

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): June 23, 2020

Titan Pharmaceuticals, Inc.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of incorporation)

001-13341

(Commission File Number)

94-3171940

(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))

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

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

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 a Material Definitive Agreement.

On June 23, 2020, Titan Pharmaceuticals, Inc. (the “Company” or “Titan”) entered into an Agreement for Co-Promotion Partnership (the “Agreement”) with Indegene, Inc., a leading healthcare solutions company (“Indegene”), to establish multichannel digital marketing programs throughout the United States and expand the capabilities for the engagement of health care providers (“HCPs”) who are eligible to prescribe Titan’s Probuphine® (buprenorphine) implant to appropriate patients suffering from Opioid Use Disorder, or OUD.

Under the terms of the four-year Agreement, Indegene’s sophisticated multichannel marketing tools, predictive analytics, webinars and social media campaigns will be used along with its dedicated tele-representatives to help expand the universe of Probuphine Risk Evaluation and Mitigation Strategy (“REMS”)-certified HCPs and enable further expansion of maintenance treatment with Probuphine for appropriate OUD patients. The Company will continue its ongoing commercial efforts with its field sales and medical liaison personnel who will also provide support to Indegene as needed. Titan will be responsible for all training of HCPs, administration of the REMS program and regulatory affairs.

A copy of the press release issued on June 24, 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: June 25, 2020

TITAN PHARMACEUTICALS, INC.

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



TITAN PHARMACEUTICALS AND INDEGENE ENTER INTO PROBUPHINE® CO-PROMOTION PARTNERSHIP

SOUTH SAN FRANCISCO, CA – June 24, 2020 – Titan Pharmaceuticals, Inc. (NASDAQ: TTNP) (“Titan” or the “Company”) today announced that it has entered into a co-promotion partnership with Indegene Inc. to establish multichannel digital marketing programs throughout the United States and expand the capabilities for the engagement of health care providers (“HCPs”) who are eligible to prescribe Titan’s Probuphine® (buprenorphine) implant.

Indegene is a leading healthcare solutions company with a unique blend of life sciences domain expertise and state-of-the-art technology capabilities that will complement and help accelerate the build out of the current commercial operations at Titan. Under the terms of the renewable four-year agreement, Indegene's sophisticated multichannel marketing tools, predictive analytics, webinars and social media campaigns will be used along with its dedicated tele-representatives to help expand the universe of Probuphine Risk Evaluation and Mitigation Strategy (“REMS”)-certified HCPs and enable further expansion of maintenance treatment with Probuphine for eligible Opioid Use Disorder (“OUD”) patients. Titan will continue its ongoing commercial efforts with its field sales and medical liaison personnel who will also provide support to Indegene as needed. Titan will be responsible for all training of HCPs, administration of the REMS program and regulatory affairs.

“This partnership with Indegene further strengthens and expands our Probuphine commercial operations, especially with the COVID-19-related restrictions that have limited in-person HCP outreach capabilities,” said Titan's President and CEO, Sunil Bhonsle. “Indegene brings a wealth of business expertise and experience in the digital arena working globally with large and small pharmaceutical companies that is invaluable in today’s changing environment. This partnership accelerates the expansion of our capabilities to potentially achieve our goals and enable access to Probuphine for eligible patients suffering from OUD, especially at a time when a six-month maintenance treatment option could be very important in minimizing frequent direct contact.”

Please see Probuphine Full Indication and Important Safety Information and Boxed Warning below, and link below to Full Prescribing Information.

“We are looking forward to partnering with Titan using our proven AI-driven Next Generation Commercialization Platform,” said Gaurav Kapoor, Executive Vice President of Indegene Inc. “This partnership comes at a meaningful time, when the COVID-19 pandemic is exacerbating the opioid crisis while limiting direct engagement with the HCPs that treat OUD patients. I believe the ‘new normal’ model in pharma commercial operations will start relying just as much on digital programs with remote representatives, as field representatives providing face-to-face interaction. We at Indegene are making significant investments to be at the forefront of this transition and are excited to see Titan embrace this innovative approach.”

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.

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 Indegene, Inc.

Indegene is a leading global healthcare solutions company that enables healthcare organizations address complex challenges to improve health and business outcomes. Indegene helps drive effectiveness and efficiency while bringing pharma products to market through modern commercial and medical operations by combining deep medical understanding, modern technology, and flexible engagement models. Indegene has a global footprint with offices in North America, Europe, China and India.

About Titan Pharmaceuticals

Titan Pharmaceuticals, Inc. (NASDAQ:TTNP), based in South San Francisco, CA, is a commercial stage company developing proprietary therapeutics with its ProNeur® 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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