August 14, 2019

Titan Pharmaceuticals Reports Second Quarter 2019 Financial Results

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

Second Quarter 2019 and Recent Business Highlights

- In May 2019, Titan announced a product purchase and supply agreement for Probuphine® (buprenorphine) with Accredo® specialty pharmacy, a subsidiary of Express Scripts.
- In June 2019, Titan announced a pharmacy services agreement for Probuphine with Southside Specialty Pharmacy.
- In June 2019, Titan and Molteni & C. dei F.lli Alitti Società di Esercizio S.p.A. ("Molteni") announced that the European Commission approved Sixmo®-buprenorphine, the brand name for Probuphine implant in the European Union ("EU").
- In July 2019, Titan announced a specialty product distribution agreement for Probuphine with CVS Caremark, a subsidiary of CVS Health.
- In August 2019, Titan completed a $2.1 million offering resulting in net proceeds of approximately $1.8 million.

"During the second quarter, we continued to build on the foundation required to transition from a small product development company to a successful commercial enterprise. We now have a new user-friendly hub for processing Probuphine prescriptions and product orders, as well as a wider and more streamlined distribution network to support the commercialization of the product, all of which are essential for achieving commercial success," said Titan's President and CEO, Sunil Bhonsle. "The global footprint of Probuphine expanded when Titan and our partner, Molteni, achieved a major milestone in June with the approval in the EU of Sixmo. We hope to see operational and commercial synergies as we continue supporting Molteni in preparation for Sixmo's progressive launch across the world's second largest market for buprenorphine-based products, and look forward to initiating product shipments to Molteni by the end of this year."

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, "In addition to obtaining regulatory approval in a third major market, we are working hard to continue building our commercial capabilities. We are seeing an increase in Probuphine prescribers which we believe, when combined with our improved capabilities, will translate to product growth. Moving forward, with sufficient resources, we can expect to see this progress to be increasingly reflected in our financial results."

Second Quarter 2019 Financial Results

For the three months ended June 30, 2019, Titan reported approximately $0.5 million in revenues, which reflect approximately $0.3 million in product revenues and $0.2 million of grant revenues. This compared with revenues of approximately $2.7 million in the same period in 2018, which were primarily related to license revenues from the sale of European intellectual property rights to Molteni; and the return of the Braeburn license and earned royalties.

Total operating expenses for the second quarter of 2019 were approximately $5.4 million, compared with approximately $3.3 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 both the quarters ended June 30, 2019 and June 30, 2018 were approximately $1.9 million. SG&A expenses for the 2019 second quarter were approximately $3.2 million, compared with approximately $1.4 million in the same quarter a year ago. The increase in SG&A expenses for the three months ended June 30, 2019 was primarily due to expenses associated with the commercialization of Probuphine, which included increases in employee related expenses of approximately $0.8 million, consulting and professional fees of approximately $0.5 million, other outside services of approximately $0.3 million, travel related expenses of approximately $0.2 million and facilities related expenses of approximately $0.1 million. Costs of goods sold, which reflects product costs and other distribution expenses associated with sales of Probuphine, were approximately $0.2 million for the second quarter of 2019, compared with cost of goods sold of approximately $70,000 for the three months ended June 30, 2018.

Net other expense was approximately $0.3 million for the three month period ended June 30, 2019, compared with net other expense of approximately $0.2 million in the same quarter a year ago. The increase was primarily attributable to loss on debt extinguishment associated with the conversion of the Molteni convertible loan.

Net loss applicable to common shareholders in the second quarter of 2019 was approximately $5.2 million, or approximately $0.38 per share, compared with a net loss applicable to common shareholders of approximately $0.9 million, or approximately $0.25 per share, in the same quarter in 2018.

As of June 30, 2019, Titan had cash and cash equivalents of approximately $2.3 million. Titan believes that its cash and cash equivalents as of June 30, 2019, along with the approximately $1.8 million of net proceeds from the registered direct offering and concurrent

private placement completed in August 2019, will be sufficient to fund its operation through October 2019.

Conference Call Details

Titan management will host a conference call today at 4:30 p.m. EDT to review these financial results and discuss business developments in the period. The conference call will be hosted by Sunil Bhonsle, President and CEO; 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 9110840. 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 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 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 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, 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,	
	2019	**2018**	**2019**	**2018**
Revenue:				
License revenue	$ -	$ 2,593	$ 313	$ 3,657
Product revenue	304	75	621	75
Grant revenue	198	-	513	-
Total revenue	502	2,668	1,447	3,732
Operating expense:				
Cost of goods sold	246	70	550	70
Research and development	1,907	1,857	3,751	3,713
Selling, general and administrative	3,231	1,380	6,313	2,995
Total operating expense	5,384	3,307	10,614	6,778
Loss from operations	(4,882)	(639)	(9,167)	(3,046)
Other income (expense), net	(315)	(230)	(547)	(428)
Net loss and comprehensive loss	$ (5,197)	$ (869)	$ (9,714)	$ (3,474)
Basic and diluted net loss per common share	$ (0.38)	$ (0.25)	$ (0.73)	$ (0.98)
Weighted average shares used in computing basic and diluted net loss per share	13,576	3,534	13,397	3,534

CONDENSED BALANCE SHEETS
(in thousands)
(unaudited)

	June 30, 2019	**December 31, 2018**
Assets		
Cash and cash equivalents	$ 2,292	$ 9,295
Restricted cash	-	361
Receivables	1,140	1,737
Inventory	1,317	1,262
Contract assets	-	99
Prepaid expenses and other current assets	744	547
Total current assets	5,493	13,301
Furniture and equipment, net	754	794
Operating lease right-of-use asset	514	-
Total assets	$ 6,761	$ 14,095
Liabilities and Stockholders' Equity (Deficit)		

Current liabilities	$ 4,342	$ 3,452
Operating lease liability, non-current	292	-
Long-term debt, non-current	2,698	3,787
Derivative liability	-	25
Stockholders' equity (deficit)	(571)	6,831
Total liabilities and stockholders' equity (deficit)	$ 6,761	$ 14,095

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