISTORICAL STOCK PRICE



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