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): November 8, 2021

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)

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 7.01. Regulation FD Disclosure

On November 8, 2021, Titan Pharmaceuticals, Inc. (the "Company") announced that additional positive data from an ongoing *in vivo* study of its human kappa-opioid receptor agonist ("TP-2021") ProNeura®-based implant in an established 5'-guanidinonaltrindole (5'-GNTI) itch-induced mouse model had been reported in a presentation given earlier in the day at the Society for Neuroscience 2021 Meeting.

A copy of the slide presentation, which will be posted on the Company's website, is attached hereto as Exhibit 99.1 and incorporated herein by reference. The presentation is being furnished pursuant to Item 7.01 of this Current Report and shall not be deemed "filed" for the purposes of Section 18 of the Securities and Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that Section. This information shall not be incorporated by reference into any registration statement pursuant to the Securities Act of 1933, as amended.

Item 8.01. Other Events.

On November 8, 2021, the Company announced the presentation of data from an ongoing *in vivo* study of its TP-2021 ProNeura®-based implant. A copy of the press release is attached hereto as Exhibit 99.2 and incorporated by reference herein.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

The following exhibit is filed herewith:

Exhibit Number	Description
99.1	Presentation at the Society of Neuroscience
99.2	Press release

104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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: November 9, 2021

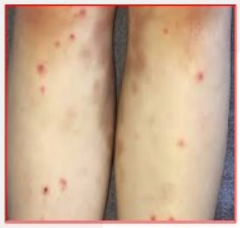
TITAN PHARMACEUTICALS, INC.

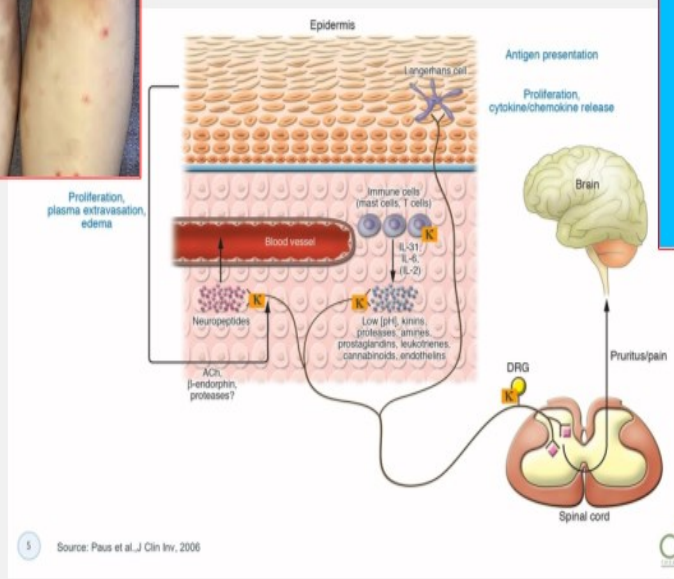
By: /s/ Kate Beebe DeVarney, Ph.D.
Name: Kate Beebe DeVarney, Ph.D.
Title: President and Chief Operating Officer

Sustained anti-pruritic effect in mice with TP-2021, a kappa opioid agonist peptide, delivered by subdermal ProNeura® Implants

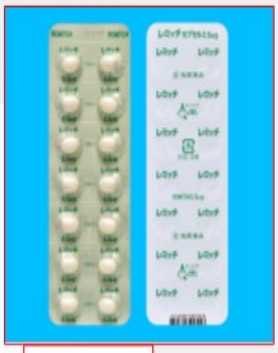
B. B. Land[1], S. Sreedharan[2], R. Patel[2], T. Beck[3], K. DeVarney[2], M. Rubin[2], *C. Chavkin[1];
[1]Pharmacol., Univ. of Washington, Seattle, WA; [2]Titan Pharmaceuticals, South San Francisco, CA; [3]Med. Univ. of South Carolina, Charleston, SC

KAPPA OPIOID RECEPTOR AGONISTS IN CHRONIC PRURITUS





Nalfurafine



Difelikefalin

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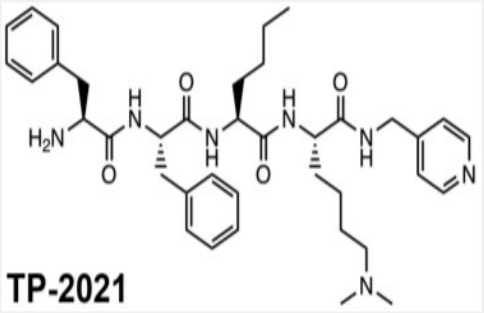
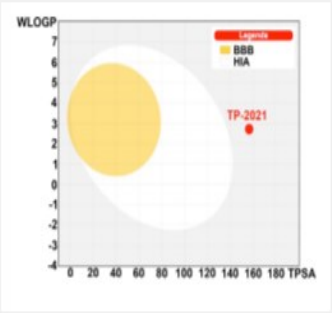
TP-2021 - A PERIPHERAL KAPPA OPIOID RECEPTOR AGONIST





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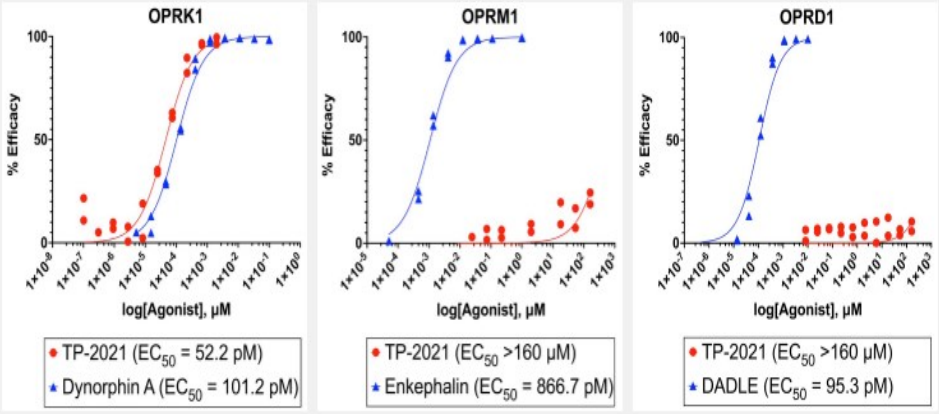
TP-2021 BINDS SELECTIVELY TO KAPPA OPIOID RECEPTORS



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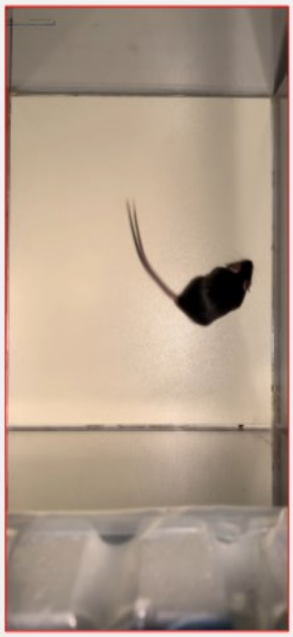
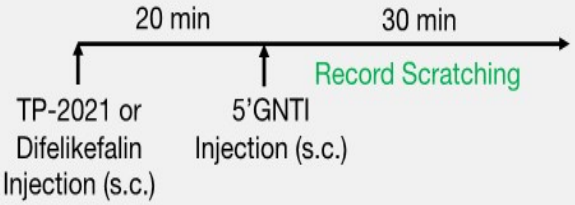
MOUSE PRURITUS MODEL



Acute Bolus Injection



Chronic Subdermal Implantation

Day 0: Implant or control

Days 1, 14, 28, 56: 5'GNTI Challenge

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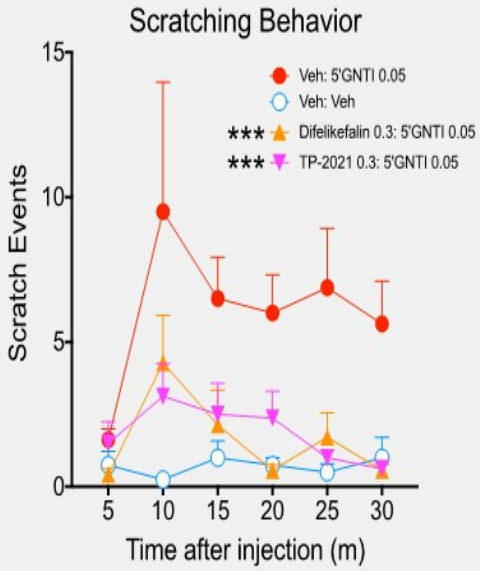
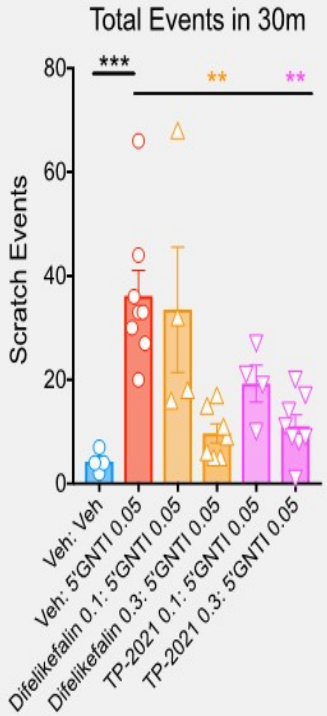
EVALUATION OF TP-2021 SC BOLUS IN MOUSE PRURITUS MODEL





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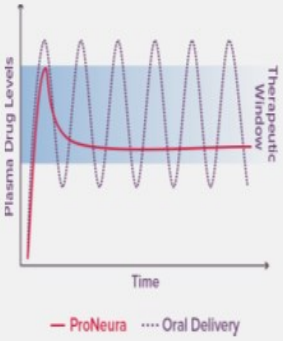
PRONEURA - A LONG-TERM DRUG DELIVERY PLATFORM



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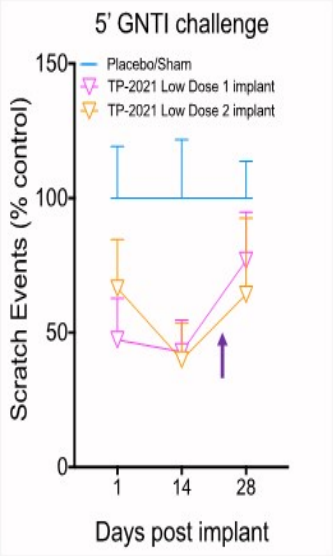
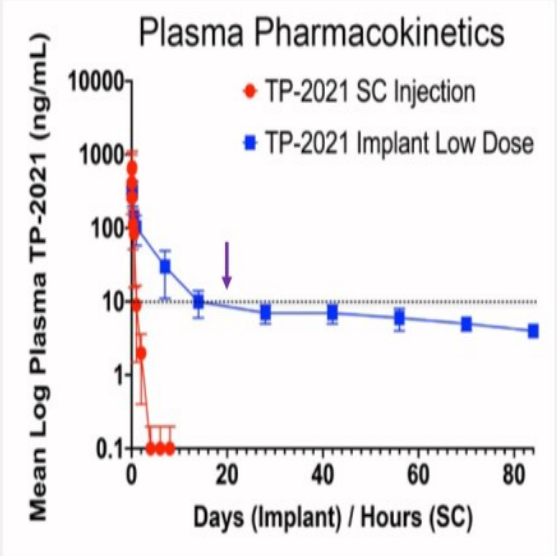
LOW-DOSE TP-2021 IMPLANTS IN MOUSE PRURITUS MODEL





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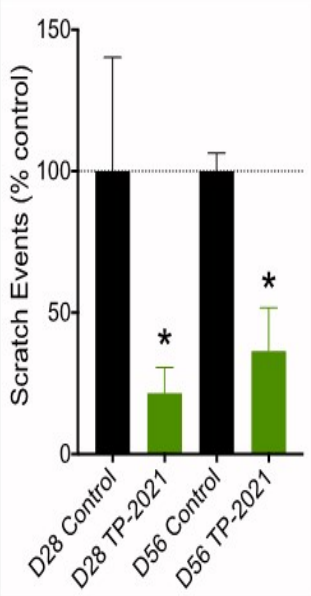
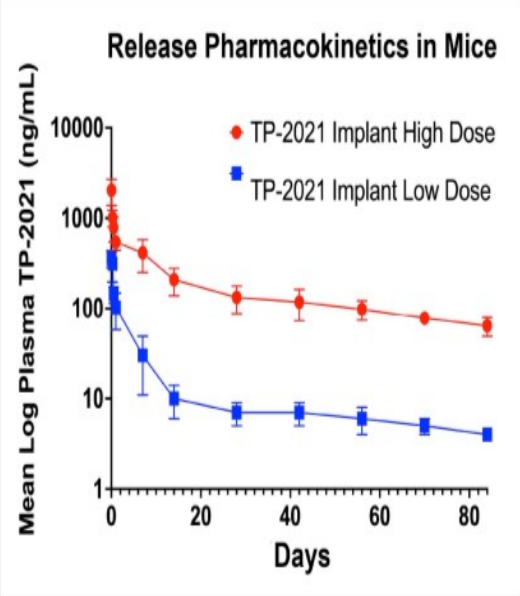
HIGH-DOSE TP-2021 IMPLANTS IN MOUSE PRURITUS MODEL





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SUMMARY

- TP-2021 is a highly selective and potent kappa opioid receptor agonist
- TP-2021 shows similar anti-pruritic efficacy and potency to Difelikefalin when delivered by subcutaneous injection
- Low dose subdermal TP-2021-ProNeura implants show anti-pruritic efficacy, which diminishes after 2 weeks
- A single high-dose TP-2021-ProNeura implant shows sustained anti-pruritic efficacy, thus far through Day 56, with further efficacy assessments continuing

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CONCLUSION

- TP-2021-ProNeura implants present a viable solution for treatment of chronic pruritus and related conditions for potentially 6 months or longer

- A single administration of TP-2021-ProNeura implant could potentially abrogate the need for daily administration, even if a peptide with oral bioavailability is therapeutically achievable

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CONTRIBUTORS

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Sophia Mar

Titan Pharmaceuticals

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Raj Patel, Ph.D.
Tyler Beck
Kate DeVarney, Ph.D.
Marc Rubin, M.D.

Funding

University of Washington

Reagents

Titan Pharmaceuticals

Exhibit 99.2

SUSTAINED ANTI-PRURITIC EFFECT OF TITAN'S TP-2021 IMPLANT REPORTED TODAY AT NEUROSCIENCE 2021

SOUTH SAN FRANCISCO, CA – November 8, 2021 – Titan Pharmaceuticals, Inc. (NASDAQ: TTNP) ("Titan" or the "Company") announced that, in a presentation given today at the Society for Neuroscience 2021 Meeting, Ben Land, Ph.D., Research Assistant Professor at the University of Washington's Department of Pharmacology, reported additional positive data from an ongoing in vivo study of its human kappa-opioid receptor agonist ("TP-2021") ProNeura®-based implant in an established 5'-guanidinonaltrindole (5'-GNTI) itch-induced mouse model.

As previously reported, low dose TP-2021 implants had demonstrated anti-pruritic effects for up to 2 weeks in this model. Higher-dose TP-2021 implants were subsequently formulated and the study repeated after content analysis of the removed low-dose implants indicated potential drug release duration of approximately four months, but at levels below the anti-pruritic efficacy threshold.

A significant reduction in scratching behavior was maintained in mice who received the high-dose TP-2021 implant at both Day 28 and Day 56 post-implantation, compared with those that received the placebo implant, with no safety issues observed. In addition, the high-dose TP-2021 implant provided sustained supra-therapeutic plasma levels of TP-2021 through Day 84. As a result, the efficacy assessment is continuing.

"These results indicate that TP-2021 implants can release drug above the therapeutic threshold in this mouse pruritus model for several months following a single treatment," said Dr. Land. "Difelikefalin (Korsuva™) intravenous injection set the guidepost for the treatment of chronic kidney disease patients undergoing hemodialysis. Demonstration of efficacy of an oral formulation meant for treating other pruritic indications, such as atopic dermatitis, has thus far not been achieved. Titan's ProNeura-based TP-2021 implants present a viable solution for the delivery of sustained therapeutic levels of a peripheral kappa agonist for potentially up to 6 months or longer for the treatment of chronic pruritus and related conditions. A single administration of TP-2021 using ProNeura implant(s) could potentially avoid the need for frequent oral administration, even if a peptide with oral bioavailability can be successfully developed."

Kate Beebe DeVarney, Ph.D., President and Chief Operating Officer of Titan, commented, "Based on TP-2021's high potency and three-month post-implantation plasma levels, we believe TP-2021 ProNeura implants could potentially maintain supra-therapeutic levels for a prolonged period, and we are looking forward to receiving additional efficacy and durability data in the coming months."

Marc Rubin, M.D. Titan's Executive Chairman, added, "These data suggest that a single administration of TP-2021 implant(s) presents a viable solution for the long-term, continuous treatment of severe chronic pruritus associated with certain kidney, liver, and skin conditions."

About Chronic Pruritus

Chronic pruritus is an often debilitating condition, resulting in the need to scratch that lasts more than 6 weeks. It is a prevalent symptom associated with a number of serious cutaneous and systemic conditions. Due to its complex pathogenesis and numerous contributing factors, effective treatment of chronic pruritus remains challenging.

About Titan Pharmaceuticals

Titan Pharmaceuticals, Inc. (NASDAQ:TTNP), based in South San Francisco, CA, is a development 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 our ability to raise capital, 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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