

Titan Pharmaceuticals Announces Third Quarter 2013 Financial Results

Management Team to Host Conference Call November 15 at 1:00 p.m. ET / 10:00 a.m. PT

SOUTH SAN FRANCISCO, CA -- (Marketwired) -- 11/14/13 -- <u>Titan Pharmaceuticals, Inc.</u> (OTCBB: TTNP) today reported financial results for the third quarter ended September 30, 2013.

Net loss for the quarter ended September 30, 2013 was approximately \$1.1 million, or approximately \$0.01 per share, compared to a net loss of approximately \$8.0 million, or approximately \$0.12 per share, for the comparable period in 2012. License revenues of approximately \$2.2 million for the three months ended September 30, 2013 reflect the amortization of the upfront license fee received from Braeburn in December 2012 for its license agreement for the U.S. and Canadian rights to commercialize Probuphine®, the company's investigational subdermal implant designed to deliver continuous, blood levels of buprenorphine for six months following a single treatment. Titan generated no grant or royalty revenue during the three months ended September 30, 2013.

Total operating expenses for the third quarter ended September 30, 2013 were approximately \$2.3 million, compared with approximately \$3.9 million for the comparable period in 2012, and consisted largely of research and development (R&D) expenses of approximately \$1.7 million, compared to approximately \$3.0 million of R&D expenses for the comparable period in 2012. This decrease in R&D costs was primarily associated with a decrease in external R&D expenses related to the preparation and review of the New Drug Application (NDA) for Probuphine by the U.S. Food and Drug Administration (FDA). General and administrative (G&A) expenses for the quarter were approximately \$0.6 million, compared to approximately \$0.9 million for the comparable period in 2012. The decrease in G&A expenses was primarily related to decreases in non-cash stock compensation of approximately \$0.2 million and legal fees of approximately \$0.1 million.

At September 30, 2013, Titan had approximately \$9.0 million of cash compared to approximately \$18.1 million at December 31, 2012. Titan believes that its working capital at September 30, 2013, together with the \$5.0 million in proceeds from the recently announced sale of common stock to Braeburn, is sufficient to fund its planned operations into January 2015.

Key recent updates include:

• On November 12, Titan announced a \$5 million equity investment by Braeburn Pharmaceuticals as well as adjusted terms to its license agreement for the U.S. and Canadian commercialization rights for Probuphine. Under the terms of the license agreement amendment, there will be a reduction in the milestone payment upon approval by the FDA of the Probuphine NDA from \$45 million to \$15 million, and an increase in the total amount of potential sales milestones payments to Titan from \$130 million to \$165 million. The sales threshold to achieve the highest royalty tier has been lowered. Braeburn also agreed to assume responsibility for all third-party expenses related to the Probuphine regulatory process. The collaboration amendment also contains a provision entitling Titan to receive a low single-digit royalty on sales by Braeburn of other mid or long-term continuous delivery treatments for opioid dependence, up to a maximum of \$50 million. In addition, Titan has the right to elect to participate in sales by Braeburn of other products in the addiction market in exchange for a similar reduction in Titan's royalties on Probuphine. The amendment will be effective upon the closing of the sale of shares.

- In September, Titan announced that the FDA had granted its request for a meeting to discuss Probuphine. The goal of this meeting is to understand more fully the issues raised in the April 2013 Complete Response Letter (CRL) to the NDA for Probuphine for the maintenance treatment of opioid dependence in adults, review and discuss the available data from the Probuphine studies conducted to date and gain further clarity regarding the regulatory path forward for Probuphine. Comprehensive briefing materials addressing the issues raised in the CRL have been submitted to the FDA and the meeting is scheduled for November 19, 2013.
- In August, Titan announced the publication of data from its positive confirmatory Phase 3 clinical trial of Probuphine in the journal <u>Addiction</u>.

"As you know, the focus for the third quarter was on the preparation of the briefing material for the upcoming FDA meeting which was provided to the FDA in early October," said Sunil Bhonsle, president of Titan Pharmaceuticals. "The goal of this FDA meeting is to understand more fully the issues raised in the CRL, review and discuss the information in the briefing book and gain further clarity regarding the regulatory path forward. The financial results for the quarter were as expected, and the recently announced investment in Titan by Braeburn Pharmaceuticals should help support our operations into the beginning of 2015."

"The board is pleased with the progress made by Titan and Braeburn in preparation for the upcoming meeting with the FDA," said Marc Rubin, M.D., executive chairman of Titan Pharmaceuticals. "Given the generally uncertain nature of the regulatory process with respect to timing and outcome, the board felt it was prudent to raise additional capital, and is very pleased with the at market transaction without warrants concluded with Braeburn this week. Braeburn's investment in Titan strengthens our partnership and brings the companies in alignment to continue advancing the Probuphine program toward our ultimate goal -- to make Probuphine available to those clinicians, patients and families that need it."

About Opioid Dependence

According to recent estimates, there are 2.2 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 \$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 in 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 confirmatory study of 287 patients (published in the journal *Addiction*).

Conference Call

Titan management will host a live conference call at 1 p.m. ET / 10 a.m. PT on Friday, November 15, 2013 to provide the Company's financial results as of September 30, 2013. Participating on the call will be Mr. Bhonsle, Dr. Rubin, Brian Crowley, vice president of finance and Katherine Glassman-Beebe, Ph.D. executive vice president and chief development officer.

The live webcast of the call may be accessed by visiting the Titan website at <u>www.titanpharm.com</u>. The call can also be accessed by dialing *888-504-7963*, participant code: 9627990 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 <u>www.titanpharm.com</u>.

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)

	Three Months Ended September 30,				Nine Months Ended September 30,					
	2013		2012		2013		2012			
Revenue:										
License revenue	\$	2,198	\$	-	\$	8,146	\$	-		
Royalty revenue		-		1,228		1,424		3,816		
Grant revenue					<u> </u>			42		
Total revenue		2,198		1,228		9,570		3,858		
Operating expense:										
Research and development		1,679		2,995		7,380		8,037		
General and administrative		647		890		2,439		3,750		
Total operating expense		2,326		3,885		9,819		11,787		
Loss from operations		(128)		(2,657)		(249)		(7,929)		
Other income (expense), net		(1,017)		(5,356)		10,169		(6,972)		
Net income (loss) and comprehensive income (loss)	<u>\$</u>	(1,145)	<u>\$</u>	(8,013)	\$	9,920	<u>\$</u>	(14,901)		
Basic net income (loss) per share	\$	(0.01)	\$	(0.12)	\$	0.12	\$	(0.23)		
Diluted net income (loss) per share	\$		\$	(0.07)	\$	0.11	\$	(0.19)		
Weighted average shares used in computing basic net income (loss) per share		82,544		66,839		81,125		63,748		
Weighted average shares used in computing diluted net income (loss) per share		82,544		66,839		81,832		70,189		
CONDENSED BALANCE SHEETS										

(in thousands)

(unaudited)

September 30,	December 31,
2013	2012

Cash	\$	8,998	\$ 18,102
Receivables		4,590	4,646
Prepaid expenses and other current assets		262	687
Total current assets		13,850	 23,435
Furniture and equipment, net		1,670	 1,392
	\$	15,520	\$ 24,827
Liabilities and Stockholders' Equity (Deficit)			
Current liabilities	\$	12,250	\$ 21,393
Warrant liabilities		2,248	8,240
Royalty liability		-	8,962
Long-term debt		-	9,360
Stockholders' equity (deficit)		1,022	 (23,128)
	\$	15,520	\$ 24,827

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Source: Titan Pharmaceuticals, Inc.