

# Titan Pharmaceuticals Reports Third Quarter 2017 Financial Results

Titan Management Team to Host Conference Call Nov. 9 at 4:15 p.m. EST / 1:15 p.m. PST

SOUTH SAN FRANCISCO, Calif., Nov. 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<sup>™</sup> long-term, continuous drug delivery technology, today reported financial results for the third quarter 2017, and provided an update on its business.



#### **Business highlights include:**

# Probuphine® for Opioid Addiction

- License revenue from Probuphine was approximately \$40,000 in the third quarter 2017, a decline from the previous quarter.
- Titan is actively interacting with its Probuphine commercialization partner, Braeburn Pharmaceuticals, Inc., to more fully understand and help address the issues limiting the sales of the product.
- Titan submitted the Marketing Authorization Application for Probuphine with the European Medicines Agency on Nov. 6, 2017.
- In October 2017, Titan received a notice of allowance from the European Patent Office for a patent covering methods of use claims for treating opioid dependence with a subdermal implant containing buprenorphine. Upon issuance, this patent is expected to provide protection for Probuphine in Europe into 2023.
- Discussions with potential commercial partners for Probuphine in Europe and elsewhere are continuing.

## Ropinirole Implant for Parkinson's Disease

• In October, the first patient was treated in a Phase 1/2 trial of the company's ropinirole

implant intended for the treatment of the signs and symptoms of idiopathic Parkinson's disease, and the study is progressing as planned. This followed the U.S. Food and Drug Administration's clearance of the Investigational New Drug application for the ropinirole implant in August.

### Other ProNeura Implant Development Programs

- Titan and Opiant Pharmaceuticals, Inc. announced in October that the companies are collaborating on a feasibility assessment of a subcutaneous implant using the ProNeura technology to administer an opioid antagonist for the prevention of opioid relapse and overdose in individuals with opioid use disorder.
- Early non-clinical testing is being conducted for the development of a kappa opioid receptor agonist implant for the treatment of chronic pain. If successfully developed and approved, this would offer a potential non-addictive opioid analgesic for the treatment of chronic pain.
- Formulation studies and early in vitro testing is being conducted for the potential development of an implant with a currently approved peptide for the treatment of adult type 2 diabetes mellitus.
- Titan is completing non-clinical evaluation of its re-formulated ProNeura subdermal implant for the long-term, sustained delivery of liothyronine (L-T3) for the treatment of hypothyroidism and will evaluate further development dependent on available resources. In October 2017, Titan presented data from a non-clinical study on the use of its T3 implant during a poster session at the annual conference of the American Thyroid Association.
- Titan, Southwest Research Institute and the Walter Reed Army Institute of Research (WRAIR) are collaborating in the early non-clinical evaluation of the ProNeura platform for malaria prophylaxis treatment. In November 2017, the WRAIR presented encouraging non-clinical data from this collaboration during a poster session at the annual meeting of the American Society of Tropical Medicine & Hygiene, demonstrating sustained release of the anti-malarial drug atovaquone and protection from malaria for up to 12 weeks.

"We are surprised and very disappointed with the decline in sales of Probuphine in the third quarter. Based on feedback from Braeburn and key opinion leaders we believe that access to care for patients has been negatively impacted by issues related to the timing and amount of reimbursement to patients and their doctors from insurance providers, as well as the requirements of the REMS program," said Titan President and CEO Sunil Bhonsle. "We are in ongoing discussions with Braeburn senior management to fully understand all of these issues as we evaluate possible means of overcoming the impediments to Probuphine uptake experienced to date."

"The paradigm for treating opioid addiction is poised to undergo a significant shift from oral medications to extended release and depot formulations. While we believe that Probuphine should benefit from this trend, we must also continue to closely monitor this changing landscape in order to identify the best position for the product in the marketplace," said Executive Chairman Marc Rubin, M.D. "In the meantime, we continue to be encouraged by the progress we are making in our portfolio of other ProNeura-based product candidates. We believe drug delivery platforms such as ProNeura can have significant advantages over existing treatment regimens and represent an important option for the future of chronic

disease treatment."

#### Third Quarter 2017 Financial Results

In the third quarter of 2017, Titan reported approximately \$40,000 in license revenue from royalties earned on net sales of Probuphine by Braeburn, compared with approximately \$26,000 in the same period a year ago.

Total operating expenses for the third quarter ended Sept. 30, 2017 were approximately \$4.1 million, compared with approximately \$2.6 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 Sept. 30, 2017 were approximately \$2.7 million, compared with approximately \$1.6 million for the same quarter in 2016, an increase of approximately \$1.1 million. The increase in R&D expenses was primarily associated with increases in external expenses related to the support of the ropinirole implant program and some expenses on other ProNeura product development programs. G&A expenses for the third quarter 2017 were approximately \$1.4 million, compared with approximately \$1.1 million in the same quarter a year ago. The increase was primarily related to increases in non-cash stock compensation and employee-related expenses, fees and expenses related to the Horizon loan and other expenses.

Net loss applicable to common shareholders in the third quarter of 2017 was approximately \$4.2 million, or approximately \$0.20 per share, compared with net loss of approximately \$2.6 million, or approximately \$0.12, per share in the same quarter in 2016.

At Sept. 30, 2017, Titan had cash and cash equivalents of approximately \$11.7 million, which the company believes is sufficient to fund planned operations through August 2018. Titan is evaluating potential funding options, including, but not limited to partnering opportunities for Probuphine outside of the U.S., collaborations for one or more of the company's ProNeura programs, and various financing strategies.

#### Conference Call

Titan management will host a live conference call today at 4:15 p.m. EST / 1:15 p.m. PST to discuss the company's financial results as of Sept. 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 the Events page on Titan's website. The call can also be accessed by dialing 1-855-940-9476 (or 1-412-317-5223 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 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 <a href="https://www.titanpharm.com">www.titanpharm.com</a>.

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.

#### CONTACT:

Titan Pharmaceuticals, Inc.: Sunil Bhonsle, President (650) 244-4990

Investors: Stephen Kilmer (650) 989-2215 skilmer@titanpharm.com

Media: Susan Thomas (650) 989-2216 <a href="mailto:sthomas@titanpharm.com">sthomas@titanpharm.com</a>

TITAN PHARMACEUTICALS, INC.
CONDENSED STATEMENTS OF OPERATIONS AND COMPREHENSIVE INCOME (LOSS)
(in thousands, except per share amount)
(unaudited)

Three Months Ended September 30,

Nine Months Ended September 30,

|   | 2017 |         | 2016 |         | 2017 |          | 2016 |        |
|---|------|---------|------|---------|------|----------|------|--------|
| Revenue:  |      |         |      |         |      |          |      |        |
| License revenue   | \$   | 40      | \$   | 26      | \$   | 157      | \$   | 15,030 |
| Total revenue   |      | 40      |      | 26      |      | 157      |      | 15,030 |
| Operating expense:  |      |         |      |         |      |          |      |        |
| Research and development  |      | 2,714   |      | 1,590   |      | 7,341    |      | 4,036  |
| General and administrative  |      | 1,396   | -    | 1,052   |      | 3,944    |      | 3,397  |
| Total operating expense   |      | 4,110   | -    | 2,642   |      | 11,285   |      | 7,433  |
| Income (loss) from operations   |      | (4,070) |      | (2,616) |      | (11,128) |      | 7,597  |
| Other income (expense), net   |      | (121)   |      | (4)     |      | 481      |      | (135)  |
| Net Income (loss) and comprehensive income (loss)                             | \$   | (4,191) | \$   | (2,620) | \$   | (10,647) | \$   | 7,462  |
| income (ioss)   | Ψ    | (4,131) | Ψ    | (2,020) | Ψ    | (10,047) | Ψ    | 7,402  |
| Basic net income (loss) per share   | \$   | (0.20)  | \$   | (0.12)  | \$   | (0.50)   | \$   | 0.36   |
| Diluted net income (loss) per share   | \$   | (0.20)  | \$   | (0.12)  | \$   | (0.50)   | \$   | 0.35   |
| Weighted average shares used in computing basic net income (loss) per share   |      | 21,204  |      | 21,199  |      | 21,202   |      | 20,591 |
| Weighted average shares used in computing diluted net income (loss) per share |      | 21,204  |      | 21,199  |      | 21,222   |      | 21,447 |

# CONDENSED BALANCE SHEETS (in thousands)

|  | September 30,<br>2017 | December 31,<br>2016<br>(unaudited) |  |  |
|--|-----------------------|-------------------------------------|--|--|
|  | (unaudited)           |                                     |  |  |
| Assets                                     |                       |                                     |  |  |
| Cash and cash equivalents                  | \$ 11,688             | \$ 14,006                           |  |  |
| Receivables                                | 91                    | 3,587                               |  |  |
| Prepaid expenses and other current assets  | 277                   | 237                                 |  |  |
| Total current assets                       | 12,056                | 17,830                              |  |  |
| Furniture and equipment, net               | 684                   | 837                                 |  |  |
| Total assets                               | \$ 12,740             | \$ 18,667                           |  |  |
| Liabilities and Stockholders' Equity       |                       |                                     |  |  |
| Current liabilities                        | \$ 1,972              | \$ 4,857                            |  |  |
| Long-term debt                             | 6,725                 | -                                   |  |  |
| Warrant liabilities                        | 5                     | 619                                 |  |  |
| Stockholders' equity                       | 4,038                 | 13,191                              |  |  |
| Total liabilities and stockholders' equity | \$ 12,740             | \$ 18,667                           |  |  |

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