

May 14, 2014



# Titan Pharmaceuticals Announces First Quarter 2014 Financial Results

**Titan Management Team to Host Conference Call May 15 at 10 a.m. PT/ 1 p.m. ET**

SOUTH SAN FRANCISCO, CA -- (Marketwired) -- 05/14/14 -- [Titan Pharmaceuticals, Inc.](http://www.titanpharm.com) (OTCBB: TTNP), a specialty pharmaceutical company developing proprietary therapeutics for the treatment of opioid dependence and other serious medical disorders, today reported financial results for the first quarter ended March 31, 2014.

Titan generated total revenue in the first quarter of 2014 of approximately \$0.9 million, compared with approximately \$5.2 million in the first quarter of 2013. First quarter 2014 revenues consisted of license revenue of approximately \$0.9 million, compared with license revenue of approximately \$3.8 million for first quarter 2013. License revenue in the quarters ended March 31, 2014 and 2013 reflects the amortization of the upfront license fee received from development and commercialization partner Braeburn Pharmaceuticals in December 2012. Titan did not recognize any Fanapt® royalty revenues during the quarter ended March 31, 2014, compared with net royalty revenue of \$1.4 million during the first quarter in 2013. Beginning in April 2013, Titan discontinued recognizing Fanapt royalty revenues, as all royalties are being paid to third parties.

Total operating expenses for the quarter ended March 31, 2014 were approximately \$1.8 million, compared with approximately \$5.0 million in the same quarter in 2013. These expenses consisted primarily of research and development (R&D) expenses of approximately \$1.0 million, compared with approximately \$3.9 million in the first quarter of 2013, a decrease of approximately \$2.9 million or 74 percent. The decrease in R&D costs was due to lower external R&D expenses related to the Probuphine® product development program and preparation and review of the new drug application (NDA) for Probuphine with the U.S. Food and Drug Administration. General and administrative (G&A) expenses for the first quarter of 2014 were approximately \$0.9 million, compared with approximately \$1.1 million for the same period in 2013, a small decrease of approximately \$0.2 million, or 18 percent.

Net other expense for the first quarter of 2014 was approximately \$0.9 million, which was primarily related to non-cash losses on changes in the fair value of warrants. Net other income for the first quarter of 2013 was approximately \$5.8 million, consisting primarily of approximately \$9.0 million in other income generated by the termination of Titan's royalty repurchase agreement with Deerfield and an approximately \$1.9 million gain resulting from the settlement of indebtedness to Deerfield as a result of the exercise of all of the Deerfield warrants, which were offset in part by interest expense of approximately \$1.6 million related to the Deerfield loans, non-cash losses on changes in the fair value of warrants of

approximately \$3.0 million and approximately \$0.5 million in other expenses related to unamortized transaction fees related to the initial Deerfield debt transaction.

Net loss for the first quarter 2014 was approximately \$1.8 million, or approximately \$0.02 per share, compared with net income of approximately \$6.0 million, or approximately \$0.08 per share in the same quarter in 2013.

At March 31, 2014, Titan had cash of approximately \$10.2 million. Titan believes that its working capital at present is sufficient to fund planned operations into April 2015.

During the first quarter of 2014, Titan's primary focus remained on securing a path forward for Probuphine®, the company's investigational subdermal implant for the long-term maintenance treatment of opioid dependence developed using Titan's ProNeura™ drug delivery system. After reaching an agreement in principle with the FDA on the design of a clinical study to support the resubmission of the Probuphine NDA, Titan and Braeburn announced on April 30, 2014 that the FDA had provided clear guidance on the full clinical study protocol of Probuphine, paving the way to commence the new clinical study. As a result, preparations are now under way to qualify investigator sites, obtain Institutional Review Board Approval and train clinicians in study procedure. The study is expected to begin enrollment around mid-year, and study completion is anticipated by the middle of 2015.

"We have made significant progress moving Probuphine forward since the beginning of 2014. Our discussions with the FDA in the first quarter were productive and insightful, and resulted in clear guidance from the FDA on a new study," Titan President and CEO Sunil Bhonsle said. "As we work with our partner, Braeburn, to prepare for commencing patient enrollment around mid-year and to complete the study next year, we remain optimistic that we will be able to resubmit our NDA for Probuphine in 2015. We will continue to provide progress reports periodically. If approved, Probuphine has the potential to be the first long-term maintenance treatment of opioid dependence to provide continuous, round-the-clock blood levels of buprenorphine for six months."

"The board is pleased with the progress Titan has made this quarter, and we are confident that Probuphine is now on a solid path forward," said Marc Rubin, M.D., executive chairman of Titan. "As we continue to advance Probuphine, we are also looking to further deliver on the value of the ProNeura drug delivery system. In the coming months we will be consulting with scientific advisors and key opinion leaders and seeking regulatory guidance on the submission of an investigational new drug application for ProNeura for Parkinson's disease by late next year."

### ***About Opioid Dependence***

According to recent estimates, there are approximately 2.7 million people with opioid dependence in the U.S. Approximately 20 percent of this population is addicted to illicit opioids, such as heroin, and the other 80 percent to prescription opioids, such as oxycodone, hydrocodone, methadone, hydromorphone and codeine. Before the year 2000, medication-assisted therapies for opioid dependence had been sanctioned to a limited number of facilities in the U.S. The Drug Addiction Treatment Act of 2000 (DATA 2000) allowed medical office-based treatment of opioid dependence and greatly expanded patient access to medication-assisted treatments. As a result, an estimated 1.2 million people in the U.S. sought treatment for opioid dependence in 2011.

### **About Probuphine®**

Probuphine is an investigational subdermal implant designed to deliver continuous, around-the-clock blood levels of buprenorphine for six months following a single treatment, and to simplify patient compliance and retention. Buprenorphine, an approved agent for the treatment of opioid dependence, is currently available in the form of daily dosed sublingual tablets and film formulations, with reported 2012 sales of approximately \$1.5 billion in the United States.

Probuphine was developed using ProNeura™, Titan's continuous drug delivery system that consists of a small, solid implant made from a mixture of ethylene-vinyl acetate (EVA) and a drug substance. The resulting construct is a solid matrix that is placed subdermally, normally in the upper arm in a simple office procedure, and removed in a similar manner at the end of the treatment period. The drug substance is released slowly and continuously through the process of dissolution resulting at a steady rate of release.

The efficacy and safety of Probuphine has been studied in several clinical trials, including a 163-patient, placebo-controlled study over a 24-week period (published in the Journal of the American Medical Association (JAMA)), and a follow-on study of 287 patients (published in the journal Addiction).

### **ProNeura™ Technology**

Probuphine is the first product to utilize Titan's proprietary, long-term drug delivery technology, ProNeura, which has the potential to be used in developing products for the treatment of other chronic conditions. In July 2012, Titan announced that it had successfully completed preclinical investigation into the feasibility of a long-term, around-the-clock, non-fluctuating dopamine agonist treatment for Parkinson's disease, where maintaining stable, around-the-clock blood levels of dopamine agonists may benefit the patient and improve medical outcomes. Titan has been issued patents covering certain dopamine agonist implants in Europe, Japan, Australia, Canada, South Korea, Mexico, New Zealand, South Africa, and Hong Kong, while prosecution of patent applications continues in the U.S., Israel, India and China.

### **Conference Call**

[Titan Pharmaceuticals, Inc.](#) (OTCBB: TTNP) will host a live conference call at 10 a.m. PT / 1 p.m. ET on Thursday, May 15, 2014 to discuss the company's financial results as of March 31, 2014. The call will be hosted by Sunil Bhonsle, president and CEO; Katherine Glassman-Beebe, Ph.D., executive vice president and chief development officer; Brian Crowley, vice president of finance, and Marc Rubin, M.D., executive chairman.

The live webcast of the call may be accessed by visiting the Titan website at [www.titanpharm.com](http://www.titanpharm.com). The call can also be accessed by dialing 888-438-5491, participant code 2873375, five minutes prior to the start time. A replay of the call will be available on the company website approximately two hours after completion of the call and will be archived for two weeks.

### **About Titan Pharmaceuticals**

Titan Pharmaceuticals Inc. (OTCBB: TTNP), based in South San Francisco, CA, is a specialty pharmaceutical company developing proprietary therapeutics primarily for the treatment of serious medical disorders. The company's lead product candidate is

Probuphine®, a novel and long-acting formulation of buprenorphine for the long-term maintenance treatment of opioid dependence. Probuphine employs Titan's proprietary drug delivery system ProNeura™, which is capable of delivering sustained, consistent levels of medication for six months or longer. Titan has granted North American commercial rights for Probuphine to Braeburn Pharmaceuticals. If approved, Probuphine would be the first and only commercialized treatment of opioid dependence to provide continuous, round-the-clock blood levels of buprenorphine for six months following a single procedure. The ProNeura technology has the potential to be used in developing products for treating other chronic conditions, such as Parkinson's disease, where maintaining consistent blood levels of a dopamine agonist may benefit the patient and improve medical outcomes. For more information about Titan, please visit [www.titanpharm.com](http://www.titanpharm.com).

*This press release may contain "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. Such statements include, but are not limited to, any statements relating to our product development programs and any other statements that are not historical facts. Such statements involve risks and uncertainties that could negatively affect our business, operating results, financial condition and stock price. Factors that could cause actual results to differ materially from management's current expectations include those risks and uncertainties relating to the regulatory approval process, the development, testing, production and marketing of our drug candidates, patent and intellectual property matters and strategic agreements and relationships. We expressly disclaim any obligation or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein to reflect any change in our expectations or any changes in events, conditions or circumstances on which any such statement is based, except as required by law.*

**TITAN PHARMACEUTICALS, INC.**

**CONDENSED STATEMENTS OF OPERATIONS AND COMPREHENSIVE INCOME  
(LOSS)**

**(in thousands, except per share amount)  
(unaudited)**

	<b>Three Months Ended March 31,</b>	
	<b>2014</b>	<b>2013</b>
Revenue:		
License revenue	\$ 911	\$ 3,750
Royalty revenue	-	1,424
Total revenue	911	5,174
Operating expenses:		
Research and development	949	3,912
General and administrative	896	1,091
Total operating expense	1,845	5,003
Income (loss) from operations	(934 )	171

Other income (expense), net	<u>(870 )</u>	<u>5,830</u>
Net income (loss) and comprehensive income (loss)	<u>\$ (1,804 )</u>	<u>\$ 6,001</u>
Basic net income (loss) per share	<u>\$ (0.02 )</u>	<u>\$ 0.08</u>
Diluted net income (loss) per share	<u>\$ (0.02 )</u>	<u>\$ 0.07</u>
Weighted average shares used in computing basic net income (loss) per share	<u>88,929</u>	<u>78,256</u>
Weighted average shares used in computing diluted net income (loss) per share	<u>88,929</u>	<u>86,762</u>

**CONDENSED BALANCE SHEETS**  
(in thousands)  
(unaudited)

	<b>March 31, 2014</b>	<b>December 31, 2013</b>
<b>Assets</b>		
Cash	\$ 10,239	\$ 11,798
Receivables	4,080	4,818
Prepaid expenses and other current assets	<u>286</u>	<u>204</u>
Total current assets	14,605	16,820
Furniture and equipment, net	<u>1,518</u>	<u>1,603</u>
Total assets	<u>\$ 16,123</u>	<u>\$ 18,423</u>
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities	\$ 9,160	\$ 10,846
Warrant liabilities	2,681	1,817
Stockholders' equity	<u>4,282</u>	<u>5,760</u>
Total liabilities and stockholders' equity	<u>\$ 16,123</u>	<u>\$ 18,423</u>

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