March 30, 2020

Titan Pharmaceuticals Reports Fourth Quarter And Full Year 2019 Financial Results

SOUTH SAN FRANCISCO, Calif., March 30, 2020 /PRNewswire/ -- Titan Pharmaceuticals, Inc. (NASDAQ: TTNP) ("Titan" or the "Company") today reported financial results for the fourth quarter and full year ended December 31, 2019 and provided an update on its business.

Full Year 2019 Business Highlights

- In early 2019, Titan reported completion of the initial activities planned for the reacquisition of Probuphine® (buprenorphine) implant, Titan's novel six-month maintenance treatment for opioid use disorder ("OUD") in eligible patients, from its former licensee. This included the recruitment and onboarding of a small number of highly qualified commercial and medical affairs personnel to reengage with health care providers who had previously treated patients with Probuphine, providing retraining and medical liaison assistance where needed, and assuring the medical community of the continued supply of the product with the goal to stabilize Probuphine usage.
- A key objective for Titan in the first half of 2019 was to improve the overall commercial services provided to the health care providers and patients through streamlining the product distribution and third party payor reimbursement process. This was accomplished through the following steps that were completed by August 2019:
    - Entering into an agreement with AppianRx to establish a new 'hub' that provides a full suite of patient and healthcare provider support services related to Probuphine, including an improved product ordering system and performing REMS required verification steps, and initial assessment of third party payor benefits available to the patient.
    - Establishing specialty pharmacy distribution and services agreements for Probuphine with a number of well recognized companies, including AllianceRx Walgreens Prime, Accredo® specialty pharmacy (a subsidiary of Express Scripts), CVS Caremark (a subsidiary of CVS Health) and Southside Specialty Pharmacy, with the goal to improve third party payor access and improve product

distribution.

- Also in the first half of 2019, Titan and Molteni & C. dei F.lli Alitti Società di Esercizio S.p.A. ("Molteni"), Titan's Probuphine partner for Europe and certain other territories, worked closely to meet with the Committee for Medicinal Products for Human Use of the European Medicines Agency and address all their questions regarding Sixmo®-buprenorphine (the brand name for Probuphine implant in the European Union) which led to the adoption of a positive opinion recommending the granting of a marketing authorization. Those efforts culminated in the European Commission approving Sixmo in June 2019 for substitution treatment for opioid dependence in clinically stable adult patients who require no more than 8 mg/day of sublingual buprenorphine, within a framework of medical, social and psychological treatment.
- While Titan successfully established the infrastructure to support Probuphine and began to stabilize revenues, it became clear that it was also necessary to expand the sales outreach to grow the business. Accordingly, in the second half of 2019 Titan completed two financing transactions (August and October 2019) that provided total net proceeds of approximately $9.9 million, after which the Company began the process to expand the sales and commercial team.
- Also, in the second half of 2019, the National Institutes of Health's National Institute on Drug Abuse ("NIDA") approved approximately $6.1 million in second-year funding for Titan's non-clinical development of a ProNeura™ based six-month implantable formulation of Nalmefene, an opioid antagonist, intended for the prevention of relapse to opioid addiction, following opioid detoxification.

Year-to-Date 2020 Business Highlights

- In January 2020, Titan completed an offering resulting in net cash proceeds of approximately $1.9 million.
- In January 2020, Titan signed an agreement for Probuphine to be included on the Federal Supply Schedule, providing U.S. veterans and other federal government agencies with access to Titan's novel six-month maintenance treatment for OUD in eligible patients.
- Since January 1, 2020, the Company has received proceeds of approximately $6.2 million as a result of the exercise of previously issued common stock purchase warrants.

"Throughout 2019, we focused on initiatives to successfully transition to a commercial-stage company," said Titan's President and CEO, Sunil Bhonsle. "I am very pleased with our team's progress during 2019, which, among other things, includes executing arrangements with multiple top tier specialty pharmacy companies, establishing a new patient services 'hub,' and obtaining insurance coverage from a broad range of third party payors – all of which served to broaden product access for healthcare providers and patients. While we primarily focused on stabilizing our product revenue during the transition, our goal during the remainder of 2020 is to focus on executing our sales growth initiatives in the U.S. and extending the commercial reach of Probuphine to eligible patients suffering from OUD."

Probuphine is indicated for the maintenance treatment of OUD in eligible patients. Please see Full Prescribing Information including Boxed Warning below.

"An important 2019 milestone for Titan was the European Commission's approval of Sixmo,

Probuphine's brand name in the EU," said Titan's Executive Chairman, Dr. Marc Rubin. "Our EU commercialization partner, Molteni, is located in Italy, one of the countries hit hardest by the global COVID-19 pandemic. While the launch of Sixmo may be delayed as a result, we are confident that Molteni is poised to aggressively roll-out the product across Europe once the situation allows."

Dr. Rubin continued, "As the developments involving the COVID-19 pandemic continue to evolve, we are monitoring and implementing recommendations from local, national and global health organizations. Titan's top priorities are the health and safety of our employees, customers and the communities in which we live and work. To that end, we have put proactive, precautionary measures in place, such as sheltering in place and working from home, freezing all non-essential travel, and we have pivoted to virtual sales and business meetings only, with the goal of keeping everyone safe. At the same time, we remain deeply committed to continuing to execute additional components of our growth plan throughout 2020. These include initiatives to increase awareness and adoption of Probuphine, advance our Nalmefene program toward the clinic, and explore opportunities for the use of our ProNeura platform technology in additional important medical applications. Everyone at Titan is working remotely and being productive. We sincerely hope that all of our stakeholders will be safe and healthy as well."

Fourth Quarter 2019 Financial Results

For the three months ended December 31, 2019, Titan reported approximately $1.2 million in revenue, which reflect approximately $0.2 million in product sales and approximately $1.0 million related to the Company's NIDA grant. This compared with revenues of approximately $1.2 million in the same period in 2018, which was comprised of $0.2 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 $0.7 million related to the NIDA grant.

Total operating expenses for the fourth quarter of 2019 were approximately $5.0 million, compared with approximately $4.5 million from the same quarter in 2018, 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 both the quarter ended December 31, 2019 and the same quarter in 2018 were approximately $1.9 million. SG&A expenses for the 2019 fourth quarter were approximately $2.6 million, compared with approximately $2.4 million in the same quarter a year ago. Costs of goods sold for the fourth quarter of 2019 were approximately $0.6 million, compared with approximately $0.3 million in the 2018 fourth quarter.

Net other expense, consisting primarily of interest expense, was approximately $0.1 million in the fourth quarter of 2019, compared with net other expense of approximately $0.2 million in the fourth quarter of 2018.

Net loss applicable to common stockholders in the fourth quarter of 2019 was approximately $4.0 million, or approximately $0.08 per share, compared with a net loss applicable to common stockholders of approximately $3.5 million, or approximately $0.29 per share, in the same quarter in 2018.

Full Year 2019 Financial Results

Total revenues for the full year ended December 31, 2019 were approximately $3.6 million, reflecting approximately $0.3 million in license revenue, approximately $1.0 million from sales of Probuphine and approximately $2.3 million related to Titan's NIDA grant. This compares to total revenues of approximately $6.6 million in 2018 which included approximately $5.4 million in license revenue, approximately $0.5 million from sales of Probuphine and approximately $0.7 million related to Titan's NIDA grant. The approximately $3.0 million decrease resulted primarily from non-recurring license revenue in 2018 of approximately $3.2 million in upfront and milestone payments from Molteni, and approximately $2.1 million related to reacquiring the rights to Probuphine from our former licensee which was partially offset by increases in product revenue of approximately $0.5 million, and grant revenues of approximately $1.6 million in 2019 and approximately $0.3 million of license revenue which represented the remaining amortization of the Molteni upfront payment in 2019.

Total operating expenses in 2019 were approximately $20.5 million, compared with approximately $14.9 million in 2018, and consisted primarily of R&D and SG&A expenses. R&D expenses for the year ended December 31, 2019 were approximately $7.3 million compared to approximately $7.5 million in 2018. The decrease in R&D costs was primarily associated with decreases in employee-related expenses and other research and development expenses, partially offset by increased activities related to the NIDA grant and an increase in our contract manufacturing costs. SG&A expenses for 2019 were approximately $11.9 million, compared to approximately $6.9 million in 2018. The increase in SG&A expenses was primarily due to higher sales and marketing expenses related to establishing the infrastructure to streamline the Probuphine ordering and distribution network and the increased expenses associated with expanding Titan's Probuphine commercial activities.

Net other income for the year ended December 31, 2019 was approximately $0.4 million, compared to net other expense of approximately $0.8 million in 2018. Net other income in 2019 was primarily due to non-cash gain on changes in the fair value of warrants. Net other expense in 2018 was primarily due to interest expense on the Company's debt.

Net loss applicable to common stockholders for 2019 was approximately $16.5 million, or $0.72 per share, compared with net loss applicable to common stockholders of approximately $9.3 million, or $1.64 per share, for 2018.

As at December 31, 2019, Titan had cash and cash equivalents of approximately $5.2 million, which the Company believes, together with the net cash proceeds of approximately $8.0 million received from the January 2020 offering and exercises of warrants in the first quarter of 2020, are sufficient to fund planned operations into the fourth quarter of 2020.

Conference Call Details

Titan management will host a conference call today at 4:30 p.m. ET / 1:30 p.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; Dane Hallberg, Executive Vice President and Chief Commercial 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 2248161. 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 December 31,		Year Ended December 31,	
	2019	**2018**	**2019**	**2018**
Revenue:				

License revenue	$ 2	$ 313	$ 315	$ 5,376
Product revenue	195	217	1,006	535
Grant revenue	1,020	707	2,290	707
Total revenue	1,217	1,237	3,611	6,618
Operating expense:				
Cost of goods sold	550	290	1,288	538
Research and development	1,872	1,855	7,242	7,478
Selling, general and administrative	2,589	2,358	11,925	6,866
Total operating expense	5,011	4,503	20,455	14,882
Loss from operations	(3,794)	(3,266)	(16,844)	(8,264)
Other income (expense), net	(147)	(238)	386	(759)
Net loss and comprehensive loss	$ (3,941)	$ (3,504)	$ (16,458)	$ (9,023)
Deemed dividend on trigger of down round provision	-	-	-	(285)
Net loss attributable to common stockholders	$ (3,941)	$ (3,504)	$ (16,458)	$ (9,308)
Basic net loss per share	$ (0.08)	$ (0.29)	$ (0.72)	$ (1.64)
Diluted net loss per share	$ (0.08)	$ (0.29)	$ (0.72)	$ (1.66)
Weighted average shares used in computing basic net loss per share	49,206	11,960	22,957	5,688
Weighted average shares used in computing diluted net loss per share	49,206	11,960	22,957	5,688

* Adjusted to reflect the impact of the 1:6 reverse split effective January 24, 2019.

CONDENSED BALANCE SHEETS
(in thousands)
(unaudited)

	December 31, 2019	December 31, 2018
Assets		
Cash and cash equivalents	$ 5,223	$ 9,295
Restricted cash	-	361
Receivables	993	1,737
Inventory	998	1,262
Contract assets	-	99
Prepaid expenses and other current assets	1,094	547
Total current assets	8,308	13,301
Property and equipment, net	817	794
Operating lease right-of-use asset	397	-

Total assets	$ 9,522	$ 14,095
Liabilities and Stockholders' Equity		
Current liabilities	$ 3,600	$ 3,452
Long-term debt	4,019	3,787
Warrant liability	320	-
Derivative liability	-	25
Operating lease liability, non-current	150	-
Stockholders' equity	1,433	6,831
Total liabilities and stockholders' equity	$ 9,522	$ 14,095

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