

November 12, 2012



# Titan Pharmaceuticals Announces Third Quarter 2012 Financial Results

**Titan Management Team to Host Conference Call November 13 at 1:00pm ET / 10:00am PT**

SOUTH SAN FRANCISCO, CA -- (Marketwire) -- 11/12/12 -- [Titan Pharmaceuticals, Inc.](#) (OTCBB: TTNP) today reported financial results for the third quarter ended September 30, 2012.

Total revenues for the 2012 third quarter, consisting of royalties on net sales of Fanapt®, were approximately \$1.2 million, compared to approximately \$1.0 million for the comparable period in 2011. This royalty income will be paid by Titan to Deerfield Management Company L.P. in accordance with the terms of the agreements entered into in 2011.

Total operating expenses for the third quarter of 2012 were approximately \$3.9 million compared with approximately \$3.0 million for the third quarter of 2011, and consisted largely of research and development (R&D) expenses of approximately \$3.0 million, compared to approximately \$2.2 million for the 2011 period. The increase in R&D costs was primarily associated with an increase in external R&D expenses associated with the preparation of Probuphine® manufacturing operations at the contract manufacturer and demonstration of commercial scale production capability, as well as the preparation of the New Drug Application (NDA), which was submitted to the U.S. Food and Drug Administration in October 2012. General and administrative (G&A) expenses totaled approximately \$0.9 million for the third quarter of 2012, compared to approximately \$0.7 million for the third quarter of 2011. The increase in G&A expenses was primarily related to small increases in legal fees, non-cash stock compensation costs, facilities and other administration costs, which was offset in part by decreases in consulting and professional fees and travel costs.

Net other expense for the 2012 third quarter was approximately \$5.4 million, compared to net other income of approximately \$1.2 million in the comparable period in 2011. The 2012 period included approximately \$3.7 million related to non-cash losses resulting from increases in the fair value of outstanding warrants and approximately \$1.6 million of interest expense compared with approximately \$2.4 million related to non-cash gains resulting from decreases in the fair value of outstanding warrants and approximately \$1.2 million of interest expense during the third quarter of 2011. The approximately \$0.4 million increase in interest expense was related to the loans Titan secured from Deerfield.

Net loss applicable to common stockholders for the third quarter of 2012 was approximately \$8.0 million, or approximately \$0.12 per share, compared to a net loss of approximately \$0.8 million, or approximately \$0.01 per share, for the comparable period in 2011. Net loss for the nine-month period ended September 30, 2012 was approximately \$14.9 million, or

approximately \$0.23 per share, compared to a net loss of approximately \$12.3 million, or approximately \$0.21 per share, for the comparable period in 2011.

At September 30, 2012, Titan had cash and cash equivalents of approximately \$5.1 million, compared to approximately \$5.4 million at December 31, 2011. Titan also received approximately \$3.9 million in October 2012 upon exercise of warrants and believes that its working capital at September 30, 2012, along with the proceeds from these warrant exercises, is sufficient to sustain its planned operations through March 2013, including a scheduled installment payment to Deerfield of approximately \$2.5 million in early April 2013.

Recent key events include:

- Completion of new Probuphine manufacturing facility at the contract manufacturer and demonstration of commercial scale manufacturing capability
- Submission to the FDA of the NDA for Probuphine seeking approval for the treatment of opioid dependence
- Investment of \$4.25 million in Titan by a potential partner at \$1.25 per share (a premium of approximately 67 percent) to obtain an option to license commercial rights to Probuphine
- Exercise of Series B warrants by shareholders providing Titan with a capital influx of approximately \$4.9 million

"This has been a quarter of significant progress for Titan highlighted by the submission of our NDA for Probuphine to the FDA. The submission included a request for Priority Review designation, and if this is granted, the review process has the potential to be completed by early summer next year," said Sunil Bhonsle, President of Titan Pharmaceuticals. "We are very encouraged by the resources already allocated to the Probuphine program by the potential partner and we are all working diligently towards completing the licensing transaction to further realize value for our shareholders and to reach our ultimate goal of bringing a novel treatment option for opioid dependence to the healthcare community."

"The Board of Directors is very pleased by the excellent progress made by the Titan team, especially with the timely filing of the Probuphine NDA, which is a tremendous accomplishment for a small company," said Marc Rubin M.D., Executive Chairman of Titan. "There has been growing recognition in the medical community of the opioid addiction epidemic and the need for effective long-term treatment options. Probuphine has the potential to ensure compliance to treatment and significantly decrease abuse or accidental use, and this could be very beneficial to the patients, their families and healthcare providers."

#### *Probuphine: NDA Submitted to the FDA, Includes Priority Review Request*

In October, Titan [announced](#) the submission of an NDA to the FDA for the Company's investigational product Probuphine for the maintenance treatment of opioid dependence in adult patients. Probuphine, a novel, subdermal implant, is the first long-acting product designed to deliver six months of the drug buprenorphine hydrochloride ("buprenorphine") following a single treatment. The NDA has been submitted under Section 505(b)(2) of the Food, Drug and Cosmetic Act and references the approved sublingual tablet formulations of buprenorphine. U.S. sales of daily dosed sublingual formulations containing buprenorphine indicated for the treatment of opioid dependence were approximately \$1.3 billion in 2011.

Based upon feedback from the FDA at the pre-NDA meeting, Titan has included a request for Priority Review designation in the Probuphine NDA submission. Priority designation is given to therapies that offer major advances in treatment, including improved safety, or provide a treatment where no adequate therapy exists. If granted, the FDA action date on the NDA would be set at six months. Titan also included a detailed Risk Evaluation and Mitigation Strategy (REMS) following specific guidance from the FDA on this key document.

#### *Strategic Partnership Activities Continue to Advance*

Titan's ongoing strategic partnership discussions for the commercialization of Probuphine have advanced to the final stages. In September 2012, the Company [announced](#) it had entered into a Stock Purchase and Option Agreement. In addition to the approximately \$4.25 million investment in Titan, the potential licensee has committed significant resources to activities in support of the future commercialization of Probuphine, including the ongoing establishment of an accomplished commercial team. In October 2012, the Company announced the extension of the option to execute the proposed licensing agreement to December 31, 2012 as the potential partner continues to make progress on its internal structuring tasks.

#### *Upcoming Presentations*

- American College of Neuropsychopharmacology (ACNP) 51st Annual Meeting, Dec. 2-6, 2012, Hollywood, Florida: "Buprenorphine Implants for the Treatment of Opioid Dependence: Six and 12 Month Outcomes," poster presentation
- American Academy of Addiction Psychology (AAAP) Annual Meeting, Dec. 6-9, 2012, Aventura, Florida: "12 Month Safety, Efficacy and Patient Satisfaction with an Implantable Formulation of Buprenorphine," podium presentation

#### *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, potentially enhancing patient compliance and retention. Buprenorphine, an approved agent for the treatment of opioid dependence, is currently available in the form of daily dosed sublingual formulations, with reported 2011 annual sales of approximately \$1.3 billion in the United States. Probuphine was developed using ProNeura™, Titan's continuous drug delivery system that consists of a small, solid rod made from a mixture of ethylene-vinyl acetate (EVA) and a drug substance. The resulting construct is a solid matrix that is placed subcutaneously, normally in the upper arm in a simple office procedure, and removed in a similar manner at the end of the treatment period.

#### *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. On July 9, 2012, we announced that we 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 1 p.m. ET / 10 a.m. PT on Tuesday, November 13, 2012 to provide the Company's financial results as of September 30, 2012 and discuss its Phase 3 Probuphine program. Participating on the call will be Mr. Bhonsle, Dr. Rubin, 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 888-471-3843, Participant Code: 1379374 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, the uncertainty of patent protection for the Company's intellectual property or trade secrets, the Company's ability to establish corporate partnerships to support the development and commercialization of its products and the Company's ability to obtain additional financing. 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)  
(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
Revenue:				
Royalty revenue	\$ 1,228	\$ 973	\$ 3,816	\$ 2,291
Grant revenue	-	39	42	364
Total revenue	1,228	1,012	3,858	2,655
Operating expense:				
Research and development	2,995	2,230	8,037	9,915
General and administrative	890	739	3,750	2,480

Total operating expense	3,885	2,969	11,787	12,395
Loss from operations	(2,657)	(1,957)	(7,929)	(9,740)
Other income (expense), net	(5,356)	1,153	(6,972)	(2,565)
Net loss and comprehensive loss applicable to common stockholders	\$ (8,013)	\$ (804)	\$ (14,901)	\$ (12,305)
Basic and diluted net loss per share	\$ (0.12)	\$ (0.01)	\$ (0.23)	\$ (0.21)
Weighted average shares used in computing basic and diluted net loss per share	66,839	59,386	63,748	59,290

CONDENSED BALANCE SHEETS  
(in thousands)  
(unaudited)

	September 30, 2012	December 31, 2011
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Assets		
Cash	\$ 5,062	\$ 5,406
Receivables	3,530	3,720
Prepaid expenses and other current assets	788	836
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Total current assets	9,380	9,962
Furniture and equipment, net	1,364	255
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	\$ 10,744	\$ 10,217
	=====	=====
Liabilities and Stockholders' Deficit		
Current liabilities	\$ 10,893	\$ 5,123
Warrant liabilities	7,277	3,611
Royalty liability	10,087	9,309
Long-term debt	9,618	12,253
Stockholders' deficit	(27,131)	(20,079)
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	\$ 10,744	\$ 10,217
	=====	=====

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