

Titan Pharmaceuticals Reports First Quarter 2016 Financial Results

Titan Management Team to Host Conference Call Today at 4:15 P.M. EDT / 1:15 P.M. PDT

SOUTH SAN FRANCISCO, CA -- (Marketwired) -- 05/10/16 -- <u>Titan Pharmaceuticals, Inc.</u> (NASDAQ: TTNP), a specialty pharmaceutical company developing proprietary therapeutics for the treatment of select chronic diseases utilizing its ProNeura[™] long-term, continuous drug delivery platform, today reported financial results for the first quarter ended March 31, 2016.

Titan reported no license revenue for the first quarter of 2016, compared with approximately \$0.9 million for the comparable period in 2015. License revenue in the first quarter of 2015 reflected the amortization of the upfront license fee received from commercialization and development partner Braeburn Pharmaceuticals in December 2012.

Total operating expenses, consisting of research and development expenses (R&D) and general and administrative (G&A) expenses, were approximately \$1.8 million in the first quarter of 2016, compared with approximately \$2.5 million in the first quarter of 2015. R&D expenses for the quarter ended March 31, 2016 were approximately \$0.7 million, compared with approximately \$1.4 million for the same period in 2015. While there were increases during the first quarter of 2016 in external research and development expenses related to the support of our Probuphine® and ProNeura product development programs, employee-related expenses and other R&D expenses, these were offset by the reimbursement by Braeburn of expenses associated with Probuphine. During the first quarter of 2016, external R&D expenses related to Titan's product development programs were approximately \$0.6 million, compared with approximately \$0.4 million for the same quarter in 2015.

G&A expenses for the quarters ended March 31, 2016 and 2015 remained consistent at approximately \$1.1 million. Net other expenses for the first quarter of 2016 were approximately \$15,000 compared with approximately \$3.3 million for the same period in 2015. Net other expenses consisted primarily of non-cash gains and losses on changes in the fair value of warrants, tax expenses, and interest income. Net loss for the quarter ended March 31, 2016 was approximately \$1.8 million, or approximately \$0.09 per share, compared with approximately \$4.9 million, or approximately \$0.24 per share, in the same quarter in 2015.

At March 31, 2016 Titan had cash of approximately \$5.8 million, which the company believes is sufficient to fund operations through the end of 2016. This does not include the milestone payment of \$15 million that we will receive upon the approval of Probuphine.

"The recommendation by U.S. Food and Drug Administration's Psychopharmacologic Drugs

Advisory Committee (PDAC) in January to approve Probuphine marked yet another important step in our efforts to bring this valuable long-term maintenance treatment to those suffering from opioid addiction," said Titan CEO and President Sunil Bhonsle. "While we await the completion of FDA's review of our new drug application (NDA) for Probuphine later this month, we continue to advance our other development programs based on ProNeura. We are proceeding with the required non-clinical studies to support the potential submission of an investigational new drug (IND) application for our ropinirole implant for Parkinson's disease by the end of the year, and continuing the non-clinical development work for a ProNeura-based T-3 implant to treat hypothyroidism."

Marc Rubin, M.D., executive chairman of Titan, added, "We are excited about the potential commercialization of Probuphine, which, if approved, would be Titan's first product on the market based on our ProNeura long-term, continuous drug delivery platform. Our proprietary ProNeura technology has potential for the treatment of other select chronic diseases, and as we expand our product pipeline, significant potential for our company in the coming years."

Business highlights include:

- In January, the FDA convened a meeting of the PDAC to review the 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 late January, Titan received written feedback from the FDA on the initial development plan for its proprietary ropinirole hydrochloride (HCL) implant for Parkinson's disease. Based on the FDA's feedback on the development plan submitted in December 2015, Titan is proceeding with the required non-clinical studies to support the potential submission of an IND application in the fourth quarter of 2016, followed by the initial pharmacokinetic and proof-of-concept clinical study. Titan is pursuing a 505(b)(2) registration pathway for the product candidate.
- In April, Titan presented data from the last Phase 3 trial of Probuphine at the 47th Annual American Society of Addiction Medicine (ASAM) Annual Conference. The data indicates that participants who were clinically stable on sublingual buprenorphine at a dose of 8mg or less per day maintained stability when transferred to Probuphine, and that they were more likely to sustain abstinence from illicit opioids throughout the six months than participants who remained on sublingual buprenorphine.

Conference Call

Titan management will host a live conference call at 1:15 p.m. PT / 4:15 p.m. ET on Tuesday, May 10, 2016 to discuss the company's financial results as of March 31, 2016. 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 www.titanpharm.com. The call can also be accessed by dialing 800-279-9534, participant passcode 6051842, 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 LOSS (in thousands, except per share amount) (unaudited)

Three Months Ended

	March 31,				
Revenue:	2016			2015	
License revenue	<u>\$</u>		\$	911	
Total revenue		-		911	
Operating expense:					
Research and development	700		1,431		
General and administrative		1,131		1,095	
Total operating expense		1,831		2,526	

Loss from operations	(1,831)	(1,615)
Other Expense, net	<u>(15)</u>	(3,282)
Net loss and comprehensive loss	<u>\$ (1,846)</u>	\$ (4,897)
Basic net loss per share	<u>\$ (0.09)</u>	\$ (0.24)
Diluted net loss per share	<u>\$ (0.09)</u>	\$ (0.24)
Weighted average shares used in computing basic net loss per share	20,060	20,031
Weighted average shares used in computing diluted net loss per share	20,400	20,056

CONDENSED BALANCE SHEETS

(in thousands) (unaudited)

	March 31, 2016		December 31, 	
Assets				
Cash	\$	5,762	\$	7,857
Receivables		4,857		4,213
Prepaid expenses and other current assets		370		174
Total current assets	_	10,989		12,244
Furniture and equipment, net		1,007		1,043
Total assets	\$	11,996	\$	13,287
Liabilities and Stockholders' Equity	· -			_
Current liabilities	\$	5,080	\$	4,853
Warrant liabilities		1,440		1,444
Stockholders' equity		5,476		6,990
Total liabilities and stockholders' equity	\$	11,996	\$	13,287

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