

March 15, 2013



# Titan Pharmaceuticals Announces Fourth Quarter and Year End 2012 Financial Results

**Titan Management Team to Host Conference Call March 18 at 11:00am ET / 8:00am PT**

SOUTH SAN FRANCISCO, CA -- (Marketwire) -- 03/15/13 -- [Titan Pharmaceuticals, Inc.](http://www.titanpharm.com) (OTCBB: TTNP) today reported financial results for the fourth quarter and year ended December 31, 2012.

Total revenues for the year 2012 were approximately \$7.1 million, compared to approximately \$4.1 million in 2011. Revenues consisted of approximately \$4.8 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, approximately \$1.7 million in licensing revenues associated with the premium paid for Titan's common stock by an affiliate of Braeburn Pharmaceuticals 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 fee received from Braeburn for the exclusive U.S. and Canadian commercialization rights for Probuphine® in December 2012.

Total operating expenses for the year 2012 were approximately \$15.5 million, compared with approximately \$14.6 million for 2011, and consisted largely of research and development (R&D) expenses of approximately \$10.6 million, compared to approximately \$11.2 million for 2011. This decrease in R&D costs was primarily associated with a decrease in external R&D expenses related to the Phase 3 clinical trials for Probuphine®, which were completed in 2011. This was offset by expenses related to the establishment of a commercial scale manufacturing operation at DPT Laboratories and preparation and submission of a New Drug Application (NDA) for Probuphine with the U.S. Food and Drug Administration (FDA) in October 2012. General and administrative (G&A) expenses for 2012 were approximately \$4.9 million, compared to approximately \$3.4 million in 2011. The increase in general and administrative expenses was primarily related to increases in non-cash stock compensation costs of approximately \$0.8 million and employee and consultant related costs of approximately \$0.6 million.

Net other expense for the year 2012 was approximately \$6.8 million, compared to approximately \$4.7 million in 2011. The increase in net other expense during 2012 was primarily related to a \$1.8 million non-cash loss related to increases in the fair value of the warrants issued to Deerfield and the warrants issued as part of the April 2012 financing transaction as well as a small increase in the interest expense on the Deerfield long-term debt.

Net loss applicable to common stockholders for 2012 was approximately \$15.2 million, or \$0.23 per share, compared to a net loss of approximately \$15.2 million, or \$0.26 per share, for 2011. At December 31, 2012, Titan had cash and cash equivalents of approximately \$18.1 million compared to approximately \$5.4 million at December 31, 2011, reflecting proceeds from the sale of approximately \$5.5 million of shares of common stock and warrants to institutional investors in April 2012, the execution of the \$4.25 million stock purchase and option agreement in September 2012, the exercise of Series B warrants for approximately \$4.9 million in October 2012 and the receipt of a \$15.75 million non-refundable up-front payment for the license of the exclusive rights to commercialize Probuphine in the U.S. and Canada in December 2012. Titan believes that its working capital at December 31, 2012, together with the FDA's reimbursement of the \$2 million NDA filing fee, is sufficient to fund planned operations through June 2014.

Key recent accomplishments include:

- [Acceptance](#) of the NDA for Probuphine for the maintenance treatment of opioid dependence in adult patients and the granting of Priority Review designation by the FDA was announced in January 2013. The Psychopharmacologic Drugs Advisory Committee (PDAC) of the FDA is scheduled to review the NDA for Probuphine on March 21, 2013 and the target PDUFA date for the FDA to complete its review of the Probuphine NDA is April 30, 2013.
- [Execution](#) of a license agreement with Braeburn Pharmaceuticals for the exclusive commercialization rights to Probuphine in the U.S. and Canada, pursuant to which Titan received a non-refundable up-front payment of \$15.75 million and is entitled to receive a \$50 million milestone payment upon approval of the NDA by the FDA, tiered royalties on net sales of Probuphine ranging from the mid-teens to the low twenties, up to \$130 million upon achievement of specified sales milestones, up to \$35 million upon achievement of specified regulatory milestones related to additional indications for Probuphine.
- Completion of a new Probuphine manufacturing facility and demonstration of commercial scale manufacturing capability.
- Successful completion of an investigational non-clinical study into the feasibility of a long-term, around the clock, non-fluctuating dopamine agonist treatment for Parkinson's disease.

"This has been a breakthrough year for Titan and was capped off by the FDA's acceptance of our NDA submission for Probuphine and its Priority Review designation," said Sunil Bhonsle, president of Titan Pharmaceuticals. "Ahead of us is the upcoming advisory committee meeting later this week and the target PDUFA date of April 30, 2013. If approved for the maintenance treatment of opioid dependence in adults, Probuphine will enter a market currently approaching \$1.5 billion in annual sales of daily dosed sublingual buprenorphine formulations in the U.S."

"The board is very pleased with the progress in 2012 and is fully engaged in pursuing the goals for this year," said Marc Rubin, M.D., executive chairman of Titan Pharmaceuticals. "With the Braeburn Pharmaceuticals team's proven track record of successful commercialization and product launches, we are strongly positioned to realize the value of Probuphine for our shareholders and to reach our ultimate goal of bringing a novel treatment option for opioid dependence to patients, their families and healthcare providers."

#### *Fourth Quarter 2012 Results*

Total revenues for the fourth quarter of 2012 were approximately \$3.3 million, consisting of approximately \$0.9 million in royalty revenue 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, 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 Pharmaceuticals 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 in December 2012. Total revenues for the fourth quarter of 2011 were approximately \$1.4 million, consisting of approximately \$1.3 million in Fanapt royalties and approximately \$0.1 million in grant revenues.

Total operating expenses for the fourth quarter of 2012 were approximately \$3.7 million, consisting primarily of R&D expenses of \$2.6 million and G&A expenses of \$1.1 million. Operating expenses for the comparable period in 2011 were \$2.2 million, which included \$1.3 million in R&D expenses and approximately \$0.9 million in G&A expenses.

Net loss applicable to common stockholders for the fourth quarter of 2012 was approximately \$0.3 million, or \$0.00 per share. Net loss for the comparable period in 2011 was approximately \$2.9 million, or \$0.05 per share.

#### *About Opioid Dependence*

According to recent estimates, there are 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 capable of delivering continuous and persistent, around the clock blood levels of buprenorphine for six months following a single treatment, simplifying 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 2011 sales of \$1.3 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 in a steady rate of release similar to intravenous administration.

The efficacy and safety of Probuphine has been studied in several clinical trials, including a 163-patient, placebo-controlled study that demonstrated clinically meaningful and statistically significant treatment benefits with Probuphine over a 24-week period ([published](#) in the Journal of the American Medical Association (JAMA)), and a confirmatory study of 287

patients that showed statistically significant improvement in efficacy versus placebo, and non-inferiority with a currently marketed sublingual formulation of buprenorphine. Results of the confirmatory study were [announced](#) in July 2011. Probuphine was well-tolerated in all clinical studies, including in two open label safety studies that provided treatment with Probuphine for an additional six months to patients who completed the six-month controlled study.

#### *ProNeura™ Technology*

Probuphine is the first product to utilize our 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, round-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 the patent application continues in the U.S., Israel, India and China.

#### *Conference Call*

Titan management will host a live conference call at 11 a.m. ET / 8 a.m. PT on Monday, March 18, 2013 to provide the Company's financial results as of December 31, 2012. Participating on the call will be Mr. Bhonsle, Marc Rubin, M.D., Executive Chairman, Katherine Beebe, Ph.D., Executive Vice President and Chief Development Officer, and Brian Crowley, Vice President of Finance.

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 888-539-3678, Participant Code: 7140768 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*

For information concerning Titan Pharmaceuticals, Inc., please visit the Company's website at [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 the Company's development program and any other statements that are not historical facts. Such statements involve risks and uncertainties, including, but not limited to, those risks and uncertainties relating to difficulties or delays in development, testing, regulatory approval, production and marketing of the Company's drug candidates, adverse side effects or inadequate therapeutic efficacy of the Company's drug candidates that could slow or prevent product development or commercialization, and the uncertainty of patent protection for the Company's intellectual property or trade secrets. Such statements are based on management's current expectations, but actual results may differ materially due to various factors, including those risks and uncertainties mentioned or referred to in this press release.

TITAN PHARMACEUTICALS, INC.  
CONDENSED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS  
(in thousands, except per share amount)

	Three Months Ended December 31,		Years Ended December 31,	
	2012	2011	2012	2011
Revenue:				
Royalty revenue	\$ 934	\$ 1,294	\$ 4,750	\$ 3,585
License revenue	2,325	-	2,325	-
Grant revenue	-	119	42	483
Total revenue	3,259	1,413	7,117	4,068
Operating expense:				
Research and development	2,573	1,291	10,610	11,206
General and administrative	1,128	888	4,877	3,368
Total operating expense	3,701	2,179	15,487	14,574
Loss from operations	(442)	(766)	(8,370)	(10,506)
Other income (expense), net	162	(2,132)	(6,810)	(4,697)
Net loss and comprehensive loss applicable to common stockholders	\$ (280)	\$ (2,898)	\$ (15,180)	\$ (15,203)
Basic and diluted net loss per share	\$ -	\$ (0.05)	\$ (0.23)	\$ (0.26)
Weighted average shares used in computing basic and diluted net loss per share	74,732	59,386	66,509	59,324

CONDENSED BALANCE SHEETS  
(in thousands)

	December 31,	
	2012	2011
Assets		
Cash	\$ 18,102	\$ 5,406
Receivables	4,646	3,720

Prepaid expenses and other current assets	687	836
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Total current assets	23,435	9,962
Furniture and equipment, net	1,392	255
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	\$ 24,827	\$ 10,217
	=====	=====
Liabilities and Stockholders' Deficit		
Current liabilities	\$ 21,393	\$ 5,123
Warrant liability	8,240	3,611
Royalty liability	8,962	9,309
Long-term debt	9,360	12,253
Stockholders' deficit	(23,128)	(20,079)
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	\$ 24,827	\$ 10,217
	=====	=====

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