Zacks Small-Cap Research

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# Titan Pharmaceuticals, Inc. (TTNP-NASDAQ)

***FDA Approves Probuphine, partner outlines development plan, target price increases to $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.

| | |
|---|---|
| Current Price (06/2/16) | $5.96 |
| **Valuation** | **$12.00** |

## OUTLOOK

Titan Pharmaceuticals is a development stage company on the cusp of the launch of its lead product candidate, probuphine: an implanted, time-release medicine used for the treatment of opioid addiction. The FDA announced approval of the drug on May 26, 2016 and we anticipate launch of the drug in 3Q:16. Probuphine and the company's other drug candidates use a proprietary drug delivery system called ProNeura. Consisting of ethylene-vinyl acetate and a drug substance, ProNeura is a novel approach to delivery of drugs that benefit from long-duration slow release and controlled substance programs.

In addition to the opioid addiction indication, the company is also pursuing 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.

FDA approval of probuphine supports a price target of $12.00 per share.

## SUMMARY DATA

| | |
|---|---|
| **52-Week High** | **$7.41** |
| **52-Week Low** | **$2.98** |
| **One-Year Return (%)** | **29.0** |
| **Beta** | **1.93** |
| **Average Daily Volume (sh)** | **1,242,566** |
| **Shares Outstanding (mil)** | **20.4** |
| **Market Capitalization ($mil)** | **$120** |
| **Short Interest Ratio (days)** | **5.94** |
| **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** | **15.6** |
| **P/E using 2017 Estimate** | **9.1** |
| **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 E | $0.3 E | $0.9 E | $16.2 E |
| 2017 | | | | | $25.0 E |
| 2018 | | | | | $38.9 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 | $0.63 E | -$0.09 E | -$0.06 E | $0.38 E |
| 2017 | | | | | $0.65 E |
| 2018 | | | | | $1.22 E |

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## WHAT'S NEW

**Probuphine Approval Conference Call**

We had the opportunity to listen to Titan Pharmaceuticals' (NASDAQ: TTNP) conference call on Tuesday, May 31 where additional information was provided regarding the marketing of probuphine and the training of the physicians who will prescribe the product and perform the implantation procedures. Participants on the call included Titan's CEO, Sunil Bhonsle and Braeburn Pharmaceuticals (Private) CEO, Behshad Sheldon.

We remind investors that Braeburn will market probuphine in the United States and Canada and will pay Titan a average royalty rate in the 15% to 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 EMEA 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. Currently, 120 physicians have been trained and Braeburn plans to certify a total of 2,000 providers over the next six weeks. 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.

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.

We are puzzled by the negative reaction of the stock since approval was announced last week and since the conference call on Tuesday. While there are concerns regarding the black box warning, we believe providers are well aware of totality of risks faced by this addicted population and will conclude that usage is justified. The black box warns that that insertion and removal of probuphine is associated with the risk of implant migration, protrusion, expulsion and nerve damage. We note that Merck's Nexplanon, which is a subdermal implant for birth control does not carry a black box warning despite similar insertion, migration, protrusion, expulsion and nerve damage risks. Admittedly, Nexplanon requires only one rod to be inserted rather than four for probuphine and the procedure is

performed by OB/GYNs, but again, we believe that physicians will recognize the relative benefits of the treatment and weight the warning appropriately.

We reiterate our belief that Titan has sufficient capital resources to fund its current ropinirole and T3 programs. Following approval of probuphine, Braeburn will transfer the $15 million milestone payment to Titan and we anticipate royalty revenues to begin to flow in the coming months. 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.

Other investor concerns regarding the approval may be related to the patient population that may be prescribed probuphine. The product label limits usage to patients "who have achieved and sustained prolonged clinical stability on transmucosal buprenorphine," which is the same group that was studied in the Phase 3 trial. Braeburn noted in its ADCOM presentation that from 26% to 45% of prescriptions fall into this range and our valuation model anticipates penetration in the mid-single digit range, well below this threshold. We remind investors that The FDA had indicated that new patients (requiring 12-16 mg/day of sublingual buprenorphine) who were the subjects in the earlier controlled studies did not receive sufficient clinical benefit from the 4 implant dose (even though the primary endpoints were met) and were the rationale behind the complete response letter (CRL) issued in 2013.

We maintain our favorable view of Titan following the additional detail provided on the call and will be keeping a close eye on provider training statistics in the months to come and on initial sales levels. 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 recently increased price target of $12 per share.

**FDA Announces Approval of Probuphine**

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.

FDA Commissioner Robert Califf, M.D. set a positive tone for the approval in his statement supporting new treatment options for this destructive addiction. He noted that the "approval provides the first-ever implantable option to support patients' efforts to maintain treatment as part of their overall recovery program."

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 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.

The approval of the drug was delayed in January 2015 due to 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. In conclusion, we reiterate our recently increased price target of $12 per share and emphasize the material upside from current levels.

## PROJECTED FINANCIALS

**Titan Pharmaceuticals, Inc.** - Income Statement

| Titan Pharmaceuticals, Inc. | 2015 A | Q1 A | Q2 E | Q3 E | Q4 E | 2016 E | 2017 E | 2018 E |
|---|---|---|---|---|---|---|---|---|
| *Probuphine Sales (at Partner)* | *$0.0* | *$0.0* | *$0.0* | *$1.9* | *$5.8* | *$7.7* | *$97.3* | *$154.8* |
| *YOY Growth* | - | | | | | - | - | - |
| **Probuphine Royalty** | **$0.0** | **$0.0** | **$0.0** | **$0.3** | **$0.9** | **$1.2** | **$17.0** | **$27.9** |
| *YOY Growth* | - | - | - | - | - | - | *1372.9%* | *63.6%* |
| **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** | **$0.3** | **$0.9** | **$16.2** | **$25.0** | **$38.9** |
| *YOY Growth* | - | *-100.0%* | *1873.7%* | - | - | *866.9%* | *54.9%* | *55.3%* |
| 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 | $1.0 | $1.2 | $1.2 | $4.1 | $6.0 | $6.0 |
| SG&A | $3.8 | $1.1 | $0.9 | $1.0 | $1.0 | $4.0 | $5.0 | $6.0 |
| Operating Income | ($6.8) | ($1.8) | $13.1 | ($1.9) | ($1.3) | $8.0 | $14.0 | $26.9 |
| *Operating Margin* | - | - | *87.3%* | *-661.1%* | *-153.7%* | *49.7%* | *56.1%* | *69.1%* |
| Total Other Income | ($4.5) | ($0.0) | $0.0 | $0.0 | $0.0 | ($0.0) | $0.0 | $0.0 |
| Pre-Tax Income | ($11.3) | ($1.8) | $13.1 | ($1.9) | ($1.3) | $8.0 | $14.0 | $26.9 |
| 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) | $13.1 | ($1.9) | ($1.3) | $8.0 | $14.0 | $26.9 |
| *Net Margin* | - | - | - | - | - | - | - | - |
| **Reported EPS** | **($0.56)** | **($0.09)** | **$0.63** | **($0.09)** | **($0.06)** | **$0.38** | **$0.65** | **$1.22** |
| *YOY Growth* | *299.7%* | *-62.9%* | *-656.5%* | *1.0%* | *-45.0%* | *-167.8%* | *71.1%* | *87.1%* |
| Weight Ave. Shares Out | 20.1 | 20.4 | 20.7 | 21.0 | 21.2 | 21.0 | 21.5 | 22.0 |

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

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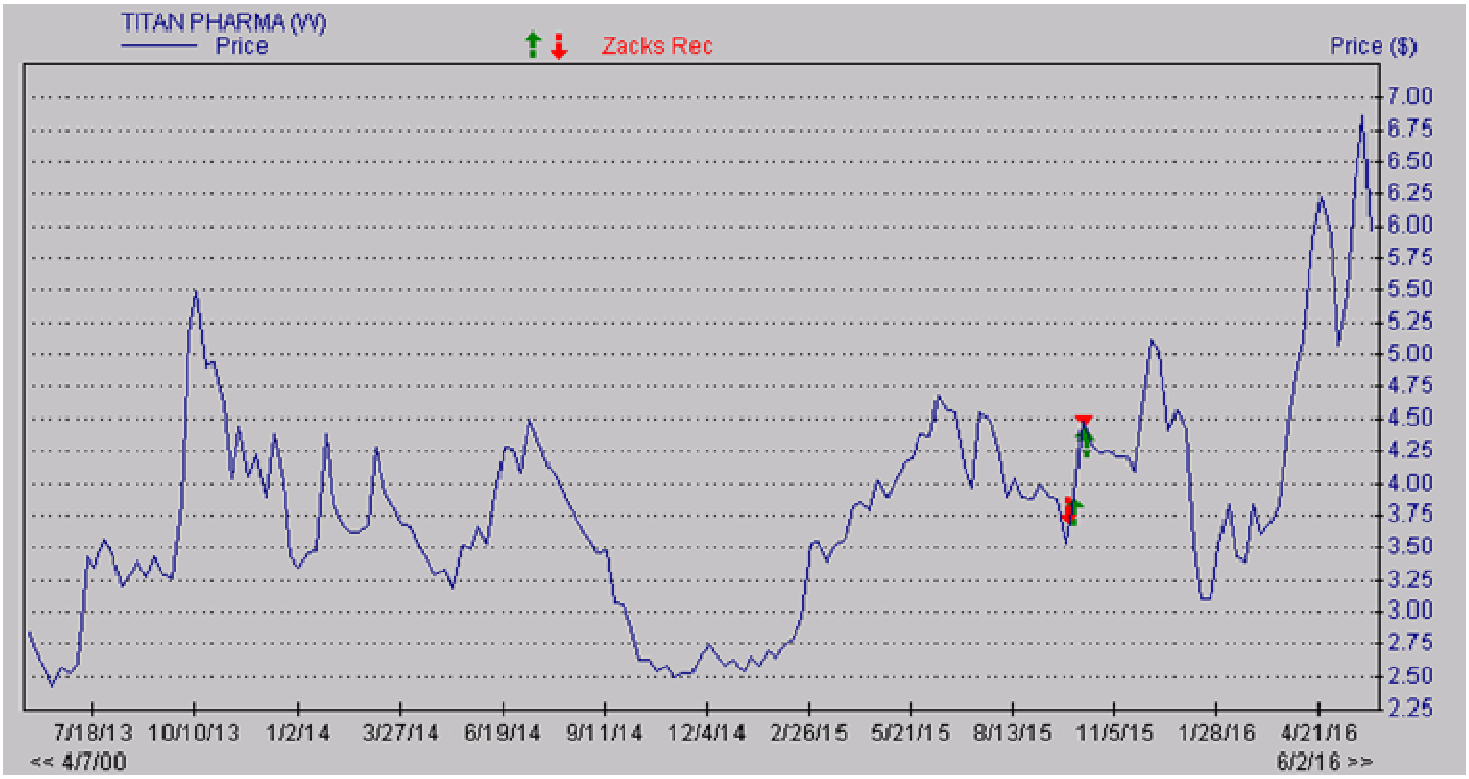
## HISTORICAL STOCK PRICE

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