November 14, 2019

Titan Pharmaceuticals Reports Third Quarter 2019 Financial Results

SOUTH SAN FRANCISCO, Calif., Nov. 14, 2019 /PRNewswire/ -- Titan Pharmaceuticals, Inc. (NASDAQ: TTNP) today reported financial results for the third quarter ended September 30, 2019 and provided an update on its business.

Third Quarter 2019 and Recent Business Highlights

- In July 2019, Titan announced a specialty product distribution agreement for Probuphine® (buprenorphine) implants with CVS Caremark, a subsidiary of CVS Health.
- In August 2019, Titan completed a $2.1 million offering resulting in net cash proceeds of approximately $1.8 million.
- In September, 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.
- In October 2019, Titan announced that Crossroads of Southern Nevada rehabilitation facility began offering Probuphine for use in eligible patients with Opioid Use Disorder ("OUD").
- In October 2019, Titan completed a $9.1 million offering resulting in net cash proceeds of approximately $8.1 million.
- In October 2019, Titan presented two posters on its Probuphine implant at the 10th American Conference on Pharmacometrics.

"This quarter, we continued to make important progress on the commercial activities for Probuphine by expanding the specialty product distribution network and implementing the patient portal to enhance the capabilities of the product order processing hub," said Titan's President and CEO, Sunil Bhonsle. "We have also been engaged in addressing the company's capital needs and raised gross proceeds of approximately $11.2 million from two financings, which enables us to expand our commercial efforts in select market segments,

including potential partnering with other companies if possible."

Probuphine is indicated for the maintenance treatment of opioid dependence in eligible patients. Please see full indication below.

Titan's Executive Chairman, Dr. Marc Rubin, commented, "While our recent financing has provided the requisite resources to execute additional components of our growth plan, we are also continuing to opportunistically improve our overall cost structure in order to further extend our cash runway. The recent receipt of a second year of NIDA funding for our Nalmefene program was a very positive development, as it enables us to progress the program toward the clinic while continuing to focus our resources on the achievement of commercial success with Probuphine. Also, in collaboration with other companies or institutions, we are exploring opportunities for the use of our ProNeura platform technology in additional important medical applications, including chronic pain and malaria prophylaxis, and just starting a non-clinical feasibility study to evaluate the long-term delivery of CBD."

Third Quarter 2019 Financial Results

For the three months ended September 30, 2019, Titan reported approximately $0.9 million in total revenues, which reflect approximately $0.2 million in product revenues and approximately $0.8 million of grant revenues. This compared with total revenues of approximately $1.7 million in the same period in 2018. The decrease was primarily related to one-time payments in 2018 from license agreements associated with Probuphine, which were partially offset by 2019 grant revenue.

Total operating expenses for the third quarter of 2019 were approximately $4.8 million, compared with approximately $3.6 million in 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 the third quarter of 2019 were approximately $1.6 million, compared with approximately $1.9 million in the same quarter in 2018. The decrease was primarily due to approximately $0.6 million of lower R&D expenses related to Probuphine and approximately $0.2 million of lower expenses related to employee compensation; partially offset by approximately $0.5 million of higher R&D expenses related to the Nalmefene product development program, which were partially reimbursed under the NIDA grant.

SG&A expenses for the 2019 third quarter were approximately $3.0 million, compared with approximately $1.5 million in the same quarter a year ago. The increase in SG&A expenses for the three months ended September 30, 2019 was primarily attributable to increases in employee-related expenses of approximately $0.5 million, expenses related to consulting, professional and outside services of approximately $0.8 million and expenses related to facilities and travel of approximately $0.2 million.

Costs of goods sold, which reflects product costs and other distribution expenses associated with sales of Probuphine, were approximately $0.2 million for both quarters ended September 30, 2019 and 2018.

Net other income was approximately $1.1 million for the three month period ended September 30, 2019, compared with net other expense of approximately $0.1 million in the

same quarter a year ago. The increase was primarily attributable to an approximately $1.0 million non-cash gain on changes in the fair value of warrants issued in connection with the August 2019 offering and an approximately $0.3 million non-cash gain on debt extinguishment associated with the modification of the Molteni convertible loan.

Net loss applicable to common shareholders in the third quarter of 2019 was approximately $2.8 million, or approximately $0.18 per share, compared with a net loss applicable to common shareholders of approximately $2.3 million, or approximately $0.64 per share, in the same quarter in 2018.

As of September 30, 2019, Titan had cash and cash equivalents of approximately $0.9 million. Titan believes that its cash and cash equivalents as of September 30, 2019, along with the approximately $8.1 million of net cash proceeds from the public offering completed in October 2019, will be sufficient to fund its operations into the third quarter of 2020.

Conference Call Details

Titan management will host a conference call today at 4:30 p.m. ET 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 9174896. 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 September 30,		Nine Months Ended September 30,	
	2019	**2018**	**2019**	**2018**
Revenue:				
License revenue	$ -	$ 1,406	$ 313	$ 5,063
Product revenue	190	244	811	318
Grant revenue	757	-	1,270	-
Total revenue	947	1,650	2,394	5,381
Operating expense:				
Cost of goods sold	188	178	738	248
Research and development	1,619	1,910	5,370	5,623
Selling, general and administrative	3,023	1,514	9,336	4,508
Total operating expense	4,830	3,602	15,444	10,379
Loss from operations	(3,883)	(1,952)	(13,050)	(4,998)
Other income (expense), net	1,080	(93)	533	(521)
Net loss and comprehensive loss	$ (2,803)	$(2,045)	$ (12,517)	$ (5,519)
Deemed dividend on trigger of down round provision	-	(285)	-	(285)
Net loss attributable to common stockholders	(2,803)	(2,330)	(12,517)	(5,804)
Basic net loss per common share	$ (0.18)	$ (0.64)	$ (0.89)	$ (1.62)
Diluted net loss per common share	$ (0.18)	$ (0.68)	$ (0.89)	$ (1.66)

Weighted average shares used in computing basic and diluted net loss per share	15,517	3,650	14,112	3,573

CONDENSED BALANCE SHEETS
(in thousands)
(unaudited)

	September 30, 2019	December 31, 2018
Assets		
Cash and cash equivalents	$ 921	$ 9,295
Restricted cash	-	361
Receivables	775	1,737
Inventory	1,309	1,262
Contract assets	-	99
Prepaid expenses and other current assets	941	547
Total current assets	3,946	13,301
Property and equipment, net	752	794
Operating lease right-of-use asset	456	-
Deferred offering costs	150	-
Total assets	$ 5,304	$14,095
Liabilities and Stockholders' Equity (Deficit)		
Current liabilities	$ 3,482	$ 3,452
Operating lease liability, non-current	222	-
Long-term debt, non-current	3,872	3,787
Warrant liability	388	-
Derivative liability	-	25
Stockholders' equity (deficit)	(2,660)	6,831
Total liabilities and stockholders' equity (deficit)	$ 5,304	$14,095

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