UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of The Securities Exchange Act of 1934

Date of Report (Date of Earliest Event Reported): October 12, 2020

Titan Pharmaceuticals, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of incorporation)

001-13341	**94-3171940**
(Commission File Number)	(IRS Employer Identification No.)

400 Oyster Point Blvd., Suite 505, South San Francisco, CA 94080
(Address of principal executive offices and zip code)

650-244-4990
(Registrant's telephone number including area code)

(Registrant's former name or former address, if changed since last report)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol	Name of each exchange on which registered
Common Stock, $0.001 par value	TTNP	Nasdaq Capital Market

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12(b) under the Exchange Act (17 CFR 240.14a-12(b))

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 1.01. Entry into Material Definitive Agreement

Item 5.02. Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.

The information set forth in the third paragraph of Item 8.01 is incorporated by reference herein.

Item 8.01. Other Events

On October 15, 2020, Titan Pharmaceuticals, Inc. (the "Company" or "Titan") issued a press release announcing its decision to discontinue selling Probuphine® (buprenorphine) implant and wind down the Company's commercialization activities and pursue a plan that will enable it to focus on the Company's ProNeura-based product development efforts. The Company based its decision on several factors, most notably that commercializing Probuphine with the requirements of the current product label and the Risk Evaluation and Mitigation Strategy, or REMS, program has proven to be onerous. Other factors that have negatively impacted Titan's ability to effectively commercialize Probuphine include the financial constraints that have limited our sales and marketing capabilities; suboptimal reimbursement rates; and the complexity of the distribution channel. The complexity of the changing environment due to the COVID-19 pandemic has further exacerbated these issues. As a result, sales of Probuphine have been, and would likely continue for the foreseeable future to be, extremely limited. After careful review of the recent sales and marketing results, the hurdles that Titan has and will continue to face, and the substantial additional expenditures and resources that would be required, the board of directors determined to advise the U.S. Food and Drug Administration ("FDA") of its decision to cease commercialization of Probuphine. A wind-down plan taking into considerations FDA and state regulatory requirements, as well as business considerations is underway.

The Company also announced that it is in negotiations with L. Molteni & C. dei F.lli Alitti Società di Esercizio S.p.A. ("Molteni") and Horizon Credit II LLC, the holders of Titan's outstanding secured debt ($4.0 million principal amount and approximately $1.2 million in payoff amounts) to eliminate such obligations. The Company is seeking to settle the debt for cash payments, the transfer of certain Probuphine assets to Molteni and the termination of the Company's rights to future payments under the asset purchase and supply agreement with Molteni in exchange for the release to Titan of the remaining collateral. This would allow the Company to continue operating as a product development company, initially focused on its nalmefene implant for the prevention of opioid relapse following detoxification and a kappa opioid receptor agonist peptide implant for the treatment of pruritus.

Consummation of a debt settlement agreement and the continuation of any product development programs, however, are contingent upon Titan's ability to raise sufficient capital during the next few weeks and there can be no assurance that the required financing will be available on acceptable terms, if at all. If the Company is unable to complete a financing, it will not have sufficient funds to continue its operations.

As previously disclosed, Sunil Bhonsle, Titan's Chief Executive Officer, expressed his desire to retire prior to the end of the year. Accordingly, Mr. Bhonsle will retire from his position and Marc Rubin, the Company's Executive Chairman, and Kate DeVarney, the Company's Executive Vice President and Chief Scientific Officer and a member of the board of directors, will assume the roles of Chairman and Chief Executive Officer and President and Chief Operating Officer, respectively.

A copy of the press release issued on October 15, 2020 is attached hereto as Exhibit 99.1 and incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

The following exhibit is filed herewith:

Exhibit Number	Description
99.1	Press Release

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Dated: October 15, 2020

TITAN PHARMACEUTICALS, INC.

By: /s/ Sunil Bhonsle
Name: Sunil Bhonsle
Title: President and Chief Executive Officer

Titan Pharmaceuticals Provides a Strategic & Corporate Update

South San Francisco, CA – October 15, 2020 – Titan Pharmaceuticals, Inc. (NASDAQ:TTNP) ("Titan" or the "Company") today announced a strategic restructuring designed to position it for future growth. Specifically, the Company plans to:

- Restructure the Company to focus on ProNeura®-based product development, specifically a kappa opioid receptor agonist and nalmefene;
- Discontinue its U.S. Probuphine® (buprenorphine) implant sales and wind down Probuphine commercialization activities;
- Make strategic senior management changes;
- Substantially reduce its operating costs; and
- Complete negotiations with its lenders to eliminate outstanding debt.

Probuphine

Probuphine is the first product based on Titan's ProNeura technology approved in the U.S., Canada and the European Union ("EU") for the maintenance treatment of opioid use disorder ("OUD") in clinically stable patients taking 8 mg or less a day of oral buprenorphine.

Commercializing Probuphine with the requirements of the current product label, as well as the Risk Evaluation and Mitigation Strategy, or REMS, program has proven to be onerous. Other factors that have negatively impacted Titan's ability to effectively commercialize Probuphine include the financial constraints that have limited our sales and marketing capabilities; suboptimal reimbursement rates; and the complexity of the distribution channel. The complexity of the changing environment due to the COVID-19 pandemic has exacerbated these issues. As a result, sales of Probuphine have been, and would likely continue for the foreseeable future to be, extremely limited.

Accordingly, Titan's Board has determined to wind down its U.S. Probuphine business and redirect its focus and resources on its ProNeura-based product development efforts.

Key ProNeura-Based Product Development Programs

Kappa Opioid Receptor Agonist Peptide Implant

In October 2020, Titan entered into a non-binding term sheet with JT Pharma for the acquisition and development of JT-09 for use in combination with Titan's ProNeura technology. James McNab, a member of our board of directors, is a principal of JT Pharma. Several years ago, we began limited laboratory work in collaboration with JT Pharma to assess the feasibility of delivering JT-09 through ProNeura implants in animal models. Our initial work focused on JT-09's ability to activate peripheral kappa opioid receptors, with the JT-09 ProNeura implants potentially providing a non-addictive treatment for certain types of pain. Recently, we have begun exploring the feasibility of using JT-09 ProNeura implants in the treatment of pruritus. We believe, based on our early animal data, that subcutaneous administration of the JT-09 ProNeura implants could potentially deliver therapeutic concentrations of JT-09 for up to one year.

Cara Therapeutics Inc. (NASDAQ:CARA) has recently demonstrated in phase 2 and phase 3 clinical trials the efficacy of a selective kappa opioid receptor agonist peptide, CR845, in the treatment of pruritus associated with end-stage kidney disease.

Nalmefene Implant

In September 2019, the National Institute for Drug Addiction ("NIDA") awarded Titan approximately $8.7 million in a two-year grant for its nalmefene implant development program for the prevention of opioid relapse following detoxification. This grant provides funds for the completion of implant formulation development, cGMP manufacturing and non-clinical studies required for filing an Investigation New Drug ("IND") application.

During the first quarter of 2020, the Company met with the U.S. Food and Drug Administration ("FDA") to review Titan's non-clinical development plans and obtain guidance regarding filing an IND.

Titan has been making good progress with the IND-enabling non-clinical studies, which it expects to complete in mid-2021, followed by filing of the IND.

Strategic Management Changes

As disclosed in August 2020, Titan's President & CEO, Sunil Bhonsle, has expressed his desire to retire. Accordingly, the current Executive Chairman, Marc Rubin, M.D., will assume the position of Chairman and CEO, and its current Executive Vice President and Chief Scientific Officer, Kate Beebe DeVarney, Ph.D., will be appointed President and Chief Operating Officer.

Significant Reduction in Operating Costs and Negotiations to Eliminate Debt

While there will be costs in the near term associated with the wind down of commercial operations and Titan's transition back to a development stage company, the change is expected to result in a lower operating cash burn moving forward. Also, in support of its efforts to continue as a research and development company, Titan is in negotiations to eliminate its outstanding debt, which is secured by a lien on all of its assets. There can be no assurance regarding the timing or outcome of these efforts, all of which will depend on the Company's ability to raise additional capital.

Comments from Management

"Marketing of Probuphine in the U.S. has used considerable resources over the past two years and would continue to require additional investments for meaningful growth," commented Dr. Rubin. "After careful review of the recent sales and marketing results, we recognize the improbability of near-term indicators of material revenue growth for Probuphine. Accordingly, we have decided to discontinue sales and wind down commercialization activities for Probuphine. Our plan is to focus on our ProNeura-based product development programs. Of course, we are also open to evaluating reasonable offers, if any, that we receive from interested third-parties to continue making Probuphine commercially available in the U.S."

Commenting on the management changes announced today, Dr. Rubin said, “On behalf of everyone at Titan, I would like to thank Sunil for his many contributions over the years and wish him well in his retirement. At the same time, I am excited that Kate has agreed to take on an expanded role as President and Chief Operating Officer. Kate’s long-standing leadership across multiple functional areas of the company has been greatly valued, and I believe she is exceptionally well qualified to lead Titan’s overall operations.”

“While I am deeply disappointed that we can no longer support the commercialization of Probuphine, I look forward to working with Marc and the Titan team to strategically advance the ProNeura delivery platform across key development programs, specifically our NIDA-funded nalmefene implant program for OUD and our newly acquired kappa opioid agonist peptide for the treatment of pruritus,” said Dr. DeVarney. “I have greatly enjoyed working with Sunil over the past 14 years and wish him all the best in his well-earned retirement.”

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 visitwww.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 ProNeura technology has the potential to be used in developing products for treating a number of chronic conditions, 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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