

# Titan Pharmaceuticals Announces Second Quarter 2013 Financial Results

# Titan Management Team to Host Conference Call August 15 at 1:00PM ET / 10:00AM PT

SOUTH SAN FRANCISCO, CA -- (Marketwired) -- 08/14/13 -- <u>Titan Pharmaceuticals, Inc.</u> (OTCBB: TTNP) today reported financial results for the second quarter ended June 30, 2013.

Net income for the quarter ended June 30, 2013 was approximately \$5.1 million, or approximately \$0.06 per share, compared to a net loss of approximately \$1.7 million, or approximately \$0.03 per share, for the comparable period in 2012. The increase in net income was a result of an increase in net other income for the three-month period ended June 30, 2013, which was approximately \$5.4 million, compared to net other income of approximately \$15,000 for the comparable period in 2012. This increase was primarily related to an approximately \$5.4 million non-cash gain from decreases in the fair value of outstanding warrants. Titan generated no grant or royalty revenue during the three months ended June 30, 2013.

Total operating expenses for the quarter ended June 30, 2013 were approximately \$2.5 million, compared with approximately \$3.1 million for 2012, and consisted largely of research and development (R&D) expenses of approximately \$1.8 million, compared to approximately \$2.0 million for 2012. This decrease in R&D costs was primarily associated with a decrease in external R&D expenses related to the 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 \$0.7 million, compared to approximately \$1.1 million for the comparable quarter in 2012. The decrease in G&A expenses was primarily related to decreases in non-cash stock compensation of approximately \$0.1 million, consulting and professional fees of approximately \$0.3 million and other administrative costs of approximately \$0.1 million.

At June 30, 2013, Titan had approximately \$11.2 million of cash compared to approximately \$18.1 million at December 31, 2012. Titan believes that its working capital at June 30, 2013 is sufficient to fund planned operations through April 2014.

#### Key recent updates include:

 On April 30, 2013, the FDA issued a Complete Response Letter (CRL) to Titan's NDA for Probuphine, an investigational, long-acting, subdermal implant formulation of buprenorphine for the maintenance treatment of adult patients with opioid dependence, requesting, among other things, additional data supporting efficacy and safety of the product and the clinical benefit to patients. The CRL also included recommendations regarding product labeling, human factors testing of the training program and the implementation of the Risk Evaluation and Mitigation Strategy (REMS).

- In April 2013, Titan announced two key Probuphine presentations at medical meetings:
  - American Society of Addiction Medicine (ASAM) 44<sup>th</sup> Annual Medical-Scientific Conference in Chicago - Walter Ling, M.D., Professor of Psychiatry, Director, Integrated Substance Abuse Programs at the David Geffen School of Medicine at UCLA, presented results of the Probuphine Phase 3 development program
  - American Psychiatric Association (APA) 166<sup>th</sup> Annual Meeting in San Francisco -Katherine Glassman-Beebe, Ph.D., executive vice president and chief development officer of Titan, presented "Buprenorphine Implants for the Maintenance Treatment of Opioid Dependence" as part of a National Institute on Drug Abuse (NIDA) Symposia
- In May 2013, Titan provided a Probuphine update during its first quarter financial results conference call, indicating that it was working closely with regulatory counsel and a team of expert advisors to systematically evaluate the options available to address the issues in the CRL. This effort continues with preparation of material that is necessary to support the NDA and Titan expects, in the next several weeks, the submission of a request for a meeting with the FDA to discuss the company's response to the CRL and obtain further regulatory process clarification.
- In May 2013, Titan announced that it had adopted a new stockholder rights plan and had amended its license agreement with Braeburn Pharmaceuticals. Later in July, Braeburn Pharmaceuticals assumed the responsibility of being the primary contact with the FDA regarding the Probuphine NDA.
- In August 2013, Titan announced the publication in the journal Addiction of data from its positive confirmatory Phase 3 clinical trial of Probuphine.

"The quarter's financial results were as expected, and, as you know, our primary focus has been on working diligently with our partner Braeburn Pharmaceuticals, as well as with a team of proven, expert advisors with experience in assisting companies through similar regulatory processes, to pursue a broad range of avenues to advance Probuphine," said Sunil Bhonsle, president of Titan Pharmaceuticals. "We continue to analyze data and generate information in preparation of a full and formal response to the CRL issued by the FDA. Titan and Braeburn are currently preparing comprehensive materials in support of the meeting we will be requesting."

#### 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<sup>™</sup>, 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 over a 24-week period (published in *Addiction*).

#### Conference Call

Titan management will host a live conference call at 1 p.m. ET / 10 a.m. PT on Thursday, August 15, 2013 to provide the Company's financial results as of June 30, 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 <a href="www.titanpharm.com">www.titanpharm.com</a>. The call can also be accessed by dialing (888) 244-2459, Participant code: 3935037 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.

## CONDENSED STATEMENTS OF OPERATIONS AND COMPREHENSIVE INCOME (LOSS)

# (in thousands, except per share amount) (unaudited)

	Three Months Ended June 30,			Six Months Ended June 30,				
		2013		2012		2013		2012
Revenue:								
License revenue	\$	2,198	\$	-	\$	5,948	\$	-
Royalty revenue		-		1,360		1,424		2,588
Grant revenue								42
Total revenue		2,198		1,360		7,372		2,630
Operating expense:								
Research and development		1,789		1,973		5,701		5,042
General and administrative		701		1,126		1,792		2,859
Total operating expense		2,490		3,099		7,493		7,901
Loss from operations		(292)		(1,739)		(121)		(5,271)
Other income (expense), net		5,356		15		11,186		(1,616)
Net income (loss) and comprehensive income (loss)	\$_	5,064	\$_	(1,724)	\$	11,065	\$_	(6,887)
Basic net income (loss) per share	\$	0.06	\$	(0.03)	\$	0.14	\$	(0.11)
Diluted net income (loss) per share	\$		\$	(0.06)	\$	0.10	\$	(0.13)
Weighted average shares used in computing basic net income (loss) per share	==	82,527	_=	64,984		80,403	==	62,185
Weighted average shares used in computing diluted net income (loss) per share		82,559		64,984		86,271		68,093

### **CONDENSED BALANCE SHEETS**

### (in thousands) (unaudited)

	J	une 30, 2013	December 31, 2012	
Assets				
Cash	\$	11,176	\$	18,102
Receivables		3,851		4,646
Prepaid expenses and other current assets		203		687
Total current assets		15,230		23,435

Furniture and equipment, net		1,392	
	\$	16,908	\$ 24,827
Liabilities and Stockholders' Equity (Deficit)	<u> </u>		
Current liabilities	\$	13,525	\$ 21,393
Warrant liabilities		1,237	8,240
Royalty liability		-	8,962
Long-term debt		-	9,360
Stockholders' equity (deficit)		2,146	(23,128)
	\$	16,908	\$ 24,827

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