

March 31, 2014



# **Titan Pharmaceuticals Announces Fourth Quarter and Year End 2013 Financial Results**

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

SOUTH SAN FRANCISCO, CA -- (Marketwired) -- 03/31/14 -- [Titan Pharmaceuticals, Inc.](http://www.titanpharm.com) (OTCBB: TTNP) today reported financial results for the fourth quarter and year ended December 31, 2013.

Total revenues for 2013 were approximately \$10.5 million, compared with approximately \$7.1 million in 2012. Revenues in 2013 consisted of approximately \$9.1 million in licensing revenues related to the amortization of the upfront license fee received from Titan's commercialization partner Braeburn Pharmaceuticals in December 2012 and approximately \$1.4 million in royalty revenues on net sales of Fanapt®, which were paid by Titan to Deerfield Management in accordance with the terms of the agreements entered into in 2011. Titan no longer recognizes Fanapt royalty revenues since all of such royalties are paid to third parties. The revenues in 2012 consisted of approximately \$4.8 million in royalties on Fanapt that were passed on to Deerfield, and approximately \$2.3 million associated with the licensing and stock purchase agreements with Braeburn.

Total operating expenses for 2013 were approximately \$11.4 million, compared with approximately \$15.5 million for 2012, and consisted largely of research and development (R&D) expenses of approximately \$8.3 million, compared with approximately \$10.6 million for 2012. This decrease in R&D expenses was primarily associated with a decrease in external costs related to the completion of the Probuphine® product development program and the preparation and review of the Probuphine new drug application (NDA) with the U.S. Food and Drug Administration (FDA). General and administrative (G&A) expenses for 2013 were approximately \$3.1 million, compared to approximately \$4.9 million in 2012. The 2013 decrease in G&A expenses was primarily related to decreases in non-cash stock compensation costs of approximately \$1.3 million, employee-related costs of approximately \$0.2 million and consulting and professional services fees of approximately \$0.3 million.

Net other income for 2013 was approximately \$10.6 million, compared to a net other expense of approximately \$6.8 million in 2012. The increase in net other income during 2013 was primarily related to approximately \$9.0 million of other income generated by the termination of Titan's royalty repurchase agreement with Deerfield, an approximately \$1.9 million gain resulting from the settlement of Titan's indebtedness to Deerfield as a result of the exercise of all of the Deerfield warrants, a decrease in interest expense of approximately \$3.3 million related to the Deerfield loans and approximately \$3.5 million related to non-cash

gains on changes in the fair value of warrants. This was offset in part by approximately \$0.5 million of other expense related to unamortized transaction fees related to the initial Deerfield debt transaction.

Net income applicable to common stockholders for 2013 was approximately \$9.7 million, or \$0.12 per share, compared to a net loss of approximately \$15.2 million, or \$0.23 per share, for 2012.

As of Dec. 31, 2013, Titan had cash and cash equivalents of approximately \$11.8 million compared with approximately \$18.1 million at December 31, 2012. Titan believes that its working capital at Dec. 31, 2013 is sufficient to fund planned operations through April 2015.

"Our plans for the year changed substantially following the decision by the FDA to decline approval of the Probuphine NDA in April 2013, and our focus shifted from planned corporate development and new product development activities to supporting Braeburn in addressing the concerns expressed by the FDA," said Titan Pharmaceuticals President Sunil Bhonsle. "The financial results for last year are reflective of these changed plans. While our first priority this year continues to be the support of activities for the continued development of Probuphine and the resubmission of the NDA, we will also evaluate opportunities for the potential approval of Probuphine outside North America and the potential development of additional products with the ProNeura™ long-term drug delivery platform as resources permit."

Key highlights include:

- In early March 2014, Titan and Braeburn reached an agreement in principle with the FDA on a path forward to address the Complete Response Letter and enable the potential resubmission of the Probuphine NDA, which, along with other steps, includes conducting an additional clinical study designed to provide a non-inferiority comparison of treatment with a dose of four Probuphine implants in stable patients undergoing maintenance treatment with 8mg or less per day of an FDA-approved sublingual formulation of buprenorphine. The clinical study protocol has been submitted to the FDA and further details of the study and implementation plans will be provided upon the completion of the FDA's review.
- In November 2013, Braeburn made a \$5 million equity investment in Titan associated with the restructuring of certain terms of the license agreement for commercialization of [Probuphine](#). Under the terms of the amended license agreement, Titan is entitled to a milestone payment of \$15 million upon FDA approval of the Probuphine NDA, potential sales milestone payments of \$165 million, regulatory milestone payments of \$35 million and tiered royalties ranging from the mid-teens to low twenties. The sales threshold to achieve the highest royalty tier was lowered and Braeburn agreed to assume responsibility for all third-party expenses relating to the Probuphine regulatory process.
- Titan amended the terms of the Deerfield warrants to permit payment of the exercise price through the reduction of the outstanding loan. In February and March, 2013, Deerfield exercised all of the Deerfield warrants resulting in a \$7.5 million reduction of Titan's indebtedness. In April 2013, Titan made the last installment payment of \$2.5 million and the company's debt obligation to Deerfield was satisfied in full. Titan also amended the agreements with Deerfield terminating Titan's option to repurchase the Fanapt royalty rights, resulting in the non-cash gain on the extinguishment of royalty

liability of approximately \$9 million.

"Since receiving the Complete Response Letter in April, 2013, we have focused largely on working with Braeburn and its team of expert clinical and regulatory advisors to secure a path forward with the FDA for Probuphine," said Titan Pharmaceuticals Executive Vice President and Chief Development Officer Kate Glassman-Beebe, Ph.D. "An agreement in principle has been reached with the FDA on a study design to support the resubmission of an NDA, and we are working diligently with Braeburn to do all that we can to lay the groundwork for this clinical study while we await the FDA's review of the study protocol. We look forward to advancing this important program to ultimately benefit the millions of people suffering from opioid dependence."

#### ***Fourth Quarter 2013 Results***

Total revenues for the fourth quarter of 2013 were approximately \$0.9 million, consisting of licensing revenues related to the amortization of the upfront license fee received from Braeburn in December 2012. This compares with total fourth quarter revenue of approximately \$3.3 million in 2012, consisting of approximately \$0.9 million in royalty revenue on net sales of Fanapt, which were paid by Titan to Deerfield in accordance with the terms of the agreements entered into in 2011 and approximately \$2.3 million in licensing revenues, consisting of approximately \$1.7 million associated with the premium paid for Titan's common stock by an affiliate of Braeburn pursuant to the September 2012 stock purchase and option agreement and approximately \$0.6 million related to the recognition of the non-refundable up-front license fee from Braeburn. The decrease in fourth quarter 2013 revenue was due to Titan no longer recognizing Fanapt royalty revenues, as all of such royalties are paid to third parties.

Total operating expenses for the fourth quarter of 2012 were approximately \$1.6 million, consisting primarily of R&D expenses of approximately \$0.9 million and G&A expenses of approximately \$0.6 million. Operating expenses for the same period in 2012 were approximately \$3.7 million, consisting primarily of R&D expenses of approximately \$2.6 million related to the preparation of the Probuphine NDA submission and FDA review, and G&A expenses of approximately \$1.1 million. The decrease in fourth quarter 2013 operating expenses reflected the completion of preparations for the NDA submission in 2012.

Net loss applicable to common stockholders for the fourth quarter of 2013 was approximately \$0.2 million, or \$0.00 per share, compared with approximately \$0.3 million, or \$0.00 per share, in the same quarter in 2012.

#### ***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 management will host a live conference call at 10 a.m. PT / 1 p.m. ET on Tuesday, April 1, 2014 to discuss the company's financial results for the fourth quarter and year ended December 31, 2013. The call will be hosted by Sunil Bhonsle, President; 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) 221-3887, Participant Code 3001910 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, around-the-clock blood levels of buprenorphine for six months. 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).

*The 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 December 31,</b>		<b>Year Ended December 31,</b>	
	<b>2013</b>	<b>2012</b>	<b>2013</b>	<b>2012</b>
Revenue:				
License revenue	\$ 911	\$ 2,325	\$ 9,057	\$ 2,325
Royalty revenue	-	934	1,424	4,750
Grant revenue	-	-	-	42
Total revenue	911	3,259	10,481	7,117
Operating expense:				
Research and development	929	2,573	8,309	10,610
General and administrative	624	1,128	3,063	4,877
Total operating expense	1,553	3,701	11,372	15,487
Loss from operations	(642 )	(442 )	(891 )	(8,370 )

Other income (expense), net	<u>433</u>	<u>162</u>	<u>10,602</u>	<u>(6,810)</u>
Net income (loss) and comprehensive income (loss)	<u>\$ (209)</u>	<u>\$ (280)</u>	<u>\$ 9,711</u>	<u>\$ (15,180)</u>
Basic net income (loss) per share	<u>\$ (0.00)</u>	<u>\$ (0.00)</u>	<u>\$ 0.12</u>	<u>\$ (0.23)</u>
Diluted net income (loss) per share	<u>\$ (0.00)</u>	<u>\$ (0.00)</u>	<u>\$ 0.10</u>	<u>\$ (0.23)</u>
Weighted average shares used in computing basic net income (loss) per share	<u>84,990</u>	<u>74,732</u>	<u>82,099</u>	<u>66,509</u>
Weighted average shares used in computing diluted net income (loss) per share	<u>85,051</u>	<u>74,732</u>	<u>82,659</u>	<u>66,509</u>

### **CONDENSED BALANCE SHEETS**

*(in thousands)*

*(unaudited)*

	<b>December 31,</b>	
	<b>2013</b>	<b>2012</b>
<b>Assets</b>		
Cash	\$ 11,798	\$ 18,102
Receivables	4,818	4,646
Prepaid expenses and other current assets	<u>204</u>	<u>687</u>
Total current assets	16,820	23,435
Furniture and equipment, net	<u>1,603</u>	<u>1,392</u>
	<u>\$ 18,423</u>	<u>\$ 24,827</u>
<b>Liabilities and Stockholders' Equity (Deficit)</b>		
Current liabilities	\$ 10,846	\$ 21,393
Warrant liabilities	1,817	8,240
Royalty liability	-	8,962
Long-term debt	-	9,360
Stockholders' equity (deficit)	<u>5,760</u>	<u>(23,128)</u>
	<u>\$ 18,423</u>	<u>\$ 24,827</u>

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