

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): February 1, 2021

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))

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 8.01. Other Events.

On February 1, 2021, Titan Pharmaceuticals, Inc. (the "Company") issued a press release announcing that studies of its kappa opioid agonist peptide, JT-09, has demonstrated high potency and specificity for the human kappa-opioid receptor. JT-09 is being developed for use in combination with the Company's ProNeura® long-term, continuous drug delivery technology for the treatment of moderate-to-severe chronic pruritus (itch). A copy of the press release 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:

| <u>Exhibit Number</u> | <u>Description</u> |
|-----------------------|-------------------------------|
| 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: February 4, 2021

TITAN PHARMACEUTICALS, INC.

By: /s/ Kate Beebe Devarney, Ph.D.

Name: Kate Beebe Devarney, Ph.D.

Title: President and Chief Operating Officer



Positive Early Study Results Help Pave Wave for Titan Pharmaceuticals to Move Forward with its JT-09 ProNeura® Development Program

South San Francisco, CA – February 1, 2021 – Titan Pharmaceuticals, Inc. (NASDAQ: TTNP) today announced that studies of its kappa opioid agonist peptide, JT-09, has demonstrated high potency and specificity for the human kappa-opioid receptor (“KOR”). JT-09 is being developed for use in combination with Titan’s ProNeura® long-term, continuous drug delivery technology for the treatment of moderate-to-severe chronic pruritus (itch).

The KOR potency studies used the cAMP Hunter™ assay with cloned human mu, delta and kappa opioid receptors. In addition, in studies conducted in collaboration with Charles Chavkin, Ph.D., Allan and Phyllis Treuer Endowed Chair of Pain Research and Professor, Department of Pharmacology, at the University of Washington Health Sciences Center, Seattle, WA, pretreatment with JT-09 or with difelikefalin (which is being developed as Korsuva™ by Cara Therapeutics, Inc.) were observed to be equally potent in reducing scratching and grooming bouts when injected subcutaneously (0.3 mg/kg) in a 5'-guanidinonaltrindole (5'-GNTI) itch-induced mouse model.

"Pilot pharmacokinetic studies in rats previously indicated that subcutaneous placement of ProNeura implants containing JT-09 could deliver potentially therapeutic concentrations of this KOR agonist for up to six months or longer," said Kate Beebe DeVarney, Ph.D., President and Chief Operating Officer of Titan.

Dr. Beebe DeVarney continued, "These additional early positive data provide strong support for us to move forward with our planned non-clinical proof-of-concept study of JT-09 ProNeura implants in this animal itch model. This is an important next step for Titan towards developing a new treatment modality for moderate-to-severe chronic pruritus that is effective, patient-friendly and convenient."

About Chronic Pruritus

Chronic pruritus is an unpleasant sensation resulting in a need to scratch that lasts more than 6 weeks. It is a prevalent and bothersome symptom associated with both cutaneous and systemic conditions. Due to its complex pathogenesis and numerous contributing factors, effective treatment of chronic pruritus therapy remains challenging.

About Titan Pharmaceuticals

Titan Pharmaceuticals, Inc. (NASDAQ: TTNP) is a development-stage biotechnology company developing proprietary therapeutics using its clinically proven 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 our ability to raise capital, the winding down of U.S. commercial activities related to 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.

Korsuva is a trademark of Cara Therapeutics, Inc.

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