April 1, 2019

Titan Pharmaceuticals Reports Fourth Quarter And Full Year 2018 Financial Results

SOUTH SAN FRANCISCO, Calif., April 1, 2019 /PRNewswire/ -- Titan Pharmaceuticals, Inc. (NASDAQ: TTNP) today reported financial results for the fourth quarter and full year ended December 31, 2018 and provided an update on its business.

Full Year 2018 Business Highlights

- In February 2018, Titan entered into an amendment to the July 2017 loan agreement with Horizon Technology Finance Corporation ("Horizon"), and prepaid $3.0 million of the outstanding $7.0 million loan balance.
- In March 2018, Titan entered into a definitive asset purchase, supply and support agreement with Molteni & C. dei F.lli Alitti Società di Esercizio S.p.A. ("Molteni") where Molteni acquired the European intellectual property related to Probuphine® (buprenorphine) implant and the exclusive right to commercialize Probuphine in Europe, as well as certain other countries. Molteni also made an indirect strategic investment in Titan by purchasing $2.4 million of the outstanding $4.0 million principal balance owed under the July 2017 loan agreement with Horizon, and assumed majority and administrative control of the debt.
- In May 2018, Titan announced the appointment of accomplished global pharmaceuticals executive, Federico Seghi Recli, to its Board of Directors as the lead independent director.
- In May 2018, Titan and Braeburn Pharmaceuticals, Inc. ("Braeburn") reached an agreement pursuant to which Titan regained all rights to the commercialization and clinical development of Probuphine implant in the United States and Canada. As part of the agreement, Titan received $1 million, all of the Probuphine inventory, and a commitment from Braeburn to provide certain transition services through the end of 2018.
- In August 2018, Titan entered into an amendment of the previously announced definitive asset purchase, supply and support agreement with Molteni, and in

connection with the amendment received approximately $1.7 million, which includes a convertible note of approximately $0.6 million.
- In September 2018, Titan initiated a pilot program in collaboration with the Nevada Center for Behavioral Health to evaluate the potential of a medication-assisted treatment program utilizing the Probuphine implant within the State of Nevada criminal justice system.
- In September 2018, Titan was awarded a two-year grant of approximately $6.7 million from the National Institutes of Health's ("NIH") National Institute on Drug Abuse ("NIDA") for the development of a ProNeura-based six-month implantable formulation of the opioid antagonist, Nalmefene. The grant supports all the development work necessary to fulfill the requirements of an Investigational New Drug ("IND") application to the U.S. Food and Drug Administration ("FDA").
- In September 2018, Titan closed an underwritten public offering, which provided net proceeds of approximately $8.5 million. Additionally, in October and November 2018, Titan received approximately $4.5 million from the full exercise of the underwriters' over-allotment option and the exercise of 2,178,484 common stock purchase warrants issued in the financing.
- In October 2018, Titan announced the appointment of Dane D. Hallberg as Executive Vice President and Chief Commercial Officer, responsible for establishing and leading all of the company's commercial activities.
- In October 2018, Knight Therapeutics Inc., Titan's marketing partner for Probuphine in Canada, commenced its product launch.

Year-to-Date 2019 Business Highlights

- In January 2019, pursuant to stockholder authorization, Titan effected a 1-for-6 reverse stock split of the company's issued and outstanding shares of common stock, warrants and options.
- In January 2019, Titan provided an update on its commercial activities, including positive initial results of the Probuphine relaunch.
- In February 2019, Titan executed a specialty pharmacy distribution and services agreement for Probuphine with AllianceRx Walgreens Prime.
- In March 2019, Titan announced an agreement with AppianRx to provide a full suite of patient support services related to Probuphine. AppianRx is an Artificial Intelligence (AI) focused healthcare solutions company providing patient centric access, adherence, compliance and distribution services to biotech and pharmaceutical manufacturers.

"Since completing the important transaction with Molteni earlier in 2018, we have continued to support Probuphine's Marketing Authorization Application in the EU and hope to receive approval in the second quarter of this year," said Titan's President and CEO, Sunil Bhonsle. "The second half of 2018 was marked by Titan's rapid advancement toward becoming a commercial-stage company following its assumption of responsibility for Probuphine sales in the U.S. starting mid-June. Over the last few months we have established a strong foundation by implementing pharmaceutical best practices in regulatory compliance, medical affairs, training and certification; and assembling a small team whose responsibilities include regional sales oversight, medical science liaison services, strategic product and brand recognition development, and Risk Evaluation Mitigation Strategy program management. In 2019, our focus will be on the continued expansion of patient access to Probuphine in the

U.S., while supporting the efforts of our commercialization partners for the product in Canada and Europe."

"We are very pleased with the progress made throughout the initial stages of our Probuphine relaunch in the United States," said Titan's Executive Chairman, Dr. Marc Rubin. "We have identified the key market segments that can benefit from treatment with Probuphine and have addressed prior bottlenecks in fulfilling product orders in a number of ways. First, we expect improved product access for physicians and their patients through our alliance with AppianRx, the 'hub' for product ordering and benefits screening activities that will come on-line early in the second quarter. Second, we established a strategic partnership with AllianceRx Walgreens Specialty Pharmacy for improved medical access and efficient product delivery through its expansive network. We hope to see the fruits of these actions reflected in our financial results later this year. As we move forward, we remain confident that our strategy is working and that Probuphine is well-positioned for global success."

Fourth Quarter 2018 Financial Results

For the three months ended December 31, 2018, Titan reported approximately $1.2 million in revenue, compared with approximately $58,000 in the same period in 2017. Revenues for the fourth quarter of 2018 reflect approximately $0.2 million in product sales, approximately $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 approximately $0.7 million related to our NIDA grant.

Total operating expenses for the fourth quarter of 2018 were approximately $4.5 million, compared with approximately $3.4 million from the same quarter in 2017, 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 December 31, 2018 were approximately $1.9 million, compared with approximately $2.3 million for the same quarter in 2017. SG&A expenses for the 2018 fourth quarter were approximately $2.4 million, compared with approximately $1.1 million in the same quarter a year ago. Costs of goods sold for the fourth quarter of 2018 were approximately $0.3 million.

Net other expense, consisting primarily of interest expense, was approximately $0.2 million in the fourth quarter of 2018, compared with net other expense of approximately $0.3 million in the fourth quarter of 2017.

Net loss applicable to common shareholders in the fourth quarter of 2018 was approximately $3.5 million, or approximately $0.62 per share, compared with a net loss applicable to common shareholders of approximately $3.7 million, or approximately $1.04 per share, in the same quarter in 2017.

Full Year 2018 Financial Results

Total revenues for the full year ended December 31, 2018 were approximately $6.6 million, reflecting approximately $5.4 million in license revenue, approximately $0.5 million from sales of Probuphine after reacquiring the product in late May 2018 and approximately $0.7 million related to our NIDA grant. This compares to total revenues of approximately $0.2 million from royalties earned on net sales of Probuphine by Braeburn in 2017.

License revenues for the year ended December 31, 2018, consisted of approximately $2.1 million and $1.1 million related to the sale to Molteni of the European intellectual property rights to Probuphine and the amendment of the Molteni purchase agreement, respectively; approximately $2.1 million related to reacquiring the rights to Probuphine and termination of the Braeburn license; and approximately $32,000 related to the recognition of royalties earned on net sales of Probuphine by Braeburn prior to termination of the License Agreement in late May 2018.

Total operating expenses in 2018 were approximately $14.9 million, compared with $14.7 million in 2017, and consisted primarily of R&D and SG&A expenses. R&D expenses for the year ended December 31, 2018 were approximately $7.5 million compared to approximately $9.6 million in 2017. The decrease in R&D costs was primarily associated with decreases in external R&D expenses related to the support of ProNeura product development programs, employee related expenses and other R&D expenses. SG&A expenses for 2018 were approximately $6.9 million, compared to approximately $5.1 million in 2017. The increase in SG&A expenses was primarily from increases in expenses related to Probuphine commercial activities, offset in part by decreases in non-cash stock-based compensation of approximately $0.2 million.

Net other expense for the year ended December 31, 2018 was approximately $0.8 million, compared to net other income of approximately $0.2 million in 2017. Net other expense in 2018 consisted primarily of $0.1 million related to non-cash gains on changes in the fair value of derivatives offset by approximately $0.9 million consisting of interest and other expenses. Net other income in 2017 consisted primarily of $0.6 million related to non-cash gains on changes in the fair value of warrant liabilities offset by approximately $0.4 million consisting of interest and other expenses.

Net loss applicable to common stockholders for 2018 was approximately $9.3 million, or $0.78 per share, compared with net loss applicable to common stockholders of approximately $14.3 million, or $4.05 per share, for 2017.

As at December 31, 2018, Titan had cash and cash equivalents of approximately $9.3 million, which the company believes, along with the $0.6 million received from the subsequent exercise of warrants, are sufficient to fund planned operations through the third quarter of 2019.

Conference Call Scheduled April 2, 2019

Titan is pleased to invite all interested parties to participate in a conference call on April 2, 2019 at 8:30 a.m. ET / 5:30 a.m. PT, during which management will discuss the financial results and provide an update on Titan's corporate developments. The 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. To participate in this conference call, please dial 1-888-317-6003 (U.S.) or 1-412-317-6061 (international) approximately 10 minutes prior to the start time, and providing passcode 8939365.

Alternatively, a live webcast and replay of the call may accessed by visiting http://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 FDA approved Probuphine in May 2016, and it is the first and only buprenorphine implant available for the maintenance treatment of opioid addiction.

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.

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 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 see Full Prescribing Information, including **BOXED WARNING**.

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 commercialization and 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 December 31,		Year Ended December 31,	
	2018	**2017**	**2018**	**2017**
Revenue:				
License revenue	$ 313	$ 58	$ 5,376	$ 215
Product revenue	217	-	535	-
Grant revenue	707	-	707	-
Total revenue	1,237	58	6,618	215
Operating expense:				
Cost of goods sold	290	-	538	-
Research and development	1,855	2,307	7,478	9,648
Selling, general and administrative	2,358	1,125	6,866	5,069
Total operating expense	4,503	3,432	14,882	14,717
Loss from operations	(3,266)	(3,374)	(8,264)	(14,502)
Other income (expense), net	(238)	(286)	(759)	195
Net loss and comprehensive loss	$ (3,504)	$ (3,660)	$ (9,023)	$ (14,307)
Deemed dividend on trigger of down round provision	-	-	(285)	-
Net loss attributable to common stockholders	$ (3,504)	$ (3,660)	$ (9,308)	$ (14,307)

Basic net loss per share	$ (0.62)	$ (1.04)	$ (0.78)	$ (4.05)
Diluted net loss per share	$ (0.62)	$ (1.04)	$ (0.79)	$ (4.22)
Weighted average shares used in computing basic net loss per share	5,688	3,534	11,960	3,534
Weighted average shares used in computing diluted net loss per share	5,688	3,534	11,960	3,538

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

CONDENSED BALANCE SHEETS
(in thousands)
(unaudited)

	December 31, 2018	December 31, 2017
Assets		
Cash and cash equivalents	$ 9,295	$ 7,522
Restricted cash	361	361
Receivables	1,737	65
Inventory	1,262	-
Contract assets	99	-
Prepaid expenses and other current assets	547	362
Total current assets	13,301	8,310
Property and equipment, net	794	595
Total assets	$ 14,095	$ 8,905
Liabilities and Stockholders' Equity		
Current liabilities	$ 3,452	$ 4,464
Long-term debt	3,787	3,584
Derivative liability	25	-
Stockholders' equity	6,831	857
Total liabilities and stockholders' equity	$ 14,095	$ 8,905

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