August 14, 2020

Titan Pharmaceuticals Reports Second Quarter 2020 Financial Results

SOUTH SAN FRANCISCO, Calif., Aug. 14, 2020 /PRNewswire/ -- Titan Pharmaceuticals, Inc. (NASDAQ: TTNP) ("Titan" or the "Company") today reported financial results for the second quarter ended June 30, 2020 and provided an update on its business.

Second Quarter 2020 Highlights

- In June 2020, Titan initiated a fully-virtual Probuphine® (buprenorphine) implant Risk Evaluation and Mitigation Strategy ("REMS") training and certification program for qualified health care providers ("HCPs") who treat patients with Opioid Use Disorder ("OUD").
- In June 2020, the Company entered into a co-promotion partnership with Indegene, Inc., a leading healthcare solutions company, to establish multichannel digital marketing programs throughout the United States to increase awareness of Probuphine as a long-term maintenance treatment for OUD, and expand the capabilities for the engagement of HCPs who can be certified to prescribe Probuphine to eligible patients.
- Since January 1, 2020, Titan received proceeds of approximately $7.0 million as a result of the exercise of previously issued common stock purchase warrants.

COVID-19 Impact and Adjusted Probuphine Commercial Strategy

Early this year, Titan implemented its staffing plans for expanded commercial operations with additions to its sales and medical liaison teams, including support from additional marketing and medical access staff to enable improved coverage across all 50 states and Puerto Rico. Unfortunately, the COVID-19 pandemic-related shelter in place and social distancing restrictions and minimized personal physician/patient interaction have hindered the full effectiveness of the commercial team. In order to try and mitigate the impact of the ongoing public health crisis, Titan has undertaken a number of key activities during this period, including:

- Training the commercial team in utilizing digital communication techniques to establish

relationships with existing and new HCPs and their staff;
- Providing Probuphine information in electronic format for ease of virtual communication for HCPs to use with their patients and to highlight the potential benefits of Probuphine as a treatment modality in the increasing telemedicine environment;
- Establishing a social media presence in select geographies to increase awareness of Probuphine and enhance its share of voice in the OUD medication assisted treatment space;
- Rapidly developing and obtaining FDA approval to implement a virtual REMS training program to certify HCPs during this period; and
- Seeking partnering opportunities to increase the commercial capabilities in support of Probuphine.

"We continue to adapt to this ever-changing pandemic environment, and thanks to our dedicated staff, we are making progress," said Titan's President and CEO, Sunil Bhonsle. "We are pleased with the FDA's prompt approval of our fully-virtual REMS training program, which enables us to continue to certify HCPs to prescribe and administer Probuphine, facilitating access to our six-month maintenance treatment option for eligible patients with OUD. Our commercial team continues to focus on digital outreach to establish relationships with the medical community and to inform HCPs, their staff and their patients of the potential benefits of Probuphine, particularly at a time when patient/physician interactions are limited. Following a substantial decline in the number of patient enrollments for Probuphine treatment during the first two months of the quarter, clinics in certain regions began to see an increase in enrollments in June, which has continued. We believe this is an early indication that the efforts of our commercial team are working and we look forward to continued progress in the coming months."

Probuphine is indicated for the maintenance treatment of OUD in eligible patients.

Please see Full Indication and Important Safety Information below, and link below to Full Prescribing Information.

"Our goal is to increase the use of Probuphine for the maintenance treatment of OUD, and in the current environment, our recently established co-promotion partnership with Indegene is timely," said Titan's Executive Chairman, Dr. Marc Rubin. "With the support of our commercial team, Indegene's capabilities provide Titan with sophisticated multichannel marketing tools, predictive analytics and social media campaigns that will be critical to expanding our outreach to the medical community and patients. The first virtual nationwide outreach campaign commenced last week, and the Titan-Indegene team is looking forward to continuing the implementation of a comprehensive program over the next few months. During the third quarter we will also implement a three-month program to seek and assist patients who may be suitable for treatment with Probuphine and connect them with REMS-certified HCPs. I want to emphasize that our progress can be sustained only if our stockholders approve the proposal to increase the authorized shares at our special stockholder meeting scheduled for August 31, 2020.

"In addition, Sunil has expressed his desire to retire, hopefully by the end of the year. To prepare for this transition, and contingent on our ability to raise additional capital, we will look for a successor with experience in the commercial space, as we continue our transition to a commercial-stage company."

Second Quarter 2020 Financial Results

For the three months ended June 30, 2020, Titan reported approximately $1.3 million in revenue, which reflects approximately $0.1 million in product sales and approximately $1.2 million related to the Company's National Institute on Drug Abuse ("NIDA") grant. This compared with revenues of approximately $0.5 million in the same period in 2019, which was comprised of $0.3 million in product sales and $0.2 million related to the NIDA grant. Product revenue during the quarter ended June 30, 2020 declined substantially from the comparable period in 2019 due to substantial decreases in unit sales volumes, increased utilization of our patient assistance programs and the COVID-19 pandemic and the related shelter in place restrictions and clinic closures. Also, the second quarter of 2019 unit sales volume included initial purchases by a specialty pharmacy.

Total operating expenses for the second quarter of 2020 were approximately $5.7 million, compared with approximately $5.4 million from the same quarter in 2019, and consisted primarily of research and development ("R&D") and selling, general and administrative ("SG&A") expenses and costs of goods sold, inclusive of distribution expenses. R&D expenses for the quarter ended June 30, 2020 were approximately $2.0 million, compared to approximately $1.9 million in the same three month period in 2019. SG&A expenses for the 2020 second quarter were approximately $3.5 million, compared with approximately $3.2 million in the same quarter a year ago. Costs of goods sold for the second quarter of 2020 were approximately $0.2 million, consistent with the 2019 second quarter.

Net other expense, consisting primarily of interest expense, was approximately $0.3 million in the second quarter of 2020, consistent with the second quarter of 2019.

Net loss applicable to common stockholders in the second quarter of 2020 was approximately $4.6 million, or approximately $0.05 per share, compared with a net loss applicable to common stockholders of approximately $5.2 million, or approximately $0.38 per share, in the same quarter in 2019.

As of June 30, 2020, Titan had cash and cash equivalents of approximately $5.5 million, which the Company believes are sufficient to fund planned operations through the third quarter of 2020.

Conference Call Details

Titan management will host a conference call today at 12:00 p.m. ET / 9:00 a.m. PT to review these financial results and discuss business developments in the period. The conference call will be hosted by Sunil Bhonsle, President and CEO; Kate Beebe DeVarney, Ph.D., Executive Vice President and Chief Scientific Officer; Brian Crowley, Vice President of Finance; Joe Schrei, Executive Director, Commercial Operations; Mike Fritz, National Sales Director; and Marc Rubin, M.D., Executive Chairman.

The live conference call may be accessed by dialing 1-888-317-6003 (U.S.) or 1-412-317-6061 (international) and providing passcode 8493149. The call will also be broadcast live and archived on Titan's website at www.titanpharm.com/news/events.

About Probuphine

Probuphine is the only subdermal implant designed to deliver buprenorphine continuously for six months following insertion.

Probuphine was developed using ProNeura®, the continuous drug delivery system developed by Titan that consists of a small, solid implant made from a mixture of ethylene-vinyl acetate and a drug substance. The resulting construct is a solid matrix that is placed subdermally, normally in the upper inner arm in an outpatient office procedure and removed in a similar manner at the end of the treatment period. The U.S. Food and Drug Administration ("FDA") approved Probuphine in May 2016, and it is the first and only buprenorphine implant available for the maintenance treatment of opioid addiction in eligible patients.

IMPORTANT SAFETY INFORMATION INCLUDING INDICATION AND **BOXED WARNING**

INDICATION

PROBUPHINE is an implant that contains the medicine buprenorphine. PROBUPHINE is used to treat certain adults who are addicted to (dependent on) opioid drugs (either prescription or illegal). PROBUPHINE is indicated for the maintenance treatment of opioid dependence in patients who have achieved and sustained prolonged clinical stability on low-to-moderate doses (doses no more than 8 mg per day) of a buprenorphine-containing product.

PROBUPHINE is part of a complete treatment program that also includes counseling and behavioral therapy.

It is not known if PROBUPHINE is safe or effective in children less than 16 years of age.

IMPORTANT SAFETY INFORMATION

WARNING: COMPLICATIONS FROM INSERTION AND REMOVAL OF PROBUPHINE

See Full Prescribing Information for complete Boxed Warning

Serious complications may happen from insertion and removal of PROBUPHINE, including:

- Nerve or blood vessel injury in your arm
- Movement of implant (migration). PROBUPHINE or pieces of it can move into blood vessels, possibly to your lung, and could lead to death
- Implant sticks out of the skin (protrusion)
- Implant comes out by itself (expulsion)

Call your healthcare provider right away if:

- PROBUPHINE sticks out of the skin or comes out by itself
- You have bleeding or symptoms of infection at the site after insertion or removal, including excessive or worsening itching, pain, irritation, redness, or swelling
- You have numbness or weakness in your arm after the insertion or removal procedure
- You have weakness or numbness in your arm, or shortness of breath

If the implant comes out by itself, keep it away from others, especially children, as it may cause severe difficulty in breathing and possibly death.

Because of the risk of complications of, migration, protrusion, expulsion and nerve injury with insertion and removal of PROBUPHINE, it is only available through a restricted program called the PROBUPHINE REMS Program. Healthcare providers who prescribe and/or insert PROBUPHINE must be certified with the program by enrolling and completing live training.

- PROBUPHINE is not available in retail pharmacies
- PROBUPHINE must be inserted or removed only in the facility of the certified prescriber

Implants may be difficult to locate if inserted too deeply, if you manipulate them, or if you gain significant weight after insertion. Your healthcare provider may do special procedures or tests, or refer you to a surgical specialist to remove the implants if they are difficult to locate.

The medicine in PROBUPHINE can cause serious and life-threatening problems, especially if you take or use certain other medicines or drugs. Call your healthcare provider right away or get emergency help if you:

Feel faint or dizzy, have mental changes such as confusion, slower breathing than you normally have, severe sleepiness, blurred vision, problems with coordination, slurred speech, cannot think well or clearly, high body temperature, slowed reflexes, feel agitated, stiff muscles or have trouble walking.

These can be signs of an overdose or other serious problems.

Coma or death can happen if you take anxiety medicines or benzodiazepines, sleeping pills, tranquilizers, or sedatives, antidepressants, or antihistamines, or drink alcohol during treatment with PROBUPHINE. Tell your healthcare provider if you are taking any of these medicines or if you drink alcohol.

Who should not use PROBUPHINE?

Do not use PROBUPHINE if you are allergic to buprenorphine or any of its ingredients, this includes buprenorphine hydrochloride and the inactive ingredient ethylene vinyl acetate or EVA.

PROBUPHINE may not be right for you. Before starting PROBUPHINE tell your doctor about all of your medical conditions, including:

Trouble breathing or lung problems, an enlarged prostate gland (men), a head injury or brain problem, problems urinating, a curve in your spine that affects your breathing, liver problems, gallbladder or adrenal gland problems, Addison's disease, low thyroid hormone levels (hypothyroidism), a history of alcoholism, a history of keloid formation, connective tissue disease (such as scleroderma), or history of MRSA infections, mental problems such as hallucinations, an allergy to numbing medicines or medicines used to clean your skin, are pregnant or plan to become pregnant or are breastfeeding or plan to breastfeed.

Tell your doctor about all the medicines you take, including prescription and over-the-

counter medicines, vitamins and herbal supplements.

What should I avoid while being treated with PROBUPHINE?

- **Do not drive, operate heavy machinery, or perform any other dangerous activities until you know how this medication affects you**
- **You should not drink alcohol** during treatment. You should not take anxiety medicines or benzodiazepines, sleeping pills, tranquilizers, or sedatives that are not prescribed to you during treatment with PROBUPHINE, as this can lead to slowed breathing, drowsiness, delayed reaction time, loss of consciousness or even death

What are the possible side effects of PROBUPHINE?

PROBUPHINE can cause serious side effects, including:

- **Infection at the insertion or removal site.** Infection may happen at the implant site during insertion or removal. Do not try to remove PROBUPHINE implants yourself
- **Opioid withdrawal.** If PROBUPHINE comes out of your arm or if you stop treatment, tell your doctor right away as you can have symptoms of shaking, sweating more than normal, feeling hot or cold more than normal, runny nose, watery eyes, goose bumps, diarrhea, vomiting and muscle aches
- **Physical dependency**
- **Liver problems**. Call your doctor right away if you notice signs of liver problems that may include your skin or the white part of your eyes turning yellow (jaundice)
- **Allergic reaction.** If you get a rash, hives, itching, swelling of your face, or wheezing, low blood pressure, dizziness or decrease in consciousness
- **Decrease in blood pressure**. You may feel dizzy when you get up from sitting or lying down
- **Sleep Apnea**. Call your doctor right away if you or someone close to you notices: Observed episodes of stopped breathing or abnormal breathing patterns during sleep

Tell your healthcare provider if you develop any of the symptoms listed.

Common side effects of PROBUPHINE include: Headache, nausea, toothache, constipation, depression, vomiting, back pain, mouth and throat pain.

Common risks with the minor surgical procedure: Itching, pain, irritation, redness, swelling, bleeding, or bruising at the insertion or removal site. Scarring around the insertion site.

Please read Full Prescribing Information, including **BOXED WARNING regarding IMPLANT MIGRATION, PROTRUSION, EXPULSION and NERVE DAMAGE ASSOCIATED WITH INSERTION AND REMOVAL.**

Titan encourages you to report negative side effects of prescription drugs to the FDA. You can visit www.fda.gov/safety/medwatch/ or call 1-800-FDA-1088.

About Titan Pharmaceuticals

Titan Pharmaceuticals, Inc. (NASDAQ:TTNP), based in South San Francisco, CA, is a commercial stage company developing proprietary therapeutics with its ProNeura® long-

term, continuous drug delivery technology. The Company's lead product is Probuphine® (buprenorphine) implant, a novel and long-acting formulation of buprenorphine for the long-term maintenance treatment of opioid dependence. 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 also 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.

Forward-Looking Statements

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; Titan's ability to access capital; 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 LOSS
(in thousands, except per share amount)
(unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	**2019**	**2020**	**2019**
Revenue:				
License revenue	$ 6	$ -	$ 6	$ 313
Product revenue	115	304	325	621
Grant revenue	1,204	198	2,330	513

Total revenue	1,325	502	2,661	1,447
Operating expense:				
Cost of goods sold	228	246	399	550
Research and development	2,007	1,907	4,284	3,751
Selling, general and administrative	3,474	3,231	6,589	6,313
Total operating expense	5,709	5,384	11,272	10,614
Loss from operations	(4,384)	(4,882)	(8,611)	(9,167)
Other expense, net	(257)	(315)	(1,614)	(547)
Net loss and comprehensive loss	$ (4,641)	$ (5,197)	$ (10,225)	$ (9,714)
Basic and diluted net loss per common share	$ (0.05)	$ (0.38)	$ (0.12)	$ (0.73)
Weighted average shares used in computing basic and diluted net loss per share	94,930	13,576	88,785	13,397

CONDENSED BALANCE SHEETS
(in thousands)
(unaudited)

	June 30, 2020	December 31, 2019
Assets		
Cash and cash equivalents	$ 5,498	$ 5,223
Receivables	1,061	993
Inventory	969	998
Prepaid expenses and other current assets	1,162	1,094
Total current assets	8,690	8,308
Property and equipment, net	799	817
Operating lease right-of-use asset	273	397
Total assets	$ 9,762	$ 9,522
Liabilities and Stockholders' Equity		
Current liabilities	$ 4,857	$ 3,600
Operating lease liability, non-current	-	150
Long-term debt, non-current	3,345	4,019
Warrant liability	-	320
Stockholders' equity	1,560	1,433
Total liabilities and stockholders' equity	$ 9,762	$ 9,522

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