March 16, 2017

Titan Pharmaceuticals Reports Full Year And Fourth Quarter 2016 Financial Results

Titan Management Team to Host Conference Call March 16 at 4:15 p.m. ET / 1:15 p.m. PT

SOUTH SAN FRANCISCO, Calif., March 16, 2017 /PRNewswire/ --Titan Pharmaceuticals, Inc. (NASDAQ: TTNP), a company developing proprietary therapeutics for the treatment of select chronic diseases utilizing its ProNeura™ long-term, continuous drug delivery technology, today reported financial results for the full year and fourth quarter 2016, and provided an update on its business.

Business highlights include:

Probuphine for opioid addiction

- The U.S. Food and Drug Administration approved Probuphine® in May 2016 for the maintenance treatment of opioid addiction, triggering a $15.0 million milestone payment from commercialization partner Braeburn Pharmaceuticals, Inc. The product was available for shipment in the latter part of June 2016 and first patients were treated soon thereafter.
- More than 2,500 health care providers received training in 2016 under the REMS program and were certified to provide Probuphine.
- More than 70 payors, including private insurers, the Centers for Medicare & Medicaid Services (CMS) and Veterans Administration programs, now cover Probuphine.
- The initial launch of Probuphine in the second half of 2016 laid the groundwork for the full commercial launch, which commenced in the first quarter of 2017 with a field sales force and medical support staff of more than 60, focusing on more than 80 key treatment centers throughout the U.S.
- Probuphine was assigned a permanent J-code from the CMS, effective in January 2017, facilitating the third-party payor reimbursement process; Braeburn continues to work to obtain additional codes to further facilitate reimbursement of Probuphine insertion and removal procedures.

- Scientific data on Probuphine confirming its effectiveness continued to be presented, including three presentations at the International Society of Addiction Medicine annual meeting in October 2016.
- In March 2017, the European Medicines Agency (EMA) confirmed that Probuphine is eligible for review and approval under the centralized procedure; Titan hopes to file a Marketing Authorization Application with the EMA in fourth quarter of 2017.

Ropinirole implant for Parkinson's disease

- Following the completion of the non-clinical studies reviewed by the FDA in the pre-IND briefing material, Titan submitted an IND to the FDA in January 2017.
- The FDA verbally requested for review additional information on the final release test data on the implant and applicator for the implant before the clinical trial proceeds; written communication is expected later in March 2017.
- Initiation of the Phase 1 pharmacokinetic study is expected in mid-2017.

T3 implant for Hypothyroidism

- Initial formulation development has been completed and in vitro and in vivo drug release studies have been conducted to further define the implant.
- A shortage of GMP-qualified T3 supply delayed the final formulation optimization studies until the first half of 2017; Titan anticipates a pre-IND review with the FDA in the third quarter of 2017.

"We are very pleased with the approval of Probuphine by the FDA in May 2016. The field of addiction treatment is undergoing a significant paradigm shift, as addiction is increasingly viewed as a chronic disease that benefits from long-term treatment focused on enhancing patient compliance and quality of life. With an expanding treatment market and a shift toward long-term product formulations as the wave of the future, we believe Probuphine is well positioned to become a preferred opioid addiction treatment," said Titan President and CEO Sunil Bhonsle. "While this shift is positive, the nature of launching a long-term treatment such as Probuphine is complex and challenging, and requires a higher level of physician and third party payor education and support. Braeburn has made good progress with the initial product launch activities to date, and is continuing to build a strong foundation this year for the long-term commercial success of Probuphine. We are very encouraged by the substantial resources Braeburn has deployed to support the full commercial launch and we remain confident in its ability to address any ongoing market challenges, allowing for the gradual uptake of Probuphine over the next several quarters."

"Probuphine's approval in 2016 provided strong validation of our ProNeura long-term, continuous drug delivery platform, and the board remains enthusiastic about the prospects of our ProNeura-based product portfolio," said Executive Chairman Marc Rubin, M.D. "As Probuphine activities progress, we will continue to evaluate additional ProNeura-based development programs and other opportunities to further build value in Titan. I would like to also welcome our new board members, Mr. Scott Smith, president of global inflammation and immunology at Celgene, and Dr. Rajinder Kumar, President and CEO of MeRad, who bring invaluable experience and skills to the team. We congratulate Mr. Smith on his recently announced promotion to President and COO at Celgene."

Full Year 2016 Financial Results

Total revenues for the full year ended Dec. 31, 2016 were approximately $15.1 million compared with approximately $1.7 million in 2015. Revenue in 2016 reflected approximately $15.0 million from a milestone payment from Braeburn, earned upon approval of Probuphine by the FDA in May 2016, and approximately $65,000 from royalties earned on net sales of Probuphine. License revenue in 2015 reflected the amortization of the upfront license fee received from Braeburn in December 2012.

Total operating expenses in 2016 were approximately $10.7 million, compared with $8.4 million in 2015, and consisted of research and development (R&D) expenses of approximately $6.1 million in 2016, compared with approximately $4.7 million in R&D expenses in 2015. This increase of approximately $1.4 million was primarily associated with external research and development expenses related to Titan's ProNeura product development programs, employee-related expenses and other R&D expenses. These increases were partially offset by the reimbursement by Braeburn of Probuphine-related expenses. General and administrative expenses (G&A) were approximately $4.6 million in 2016, compared with approximately $3.8 million in 2015, an increase of approximately $0.8 million. The increase in G&A expenses was primarily related to non-cash stock-based compensation and employee-related costs, legal and professional fees and a contractual fee obligation related to Probuphine.

Net other income for 2016 was approximately $0.8 million, consisting primarily of non-cash gains on changes in the fair value of warrant liabilities. This compares with net other expense of $4.5 million in 2015, consisting primarily of non-cash losses on changes in the fair value of warrant liabilities.

Net income applicable to common stockholders for 2016 was approximately $5.1 million, or approximately $0.25 per share, compared with net loss applicable to common stockholders of approximately $11.3 million, or approximately $0.56 per share, for 2015.

At Dec. 31, 2016, Titan had cash of approximately $14.0 million, compared with approximately $7.9 million at Dec. 31, 2015. Titan believes its working capital at Dec. 31, 2016 is sufficient to fund operations through the first quarter of 2018.

Fourth Quarter 2016 Financial Results

Titan reported approximately $35,000 in license revenue in the fourth quarter of 2016, compared with no revenue in the same period of a year ago. Total operating expenses were approximately $3.3 million, consisting primarily of R&D expenses of approximately $2.1 million and G&A expenses of approximately $1.2 million. Operating expenses for the same period in 2015 were approximately $2.3 million, consisting of R&D expenses of approximately $1.1 million and G&A expenses of approximately $1.1 million.

Net other income was approximately $0.9 million in the fourth quarter of 2016, compared with a net expense of approximately $44,000 in the fourth quarter of 2015.

Net loss applicable to common shareholders in the fourth quarter of 2016 was approximately $2.3 million or approximately $0.11 a share, which was approximately the same as in the fourth quarter of 2015.

Conference Call

Titan management will host a live conference call at 4:15 p.m. ET / 1:15 p.m. PT on Thursday, March 16, 2017 to discuss the company's financial results as of Dec. 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. A summary of the fourth quarter and full year financial results and other highlights will be included in a press release to be issued prior to the call.

The live webcast of the call may be accessed by visiting http://www.titanpharm.com/news/events. The call can also be accessed by dialing 1-877-870-4263 (or 1-412-317-0790 from outside the U.S.) five minutes prior to the start time, and asking to be joined into the Titan Pharmaceuticals, Inc. call.

A replay of the call will be available approximately one hour after completion of the call by dialing 1-877-344-7529 and entering passcode 10103098. An audio recording of the call will also be archived on the Titan website.

About Titan Pharmaceuticals

Titan Pharmaceuticals Inc. (NASDAQ: TTNP), based in South San Francisco, CA, is developing proprietary therapeutics primarily for the treatment of serious medical disorders. The company's lead product 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 in the U.S. and Canada for Probuphine to Braeburn Pharmaceuticals. Approved by the U.S. Food and Drug Administration 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 commercialization of Probuphine, 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 December 31,		Year Ended December 31,	
	2016	**2015**	**2016**	**2015**
Revenue:				
License revenue	$ 35	$ -	$ 15,065	$ 1,671
Total revenue	35	-	15,065	1,671
Operating expense:				
Research and development	2,090	1,135	6,126	4,675
General and administrative	1,199	1,115	4,596	3,755
Total operating expense	3,289	2,250	10,722	8,430
Income (loss) from operations	(3,254)	(2,250)	4,343	(6,759)
Other income (expense), net	927	(44)	792	(4,520)
Net income (loss) and comprehensive income (loss)	$ (2,327)	$ (2,294)	$ 5,135	$ (11,279)
Basic net income (loss) per share	$ (0.11)	$ (0.11)	$ 0.25	$ (0.56)
Diluted net income (loss) per share	$ (0.15)	$ (0.11)	$ 0.20	$ (0.56)
Weighted average shares used in computing basic net income (loss) per share	21,199	20,060	20,744	20,053
Weighted average shares used in computing diluted net income (loss) per share	21,566	20,060	21,459	20,053

CONDENSED BALANCE SHEETS
(in thousands)
(unaudited)

	December 31,	
	2016	**2015**
Assets		
Cash	$ 14,006	$ 7,857
Receivables	3,587	4,213
Prepaid expenses and other current assets	237	174
Total current assets	17,830	12,244
Furniture and equipment, net	837	1,043
	$ 18,667	$ 13,287
Liabilities and Stockholders' Equity		
Current liabilities	$ 4,857	$ 4,853
Warrant liabilities	619	1,444
Stockholders' equity	13,191	6,990
	$ 18,667	$ 13,287

To view the original version on PR Newswire, visit:http://www.prnewswire.com/news-releases/titan-pharmaceuticals-reports-full-year-and-fourth-quarter-2016-financial-results-300424604.html

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