May 16, 2013

Titan Pharmaceuticals Announces First Quarter 2013 Financial Results

Titan Management Team to Host Conference Call May 16 at 1:00 p.m. ET / 10:00 a.m. PT

SOUTH SAN FRANCISCO, CA -- (Marketwired) -- 05/15/13 -- Titan Pharmaceuticals, Inc. (OTCBB: TTNP) today reported financial results for the first quarter ended March 31, 2013.

Net income for the quarter ended March 31, 2013 was approximately $6.0 million, or approximately $0.08 per share, compared to a net loss of approximately $5.2 million, or approximately $0.09 per share, for the comparable period in 2012. Net income in the quarter consisted of licensing revenue of approximately $3.8 million, resulting from the amortization of the non-refundable up-front license fee of $15.75 million (approximately $15.0 million, net of expenses) related to Titan's licensing agreement with Braeburn for the exclusive U.S. and Canadian commercialization rights for Probuphine®, which was announced in December 2012. Probuphine is an investigational, long-acting, subdermal implant formulation of buprenorphine for the maintenance treatment of adult patients with opioid dependence.

Titan also generated royalty revenues on the sales of Fanapt during the three-month period ended March 31, 2013 of approximately $1.4 million, compared to approximately $1.2 million for the comparable period in 2012. The royalty revenues will be paid to Deerfield in accordance with the terms of the agreements entered into during 2011. The company generated no grant revenues during the quarter, compared to approximately $42,000 for the comparable period in 2012.

Total operating expenses for the quarter ended March 31, 2013 were approximately $5.0 million, compared with approximately $4.8 million for 2012, and consisted largely of research and development (R&D) expenses of approximately $3.9 million, compared to approximately $3.1 million for 2012. This increase in R&D costs was primarily associated with an increase in external R&D expenses related to the review of the New Drug Application (NDA) for Probuphine with the U.S. Food and Drug Administration (FDA), including preparation for the March 21, 2013 meeting of the Psychopharmacologic Drugs Advisory Committee (PDAC). General and administrative (G&A) expenses for the quarter were approximately $1.1 million, compared to approximately $1.7 million in 2012. The decrease in G&A expenses primarily related to decreases in non-cash stock compensation of approximately $0.7 million.

Net other income for the three-month period ended March 31, 2013 was approximately $5.8 million, compared to net other expense of approximately $1.6 million for the comparable period in 2012. The increase resulted from approximately $9.0 million of non-cash other income generated by the termination of our royalty repurchase agreement with Deerfield and an approximately $1.9 million non-cash gain resulting from the $7.5 million settlement of our

indebtedness to Deerfield as a result of Deerfield's exercise of 6,000,000 warrants. This was offset in part by approximately $3.0 million related to non-cash losses on changes in the fair value of warrants and approximately $0.5 million of other expense related to unamortized transaction fees related to the initial Deerfield debt transaction.

At March 31, 2013, Titan had approximately $17.6 million of cash compared to approximately $18.1 million at December 31, 2012. Titan believes that its working capital at March 31, 2013 is sufficient to fund planned operations through April 2014, inclusive of estimated expenses associated with the process for responding to the Complete Response Letter (CRL) regarding the Probuphine NDA that was received from the FDA on April 30, 2013.

Key recent updates include:

- On March 21, 2013, Titan participated in the FDA's PDAC meeting for the review of Probuphine. The committee members discussed the benefit-risk profile of Probuphine and strongly supported the approval (10 positive votes, 4 negative votes and 1 abstention) of the product. The committee also separately voted in favor of the effectiveness (10 positive votes to 5 negative votes) and safety (12 positive votes to 2 negative votes, with 1 abstention) of Probuphine. The largest portion of committee members abstained (6 abstentions, 5 positive votes and 4 negative votes) on the vote pertaining to the Risk Evaluation and Mitigation Strategy (REMS) program, as the program was still in discussion with the FDA.
- On April 30, 2013, the FDA issued a CRL to Titan's NDA for Probuphine, requesting, among other things, additional data supporting efficacy of the product and the clinical benefit to patients. The NDA had been granted Priority Review designation by the FDA. Titan believes Probuphine is a diversion-resistant formulation that is consistent with the recently-issued FDA guidance supporting diversion- and abuse-resistant products, and has demonstrated both safety and efficacy in accordance with primary endpoints that were pre-agreed with the FDA.

"This quarter began with the acceptance of the Probuphine NDA by the FDA with a Priority Review designation, and ended with a positive vote of the advisory committee in favor of approval of Probuphine. Unfortunately, at the end of April, the FDA issued a CRL declining approval of the product. We remain committed to addressing the concerns raised by the FDA in the CRL," said Sunil Bhonsle, president of Titan Pharmaceuticals. "The financial results for the first quarter were as expected, and also of note is the payment of the final installment of the Deerfield debt in April."

"The issues raised by the FDA in the CRL were an unexpected and disappointing outcome based on the positive results that we observed in our clinical development program and after receiving strong support from the PDAC in favor of approval of the product," said Katherine Glassman-Beebe, Ph.D., executive vice president and chief development officer of Titan Pharmaceuticals. "This is a 505(b)(2) submission and it is our belief that we have met the agreed-upon criteria demonstrating safe and effective treatment with Probuphine. We are diligently preparing our response to the issues raised by the FDA using existing data from the development program and will respond to the FDA at the appropriate time. We also will be requesting a meeting with the FDA to discuss Titan's response and clarification on the regulatory path forward for Probuphine."

"We are systematically evaluating the options available to us as we prepare to address the issues in the CRL, and we are all working closely with regulatory counsel and a team of expert advisors to address the FDA's response to our Probuphine NDA," said Marc Rubin, M.D., executive chairman of Titan Pharmaceuticals. "While this is a sequential process with a timeframe that is not always predictable, Titan has commenced the first step in addressing the CRL and we will determine the next steps following a dialogue with the FDA. The board fully supports this strategy and we look forward to keeping you updated and providing more details when available and appropriate."

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 and persistent, 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 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.

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 designed to evaluate efficacy versus placebo, and non-inferiority with a currently marketed sublingual formulation of buprenorphine. Results of the confirmatory study were announced in July 2011.

Conference Call
Titan management will host a live conference call at 1 p.m. ET / 10 a.m. PT on Thursday, May 16, 2013 to provide the Company's financial results as of March 31, 2013. Participating on the call will be Mr. Bhonsle and Dr. Rubin.

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 888-312-3048 Participant code: 7501798 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.

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)

	Three Months Ended March 31,	
	2013	2012
Revenue:		
License revenue	$ 3,750	$ -
Royalty revenue	1,424	1,228
Grant revenue	-	42
Total revenue	5,174	1,270
Operating expenses:		
Research and development	3,912	3,069
General and administrative	1,091	1,733
Total operating expenses	5,003	4,802
Income (loss) from operations	171	(3,532)
Other income (expense), net	5,830	(1,631)
Net income (loss) and comprehensive income (loss)	$ 6,001	$ (5,163)
Basic net income (loss) per share	$ 0.08	$ (0.09)

Diluted net income (loss) per share	$ 0.07	$ (0.09)
Weighted average shares used in computing basic net income (loss) per share	78,256	59,387
Weighted average shares used in computing diluted net income (loss) per share	86,762	59,387

CONDENSED BALANCE SHEETS
(in thousands)

	March 31, 2013	December 31, 2012
Assets		
Cash	$ 17,606	$ 18,102
Receivables	4,094	4,646
Prepaid expenses and other current assets	265	687
Total current assets	21,965	23,435
Furniture and equipment, net	1,567	1,392
	$ 23,532	$ 24,827
Liabilities and Stockholders' Deficit		
Current liabilities	$ 19,981	$ 21,393
Warrant liability	6,599	8,240
Royalty liability	-	8,962
Long-term debt	-	9,360
Stockholders' deficit	(3,048)	(23,128)
	$ 23,532	$ 24,827

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