May 15, 2019

Titan Pharmaceuticals Reports First Quarter 2019 Financial Results

SOUTH SAN FRANCISCO, Calif., May 15, 2019 /PRNewswire/ -- Titan Pharmaceuticals, Inc. (NASDAQ: TTNP) today reported financial results for the first quarter ended March 31, 2019 and provided an update on its business.

First Quarter 2019 and Recent Business Highlights

- In January 2019, Titan provided an update on its commercial activities, including positive initial results of the U.S. relaunch of Probuphine® (buprenorphine) implant, Titan's unique six-month maintenance treatment for opioid use disorder (OUD) in eligible patients.
- In February 2019, Titan executed a specialty pharmacy distribution and services agreement for Probuphine with AllianceRx Walgreens Prime. In March 2019, Walgreens placed a material bulk order to stock its specialty pharmacies in five key geographies to meet anticipated product demand, revenues from which will continue to be recognized over future quarters, in accordance with U.S. GAAP.
- In March 2019, Titan announced an agreement with AppianRx establishing a new 'hub' that provides a full suite of patient and healthcare provider support services related to Probuphine.
- In April 2019, Titan and Molteni & C. dei F.lli Alitti Società di Esercizio S.p.A. ("Molteni") announced that the Committee for Medicinal Products for Human Use ("CHMP") of the European Medicines Agency adopted a positive opinion recommending the granting of a marketing authorization for Sixmo, the brand name for Probuphine implant in the European Union. The European Commission is expected to issue its decision toward the end of June 2019.
- In May 2019, Titan announced a product purchase and supply agreement for Probuphine with Accredo® specialty pharmacy, a subsidiary of Express Scripts.

"We have made important progress on our Probuphine commercialization strategy since the beginning of 2019," said Titan's President and CEO, Sunil Bhonsle. "We significantly expanded our specialty pharmacy network by bringing on board two nationally-recognized

specialty pharmacies Alliance Rx Walgreens Prime and Accredo, and established AppianRx as the 'hub' that will streamline Probuphine's supply chain process. These new partnerships will improve access to long-term maintenance treatment with Probuphine for eligible patients and facilitate more efficient interactions among specialty pharmacies, physicians and payors. We have also made good progress in early-stage product development funded through grants from the National Institutes of Health and others, and continue to explore opportunities to expand the use of our ProNeura™ technology through more partnerships."

Titan's Executive Chairman, Dr. Marc Rubin, commented, "In addition to expanding our specialty pharmacy network and enhancing patient support services, we have continued to increase awareness of Probuphine by exhibiting at the American Society of Addiction Medicine annual meeting in April, and have expanded our base of healthcare providers who can provide treatment with Probuphine. We are pleased with the CHMP's adoption of a positive opinion regarding Sixmo in Europe. We look forward to the European Commission's final decision, and to supporting our partner, Motleni, as it prepares to launch Sixmo in the world's second largest market for buprenorphine-based products."

First Quarter 2019 Financial Results

For the three months ended March 31, 2019, Titan reported approximately $0.9 million in revenues, which reflect approximately $0.3 million in product revenues, representing a growth of approximately 46% sequentially over the prior quarter, $0.3 million of grant revenues and $0.3 million of amortization of deferred revenue from the sale of European intellectual property rights for Probuphine to Molteni. This compared with revenues of approximately $1.1 million in the same period in 2018, which were primarily related to the up-front payment from the sale of Titan's European intellectual property rights for Probuphine to Molteni.

Total operating expenses for the first quarter of 2019 were approximately $5.2 million, compared with approximately $3.5 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 quarter ended March 31, 2019 were approximately $1.8 million, compared with approximately $1.9 million for the same quarter in 2018. SG&A expenses for the 2019 first quarter were approximately $3.1 million and included approximately $1.7 million associated with sales and marketing and approximately $1.4 of general administrative expenses, compared with approximately $1.6 million in the same quarter a year ago which were essentially general and administrative expenses. Costs of goods sold, which reflects product costs and other distribution expenses associated with sales of Probuphine, were approximately $0.3 million for the first quarter of 2019. Titan did not have cost of goods sold for the three months ended March 31, 2018.

Net other expense was approximately $0.2 million for the three month periods ended March 31, 2019 and 2018, primarily attributable to interest expense on outstanding loans.

Net loss applicable to common shareholders in the first quarter of 2019 was approximately $4.5 million, or approximately $0.34 per share, compared with a net loss applicable to common shareholders of approximately $2.6 million, or approximately $0.74 per share, in the same quarter in 2018.

As of March 31, 2019, Titan had cash and cash equivalents of approximately $5.9 million.

Conference Call Details

Titan management will host a conference call today at 4:30 p.m. EDT today 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 1059834. 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 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 transmucosal buprenorphine-containing product.

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

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 and to your lung, and could lead to death.
- Implant sticks out of the skin (protrusion)
- Implant comes out by itself (expulsion)

Contraindications
Hypersensitivity to buprenorphine or any other ingredients in PROBUPHINE (e.g., EVA).

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

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 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.

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**.

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, 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,	
	2019	**2018**
Revenue:		
License revenue	$ 313	$ 1,064
Product revenue	317	-

Grant revenue	315	-
Total revenue	945	1,064
Operating expense:		
Cost of goods sold	304	-
Research and development	1,844	1,856
Selling, general and administrative	3,082	1,615
Total operating expense	5,230	3,471
Loss from operations	(4,285)	(2,407)
Other income (expense), net	(232)	(198)
Net loss and comprehensive loss	$ (4,517)	$ (2,605)
Basic and diluted net loss per common share	$ (0.34)	$ (0.74)
Weighted average shares used in computing basic and diluted net loss per common share	13,217	3,534

CONDENSED BALANCE SHEETS
(in thousands)
(unaudited)

	March 31, 2019	December 31, 2018
Assets		
Cash and cash equivalents	$ 5,909	$ 9,295
Restricted cash	-	361
Receivables	2,052	1,737
Inventory	1,246	1,262
Contract assets	-	99
Prepaid expenses and other current assets	882	547
Total current assets	10,089	13,301
Furniture and equipment, net	782	794
Operating lease right-of-use asset	569	-
Total assets	$ 11,440	$ 14,095
Liabilities and Stockholders' Equity		
Current liabilities	$ 4,761	$ 3,452
Operating lease liability, non-current	357	-
Long-term debt	3,242	3,787
Derivative liability	25	25
Stockholders' equity	3,055	6,831
Total liabilities and stockholders' equity	$ 11,440	$ 14,095

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