

# Titan Pharmaceuticals Reports Full Year and Fourth Quarter 2015 Financial Results

Titan Management Team to Host Conference Call March 15 at 1:15 p.m. PT/4:15 p.m. ET

SOUTH SAN FRANCISCO, CA -- (Marketwired) -- 03/15/16 -- <u>Titan Pharmaceuticals, Inc.</u> (NASDAQ: TTNP), a specialty pharmaceutical company developing proprietary therapeutics for the treatment of select chronic diseases utilizing its ProNeura<sup>™</sup> long-term, continuous drug delivery platform, today reported financial results for the full year and fourth quarter of 2015.

Total revenues for the full year ended Dec. 31, 2015 were approximately \$1.7 million, compared with approximately \$3.6 million in 2014, both reflecting the amortization of the upfront license fee received from commercialization partner Braeburn Pharmaceuticals, Inc. in December 2012.

Total operating expenses for the year 2015 were approximately \$8.4 million compared with approximately \$7.1 million for 2014, and consisted largely of research and development (R&D) expenses of approximately \$4.7 million compared with approximately \$4.1 million in R&D expenses for 2014. This represented an increase of approximately \$0.6 million, primarily associated with increases in external R&D expenses related to supporting Titan's Probuphine® and ropinirole implant programs. General and administrative (G&A) expenses were approximately \$3.8 million during 2015, compared with approximately \$3.0 million in 2014, an increase of approximately \$0.8 million. The increase in G&A was primarily related to increases in non-cash stock compensation and employee-related costs, as well as legal and professional fees.

Net other expense for 2015 was approximately \$4.5 million, consisting primarily of non-cash losses resulting from changes in the fair value of warrant liabilities. This compares to net other income of approximately \$1.1 million in 2014, consisting primarily of non-cash gains resulting from changes in the fair value of warrant liabilities.

Net loss applicable to common stockholders for 2015 was approximately \$11.3 million, or \$0.56 per share, compared to net loss of approximately \$2.4 million, or \$0.14 per share, for 2014.

At December 31, 2015, Titan had cash of approximately \$7.9 million, compared with approximately \$15.5 million at December 31, 2014. Titan believes that its working capital at December 31, 2015 is sufficient to fund planned operations through the end of 2016.

"In 2015, Titan continued to make significant progress in advancing our product pipeline based on our proprietary ProNeura long-term, continuous drug delivery platform. After

reporting positive topline results in a final Phase 3 study of Probuphine, the FDA accepted the resubmission of our NDA and we are now working with the agency to finalize the Risk Evaluation and Mitigation Strategy and the product labeling, as they complete the review process in advance of a May 27, 2016 action date," said Titan President and CEO Sunil Bhonsle. "We are enthusiastic about the potential for Probuphine to be the first and only 6-month subdermal implant approved for the maintenance treatment of opioid addiction, and we are actively advancing the ProNeura-ropinirole implant program with the goal to submit the IND in the fourth quarter of this year and commence the pharmacokinetic proof-of-concept clinical study shortly thereafter. We are also very pleased with the addition in the fourth quarter of a new product development program, the ProNeura-T3 implant for the treatment of hypothyroidism."

### Business highlights include:

- In January 2016, the FDA convened a meeting of the Psychopharmacologic Drugs Advisory Committee (PDAC) to review the New Drug Application (NDA) for Probuphine submitted in August 2015. Following presentations and a discussion of the information, the committee voted 12 to 5 in favor of approval of Probuphine. In February the FDA extended its action date by three months to May 27, 2016 citing the changes submitted to the Risk Evaluation and Mitigation Strategy (REMS) section of the NDA as a major amendment requiring additional time to complete its review.
- In December 2015, Titan submitted to the FDA briefing material on the ropinirole implant development program in support of the pre-IND meeting and has received written feedback from the agency. The goal is to complete the required non-clinical studies and submit the IND in the fourth quarter of this year.
- In November 2015, Titan announced the addition of an implantable triiodothyronine (T3) product for the treatment of hypothyroidism to its product development pipeline with plans to target a pre-IND meeting with the FDA in the fourth quarter of 2016. Hypothyroidism is a disease affecting about 15 million Americans, mostly women. Based upon symptoms and blood tests, it is estimated that as many as 15-20 percent of hypothyroid patients are not adequately treated with the standard therapy, resulting in a persistent deficiency in the primary active form of thyroid hormone, T3, and physicians typically add an oral T3 regimen to the treatment of these patients.
- In October 2015, Titan uplisted its common stock to the NASDAQ Capital Market following a 1-for-5.5 reverse stock split of the company's outstanding shares of common stock, warrants and options in September. The reverse stock split was approved by the company's stockholders at the August 2015 annual meeting and enabled Titan to meet the initial requirements for trading on the NASDAQ Capital Market; satisfy its obligation to have sufficient shares available for potential future exercise of the warrants issued in the 2014 public offering; and provide the company with available shares for future financings, equity compensation and other business transactions.
- In June 2015, Titan presented nonclinical data at the 19th International Congress of Parkinson's Disease and Movement Disorders demonstrating the potential of ProNeura in the treatment of Parkinson's disease. The dose-escalating study in Parkinsonian primates showed that motor function could be significantly improved with no onset of dyskinesias (involuntary movements), following the continuous, non-fluctuating release of ropinirole with the subdermal implant.
- In June 2015, Titan reported positive topline results from the final Phase 3 double-

blind, double-dummy clinical study of Probuphine, which met the pre-specified primary endpoint of non-inferiority, as well as all secondary efficacy endpoints.

"The Board is extremely pleased with the progress Titan made in 2015," said Executive Chairman Marc Rubin, MD. "In addition to advancing our product pipeline, Titan enacted a reverse stock split and uplisted to the NASDAQ, a move that increased our visibility among a broader range of investors and holds the potential for generating increased value for our stockholders. We are well positioned for a transformational 2016, with the potential commercialization of Probuphine, our first product based on Titan's proprietary ProNeura technology."

#### Fourth Quarter 2015 Results

Titan reported no revenue in the fourth quarter of 2015, compared with approximately \$0.9 million in 2014. Total operating expenses for the fourth quarter of 2015 were approximately \$2.3 million, consisting primarily of R&D expenses of approximately \$1.1 million and G&A expenses of approximately \$1.1 million. Operating expenses for the same period in 2014 were approximately \$2.2 million, consisting primarily of R&D expenses of approximately \$1.6 million and G&A expenses of approximately \$0.6 million.

Net other expense for the fourth quarter of 2015 was approximately \$44,000, compared with a net other income of approximately \$0.8 million in 2014.

Net loss applicable to common stockholders for the fourth quarter of 2015 was approximately \$2.3 million, or \$0.11 per share, compared with approximately \$0.5 million, or \$0.02 per share in 2014.

#### Conference Call

Titan management will host a live conference call at 1:15 p.m. PT / 4:15 p.m. ET on Tuesday, March 15, 2016 to discuss the company's financial results as of Dec. 31, 2015. The call will be hosted by Sunil Bhonsle, president and CEO; Kate 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 <a href="www.titanpharm.com">www.titanpharm.com</a>. The call can also be accessed by dialing 888-505-4369, participant code 1891472, 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. (NASDAQ: 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 three 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 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.

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)

	Three Months Ended December 31,				Year Ended December 31,			
		2015		2014		2015		2014
Revenue:						_		_
License revenue	\$		\$	912	\$	1,671	\$	3,646
Total revenue		-		912		1,671		3,646
Operating expense:								
Research and development		1,135		1,595		4,675		4,075
General and administrative		1,115		570		3,755		3,046
Total operating expense		2,250		2,165		8,430		7,121
Loss from operations		(2,250)		(1,253)		(6,759)		(3,475)
Other income (expense), net		(44)		780		(4,520)		1,072
Net loss and comprehensive loss	\$	(2,294)	\$	(473)	\$	(11,279)	\$_	(2,403)
Basic net loss per share	\$	(0.11)	\$_	(0.02)	\$	(0.56)	\$_	(0.14)
Diluted net loss per share	\$	(0.11)	\$_	(0.06)	\$	(0.56)	\$_	(0.20)

Weighted average shares used in computing basic net loss per share	20,060	19,668	20,053	17,057
Weighted average shares used in computing diluted net loss per share	20,060	19,708	20,053	17,060

# **CONDENSED BALANCE SHEETS**

(in thousands) (unaudited)

	December 31,			
	2015			2014
Assets				
Cash	\$	7,857	\$	15,470
Receivables		4,213		3,968
Prepaid expenses and other current				
assets		174		145
Total current assets		12,244		19,583
Furniture and equipment, net		1,043		1,268
	\$	13,287	\$	20,851
Liabilities and Stockholders' Equity				
Current liabilities	\$	4,853	\$	6,662
Warrant liabilities		1,444		5,578
Stockholders' equity		6,990		8,611
	\$	13,287	\$	20,851

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