

Titan Pharmaceuticals Reports Second Quarter 2017 Financial Results

Titan Management Team to Host Conference Call Aug. 9 at 4:15 p.m. EDT / 1:15 p.m. PDT

SOUTH SAN FRANCISCO, Calif., Aug. 9, 2017 /PRNewswire/ --<u>Titan Pharmaceuticals, Inc.</u> (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 second quarter 2017, and provided an update on its business.



Business highlights include:

Financing

 On July 27, Titan entered into a loan agreement with Horizon Technology Finance Corporation that provides up to \$10 million in available borrowing capacity. The first \$7 million tranche was funded upon execution of the loan agreement and a second \$3 million tranche is available to Titan, at its option, through March 31, 2018, subject to achieving agreed upon revenue and product development milestones, and borrowing conditions.

Probuphine® for Opioid Addiction

- Second quarter license revenue from Probuphine was \$77,000, a 93 percent increase over the prior quarter.
- Titan's development and commercialization partner, Braeburn Pharmaceuticals, Inc., reported that most patients completing their first six-month treatment with Probuphine during the second quarter opted for treatment continuation.
- Early in the second quarter, Braeburn expanded its distribution channels and processing capacity by adding a second specialty pharmacy company to increase third-party payor coverage across the country.

- Braeburn indicated continued progress with third-party payor document processing and reimbursement; however, this progress remains inconsistent among payors.
- In June 2017, Braeburn appointed former head of CNS and Pain Therapeutics for Teva Pharmaceuticals, Mike Derkacz, as its president and CEO; Mr. Derkacz has deep commercial experience launching new pharmaceutical products, particularly depot and medical device products.
- During the second quarter, the European Medicines Agency (EMA) granted a pediatric indication waiver for Probuphine, which simplifies preparation of the Marketing Authorization Application (MAA) by eliminating the need for submitting detailed clinical evaluation plans for a pediatric indication.
- The EMA appointed two member countries as rapporteur and co-rapporteur for Probuphine; Titan has established a dialogue with the regulatory authorities in both countries to familiarize them with the development of Probuphine and the safety and efficacy data set.
- Titan remains on track to submit an MAA to the EMA in the fourth quarter of 2017.

Ropinirole Implant for Parkinson's Disease

- Titan has submitted to the U.S. Food and Drug Administration (FDA) the information requested with regards to the clinical hold for the ropinirole implant Investigational New Drug (IND) application; the review date communicated by the FDA is Aug. 13, 2017.
- Titan has identified clinical sites for the Phase 1/2 pharmacokinetic study and has made preparations to initiate the first site pending FDA clearance of the IND.

Other ProNeura Implant Development Programs

- In July, Titan announced that it had entered into a Cooperative Research and Development Agreement (CRADA) with Walter Reed Army Institute of Research (WRAIR) and Southwest Research Institute (SwRI) to evaluate the development of ProNeura-based implants for a long-term regimen in the prevention of malaria.
- Results of the initial non-clinical studies of ProNeura-based implants for the prevention of malaria were presented by the Experimental Therapeutics (ET) branch of WRAIR at the 2017 Asia Pacific Military Health Exchange (APMHE) in Singapore.
- Titan is completing non-clinical evaluation of its re-formulated T3 implant for hypothyroidism and will evaluate further development dependent on available resources.
- New exploratory programs in other disease states are progressing, and implant feasibility evaluation studies are being prioritized in areas with potential for early support from commercial partners and research institutions.

"Braeburn has made steady progress in commercializing Probuphine and we are encouraged by the license revenue increase we have seen from the first to the second quarter," said President and CEO Sunil Bhonsle. "While there are still challenges, we believe Braeburn is establishing a strong foundation for future success, and we expect that thirdparty payor coverage will continue to improve, expanding access to treatment with Probuphine. We were also pleased to secure debt financing of up to \$10 million, which significantly expands our cash runway with minimal dilution for shareholders."

Executive Chairman Marc Rubin, M.D., added, "In the long-term, Titan is well positioned to benefit from the trend toward extended release formulations for opioid addiction treatment,

such as one-week and one-month depot injections, for which two companies have recently submitted their New Drug Applications to the FDA. These products, if approved, will focus on patients during the initial stages of treatment, which can enable clinicians, third-party payors and patients to become accustomed to procedure-oriented treatment, potentially further enhancing the use of Probuphine during the maintenance treatment stage. In addition to remaining enthusiastic about the prospects for Probuphine, the board is looking forward to potentially advancing Titan's ropinirole implant for Parkinson's disease into the clinic in the current quarter."

Second Quarter 2017 Financial Results

In the second quarter of 2017, Titan reported approximately \$77,000 in license revenue from royalties earned on net sales of Probuphine by Braeburn, reflecting a 93 percent increase over the prior quarter. The \$15 million in revenue in the same period of a year ago reflected the one-time milestone payment that was earned from Braeburn upon approval of Probuphine by the FDA.

Total operating expenses for the quarter ended June 30, 2017 were approximately \$3.7 million, compared with approximately \$3.0 million in the same quarter a year ago, and consisted primarily of research and development (R&D) and general and administrative (G&A) expenses.

R&D expenses for the quarter ended June 30, 2017 were approximately \$2.5 million, compared with approximately \$1.7 million for the same quarter in 2016, an increase of approximately \$0.8 million. The increase in R&D expenses was primarily associated with increases in external expenses related to the company's Probuphine and ProNeura product development programs and other research and development activities. G&A expenses for the second quarters of 2017 and 2016 were approximately \$1.2 million.

Net loss applicable to common shareholders in the second quarter of 2017 was approximately \$3.5 million, or approximately \$0.16 per share, compared with net income of approximately \$11.9 million, or \$0.58, per share in the same quarter in 2016.

At June 30, 2017, Titan had cash and cash equivalents of approximately \$8.4 million. Subsequent to the end of the second quarter, in July 2017, Titan completed a debt transaction providing Titan with up to \$10 million in borrowing capacity. A first tranche of \$7 million was funded upon execution of the loan agreement. A second tranche of \$3 million will be available to Titan, at its option, through March 31, 2018, subject to the satisfaction of certain revenue and product development milestones, and other borrowing conditions. Titan believes that funds available at June 30, 2017, together with the first tranche of the Horizon loan, are sufficient to fund operations into the first quarter of 2019.

Conference Call

Titan management will host a live conference call today at 4:15 p.m. ET / 1:15 p.m. to discuss the company's financial results as of June 30, 2017. 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.

The live webcast of the call may be accessed by visiting<u>the Events page on Titan's website</u>. 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 to the Titan Pharmaceuticals call. An audio recording of the call will also be <u>archived on the Titan</u> 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-theclock 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 <u>www.titanpharm.com</u>.

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.

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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,	
	2017	2016	2017	2016
Revenue:				
License revenue	\$77	\$ 15,004	\$ 117	\$ 15,004
Total revenue	77	15,004	117	15,004
Operating expense:				
Research and development	2,501	1,746	4,627	2,446
General and administrative	1,197	1,214	2,548	2,345
Total operating expense	3,698	2,960	7,175	4,791
Income (loss) from operations	(3,621)	12,044	(7,058)	10,213
Other income (expense), net	170	(116)	602	(131)
Net income (loss) and comprehensive				
income (loss)	\$ (3,451)	\$ 11,928	\$ (6,456)	\$ 10,082
Basic net income (loss) per share	\$ (0.16)	\$ 0.58	\$ (0.30)	\$ 0.50
Diluted net income (loss) per share	\$ (0.17)	\$ 0.55	\$ (0.33)	\$ 0.48
Weighted average shares used in computing				
basic net income (loss) per share	21,204	20,508	21,199	20,284
Weighted average shares used in computing				
diluted net income (loss) per share	21,204	21,878	21,201	21,223

CONDENSED BALANCE SHEETS (in thousands) (unaudited)

		June 30, 2017	ember 31, 2016
Assets			
	Cash and cash equivalents	\$ 8,350	\$ 14,006
	Receivables	87	3,587
	Prepaid expenses and other current assets	317	 237
	Total current assets	8,754	17,830

660		837
\$ 9,414	\$	18,667
\$ 1,869	\$	4,857
7		619
7,538		13,191
\$ 9,414	\$	18,667
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