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Titan Pharmaceuticals Reports First Quarter 2020 Financial Results

SOUTH SAN FRANCISCO, Calif., May 15, 2020 /PRNewswire/ -- Titan Pharmaceuticals, Inc. (NASDAQ: TTNP) ("Titan" or the "Company") today reported financial results for the first quarter ended March 31, 2020 and provided an update on its business.



First Quarter 2020 Highlights

- In January 2020, Titan completed an offering resulting in net cash proceeds of approximately \$1.9 million.
- Since January 1, 2020, the Company received proceeds of approximately \$6.7 million as a result of the exercise of previously issued common stock purchase warrants.

COVID-19 Impact and Adjusted Probuphine Commercial Strategy

Titan's commercial operations expansion has continued throughout the past several months, with additions to its sales and medical liaison teams, including support from additional marketing and medical access staff, that now provide coverage for all 50 states and Puerto Rico. Unfortunately, the emergence of the COVID-19 pandemic during the latter half of the first quarter and the resulting restrictions on travel and social distancing rules that have minimized personal physician/patient interaction, except in emergencies, has hindered the 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:

- Preparatory work using digital communication techniques to establish relationships with new health care providers ("HCPs") and their staff;
- Providing virtual communication tools for HCPs to use with their patients and to highlight the potential benefits of Probuphine as a treatment modality in the increasing telemedicine environment; and
- Establishing a social media presence in select geographies to increase awareness of Probuphine and enhance its share of voice in the medication assisted treatment space.

"Our first quarter of 2020 financial results were affected by the COVID-19 pandemic, and we have had to make several adjustments to our commercial tactics to best position Titan in the current environment," said Titan's President and CEO, Sunil Bhonsle. "We have been working in a virtual environment and have focused our efforts on using digital communication tools to establish strong relationships with the medical community as well as inform patients of Probuphine's long acting treatment option, which may be well-suited for telemedicine. In addition, our Medical Affairs team continues to develop a virtual process for providing training to health care providers, which, if approved by the FDA, could be a very valuable tool for Titan and health care providers alike."

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.

"The board has been very supportive of the team's initiative in the face of these new challenges, and I am very pleased with our progress," said Titan's Executive Chairman, Dr. Marc Rubin. "The unfortunate reality is that patients suffering from OUD are now facing more challenges to getting proper treatment during this pandemic, and we are working hard to ensure we can support their needs, as well as the needs of their health care providers."

First Quarter 2020 Financial Results

For the three months ended March 31, 2020, Titan reported approximately \$1.3 million in revenue, which reflects approximately \$0.2 million in product sales and approximately \$1.1 million related to the Company's National Institute on Drug Abuse ("NIDA") grant. This compared with revenues of approximately \$0.9 million in the same period in 2019, which was comprised of \$0.3 million in product sales, \$0.3 million related to the amortization of deferred revenue related to the sale to Molteni of the European intellectual property rights to Probuphine and \$0.3 million related to the NIDA grant.

Total operating expenses for the first quarter of 2020 were approximately \$5.6 million, compared with approximately \$5.2 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 March 31, 2020 were approximately \$2.3 million, compared with approximately \$1.8 million for the same three month period in 2019. SG&A expenses for the 2020 first quarter were approximately \$3.1 million, essentially unchanged from the same quarter a year ago. Costs of goods sold for the first quarter of 2020 were approximately \$0.2 million, compared with approximately \$0.3 million in the 2019 first quarter.

Net other expense, consisting primarily of interest expense, non-cash losses on changes in the fair value of warrants and costs attributable to the issuance of warrants was approximately \$1.4 million in the first quarter of 2020, compared with net other expense of approximately \$0.2 million in the first quarter of 2019.

Net loss applicable to common stockholders in the first quarter of 2020 was approximately \$5.6 million, or approximately \$0.07 per share, compared with a net loss applicable to common stockholders of approximately \$4.5 million, or approximately \$0.34 per share, in the

same quarter in 2019.

As of March 31, 2020, Titan had cash and cash equivalents of approximately \$8.0 million, which the Company believes, together with proceeds from a Paycheck Protection Program loan and the subsequent exercise of warrants, 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; 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 3367973. 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	
	March 31,	
	2020	2019
Revenue:		
License revenue	\$ -	\$ 313
Product revenue	210	317
Grant revenue	1,126	315
Total revenue	1,336	945
Operating expense:		
Cost of goods sold	171	304
Research and development	2,277	1,844
Selling, general and administrative	3,114	3,082
Total operating expense	5,562	5,230
Loss from operations	(4,226)	(4,285)
Other expense, net	(1,358)	(232)
Net loss and comprehensive loss	\$ (5,584)	\$ (4,517)
Basic and diluted net loss per common share	\$ (0.07)	\$ (0.34)
Weighted average shares used in computing basic and diluted net loss per common share	82,641	13,217

CONDENSED BALANCE SHEETS
(in thousands)
(unaudited)

	March 31,	December 31,
	2020	2019
Assets		
Cash and cash equivalents	\$ 8,038	\$ 5,223
Receivables	1,551	993
Inventory	1,064	998
Prepaid expenses and other current assets	1,493	1,094
Total current assets	12,146	8,308
Furniture and equipment, net	780	817

Operating lease right-of-use asset	336	397
Total assets	<u>\$ 13,262</u>	<u>\$ 9,522</u>
Liabilities and Stockholders' Equity		
Current liabilities	\$ 4,410	\$ 3,600
Operating lease liability, non-current	76	150
Long-term debt	3,500	4,019
Warrant liability	-	320
Stockholders' equity	<u>5,276</u>	<u>1,433</u>
Total liabilities and stockholders' equity	<u>\$ 13,262</u>	<u>\$ 9,522</u>

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