

# Titan Pharmaceuticals Reports Second Quarter 2016 Financial Results

## Titan Management Team to Host Conference Call at 4:15 p.m. EDT/1:15 p.m. PDT

SOUTH SAN FRANCISCO, CA -- (Marketwired) -- 08/09/16 -- <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 second quarter ended June 30, 2016.

Titan reported \$15.0 million in revenue for the second quarter of 2016, compared with approximately \$0.8 million for the comparable quarter in 2015. License revenue in the second quarter of 2016 reflects the one-time milestone payment that was earned from development and commercialization partner Braeburn Pharmaceuticals, Inc. (Braeburn) upon approval of Probuphine® by the U.S. Food and Drug Administration (FDA) in May 2016. Revenue in the second quarter of 2015 reflects the amortization of the upfront license fee received from Braeburn in December 2012.

Total operating expenses, consisting primarily of research and development (R&D) expenses and general and administrative (G&A) expenses, were approximately \$3.0 million in the second quarter of 2016, compared with approximately \$1.9 million in the second quarter of 2015.

R&D expenses for the quarter ended June 30, 2016 were approximately \$1.7 million, compared with approximately \$1.1 million for the same period in 2015, an increase of approximately \$0.6 million. The increase in R&D costs was primarily a result of increases in external R&D expenses related to the support of ProNeura product development programs, and increases in employee-related expenses and other R&D expenses. During the three months ended June 30, 2016, external R&D expenses related to product development programs were \$0.9 million, compared with \$0.4 million in the same quarter in 2015.

G&A expenses for the second quarter 2016 were approximately \$1.2 million, compared with approximately \$0.8 million for the same quarter in 2015, an increase of approximately \$0.4 million. The increased G&A expenses were primarily related to a contractual fee obligation of approximately \$0.2 million in connection with the milestone payment received under the Probuphine license, increases in non-cash stock compensation and employee-related costs. Net other expenses for the second quarter of 2016 were approximately \$0.1 million, compared with \$1.2 million in the same quarter of 2015. Net other expenses consisted primarily of non-cash losses on changes in the fair value of warrants.

Net income for the quarter ended June 30, 2016 was approximately \$11.9 million, or

approximately \$0.58 per share, compared with a net loss of approximately \$2.3 million, or \$0.11 per share for the comparable quarter in 2015.

At June 30, 2016 Titan had cash of approximately \$19.3 million, which the company believes is sufficient to fund operations at least through the end of 2017.

#### **Probuphine Launch Highlights**

- Following FDA approval on May 26, 2016, the Probuphine subdermal implant was commercially launched through a specialty distributor in the second half of June; first patients were treated shortly thereafter.
- As of the beginning of August, Braeburn had trained and certified more than 2,300
  health care providers from all 50 states and Puerto Rico to provide Probuphine to their
  patients, thus surpassing the halfway point of its goal to certify 4,000 health care
  providers by the end of 2016.
- To date, Braeburn has conducted meetings with 40 regional insurance plans as well as Medicare, Medicaid and the Veterans Administration, and has received positive responses for third-party payor coverage from all.

"FDA approval of Probuphine marked several significant milestones for Titan in the second quarter, most noteworthy among them being the launch of the first product based on our proprietary ProNeura long-term, continuous drug delivery platform," said President and CEO Sunil Bhonsle. "Probuphine continues to generate strong interest among the medical community. This is a testament to the need for new medication-assisted treatments for opioid addiction and to Probuphine's potential contribution to the treatment landscape as the only approved implant for the maintenance treatment of opioid dependence in patients stabilized on moderate to low doses of buprenorphine, and the only treatment to deliver medication for up to six months."

#### **Business Highlights**

- In April, data from the last Phase 3 trial of Probuphine was presented at the 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 8 mg 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.
- In May, the FDA approved Probuphine, the first product for the long-term maintenance treatment of opioid dependence in clinically stable patients on 8 mg or less a day of oral buprenorphine. The product was available in the second half of June and the first patients were treated with the Probuphine subdermal implant shortly thereafter.
- In June, Titan received a \$15 million milestone payment from Braeburn
  Pharmaceuticals for the FDA approval of Probuphine. Under terms of the license
  agreement, Braeburn will pay Titan tiered royalties on net sales in the U.S. and
  Canada at rates ranging from the mid-teens to low-twenties. Additionally, Titan is
  eligible for up to \$165 million in milestone payments based on achievement of certain
  annual sales targets, and up to \$35 million based on regulatory milestones for
  additional indications.
- In June, Titan's stock was added to the broad U.S. market Russell® 3000 Index and the small-cap Russell 2000® Index as part of Russell Investments' annual

- reconstitution of its stock indexes. This can provide broader exposure and potential interest in the Company among new institutional investors.
- In July, the Journal of the American Medical Association (JAMA) published an article
  titled "Effect of Buprenorphine Implants on Illicit Opioid Use Among Abstinent Adults
  With Opioid Dependence Treated With Sublingual Buprenorphine," detailing results of
  the final Phase 3 trial of Probuphine, PRO 814, which demonstrated Probuphine's noninferiority to sublingual buprenorphine among abstinent adults with opioid dependence.

"On the heels of Probuphine's launch, we are in a strong financial position to advance development plans for our other ProNeura-based programs, including our ropinirole implant for Parkinson's disease and our ProNeura T-3 implant to treat hypothyroidism," said Marc Rubin, M.D., executive chairman of Titan. "We expect to file an investigational new drug application (IND) for our ropinirole implant for Parkinson's disease in the fourth quarter, following completion of non-clinical studies, and to hold a pre-IND meeting with the FDA for our T-3 implant product candidate within that same timeframe."

#### Conference Call

Titan management will host a live conference call at 1:15 p.m. PT / 4:15 p.m. ET on Tuesday, Aug. 9, 2016 to discuss the company's financial results for the second quarter ended June 30, 2016 and to provide an update on the ongoing product development plans. The call will be hosted by Sunil Bhonsle, president and CEO; Kate Beebe, Ph.D., executive vice president and chief development officer; and Brian Crowley, vice president of finance.

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 888-684-1282 participant code 4286498, 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 commercial rights for the U.S. and Canada for Probuphine to Braeburn Pharmaceuticals. Approved by the FDA in May 2016, Probuphine is 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 and hypothyroidism, where maintaining consistent, around the clock blood levels of medication 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 June 30,			Six Months Ended June 30,					
		2016		2015		2016		2015	
Revenue:									
License revenue	\$	15,004	\$	760	\$	15,004	\$	1,671	
Total revenue		15,004		760		15,004		1,671	
Operating expense:									
Research and development		1,746		1,099		2,446		2,530	
General and administrative		1,214		753		2,345		1,848	
Total operating expense		2,960		1,852		4,791		4,378	
Income (loss) from operations		12,044		(1,092)		10,213		(2,707)	
Other expense, net		(116)		(1,189)		(131)		(4,471	
Net income (loss) and comprehensive income (loss)	\$	11,928	\$	(2,281)	\$	10,082	\$	(7,178)	
Basic net income (loss) per share	\$	0.58	\$	(0.11)	\$	0.50	\$	(0.36)	
Diluted net income (loss) per share	\$	0.55	\$	(0.11)	\$	0.48	\$	(0.36)	
Weighted average shares used in computing basic net income (loss) per share		20,508		20,060		20,284		20,045	
Weighted average shares used in computing diluted net income (loss) per share		21,878		20,073		21,223		20,055	

#### **CONDENSED BALANCE SHEETS**

(in thousands) (unaudited)

	June 30, 2016		De	December 31, 2015		
Assets						
Cash	\$	19,305	\$	7,857		
Receivables		4,851		4,213		
Prepaid expenses and other current assets		237		174		
Total current assets		24,393		12,244		
Furniture and equipment, net		905		1,043		
Total assets	\$	25,298	\$	13,287		
Liabilities and Stockholders' Equity						
Current liabilities	\$	6,068	\$	4,853		
Warrant liabilities		1,550		1,444		
Stockholders' equity		17,680		6,990		
Total liabilities and stockholders' equity	\$	25,298	\$	13,287		

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Source: Titan Pharmaceuticals, Inc.