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 12, 2018

OPIANT PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**001-38193**	**46-4744124**
(State or other jurisdiction of incorporation)	(Commission File Number	(IRS Employer Identification No.)

201 Santa Monica Boulevard, Suite 500 Santa Monica, CA	**90401**
(Address of Principal Executive Offices)	(Zip Code)

310 598-5410
Registrant's telephone number, including area code

(Former name or former address if changed since last report,)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the 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 under the Exchange Act (17 CFR 240.14a-12)

☐ 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 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 12, 2018, Opiant Pharmaceuticals, Inc., a Delaware corporation (the "Company"), announced positive data from a Phase I clinical study of its product candidate OPNT003 (intranasal nalmefene), and provided an update on a meeting held February 8, 2018 with the U.S. Food and Drug Administration (the "FDA") regarding its planned development program. OPNT003 is in development as a long-lasting opioid antagonist for the treatment of opioid overdose. Based on feedback from the FDA in connection with this meeting, the Company intends to pursue a 505(b)(2) development path, and anticipates the potential to submit a New Drug Application for the drug and intranasal delivery device combination in 2020. Nalmefene for injection was previously approved by the FDA for treating suspected or confirmed opioid overdose.

A copy of the press release is attached hereto as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release of the Company dated February 12, 2018.

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.

Opiant Pharmaceuticals, Inc.

Date: February 12, 2018

By: /s/ David D. O'Toole

Name: David D. O'Toole

Title: Chief Financial Officer

Exhibit 99.1

Opiant Pharmaceuticals Announces Development of OPNT003, Intranasal Nalmefene, for Treatment of Opioid Overdose

Based on FDA Feedback, Opiant Intends to Pursue 505(b)(2) Development Pathway

Opiant Anticipates Submitting an NDA for this Product Candidate in 2020

SANTA MONICA, Calif., Feb. 12, 2018 (GLOBE NEWSWIRE) -- Opiant Pharmaceuticals, Inc. ("Opiant") (NASDAQ: OPNT), a specialty pharmaceutical company developing pharmacological treatments for addictions, today announced positive data from a Phase I clinical study of its product candidate OPNT003 (intranasal nalmefene) and provided an update on a meeting held February 8, 2018 with the U.S. Food and Drug Administration (FDA) regarding its planned development program. OPNT003 is in development as a long-lasting opioid antagonist for the treatment of opioid overdose. Based on feedback from the FDA in connection with this meeting, Opiant intends to pursue a 505(b)(2) development path, and anticipates the potential to submit a New Drug Application (NDA) for the drug and intranasal delivery device combination in 2020. Nalmefene for injection was previously approved by the FDA for treating suspected or confirmed opioid overdose. The 505(b)(2) pathway allows companies to rely in part on the FDA's findings of safety and efficacy of a previously approved product and to supplement these findings with a more limited set of their own studies to satisfy FDA requirements, as opposed to conducting the full array of preclinical and clinical studies that would typically be required.

Data generated in a Phase I study completed under a clinical trial agreement with the National Institute on Drug Abuse (NIDA) provided the basis for the FDA meeting. These data demonstrate that an intranasal nalmefene formulation containing a proprietary absorption enhancer (Intravail®, from Aegis Therapeutics) resulted in rapid increases in plasma levels with an onset faster than an intramuscular injection and a comparatively long half-life (6.7-7.8 hours). Naloxone, the only FDA medication currently approved to treat opioid overdose, has a half-life of approximately 2 hours.

"We are pleased with the positive outcome of this meeting and the beneficial guidance received from the FDA," said Roger Crystal, M.D., Chief Executive Officer of Opiant. "We now have a well-defined development and regulatory pathway to pursue approval of OPNT003 in the U.S. for the treatment of opioid overdose. Following the feedback received from the FDA, we are focused on leveraging the 505(b)(2) development pathway that allows certain information required for NDA approval to be derived from studies not conducted by Opiant. We anticipate submitting an NDA for OPNT003 in 2020. Based on its profile and the Phase I trial results, we believe OPNT003 has the potential to be a transformative treatment for opioid overdose, a growing U.S. health epidemic."

"Opiant has full commercial rights to OPNT003 and has submitted a grant application to the National Institutes of Health (NIH) to fund its development to an NDA ready stage," continued Dr. Crystal. "Based on the NIH calling for longer-acting overdose-reversal drugs, we are optimistic that this grant will be funded."

Synthetic opioids, such as fentanyl, are now responsible for more overdose deaths than either heroin or prescription opioids, with over 20,000 synthetic opioid overdose deaths in 2016. Fentanyl and derivatives, such as carfentanil, are especially dangerous because of a long half-life of seven to ten hours

that may require continuous monitoring of overdose victims and repeated dosing to prevent relapse. A long-lasting overdose reversal drug may reduce this burden.

NIH leadership recently called for the development of "...stronger, longer-acting formulations of antagonists…to counteract the very high potency synthetic opioids that are now claiming thousands of lives each year." (Volkow and Collins, NEJM 2017)

An easy-to-use nasal formulation of nalmefene with a rapid onset and long duration of action would be a ready-to-use tool for non-medically trained persons to administer. If approved by the FDA, OPNT003 may be especially useful in rural areas, where a rapidly growing number of overdoses are occurring, and where access to emergency medical response may be delayed by hours.

About Opiant Pharmaceuticals, Inc.
Opiant Pharmaceuticals, Inc. is a specialty pharmaceutical company developing pharmacological treatments for addictions. The National Institute on Drug Abuse (NIDA), a division of the National Institutes of Health (NIH), describes these disorders as chronic relapsing brain diseases which burden society at both the individual and community levels. With its innovative opioid antagonist nasal delivery technology, Opiant is positioned to become a leader in these treatment markets. Opiant's first product, NARCAN® Nasal Spray, is approved for marketing in the U.S. and Canada by its partner, Adapt Pharma. Opiant owns all global development and commercial rights to OPNT003. For more information please visit: www.opiant.com.

Forward-Looking Statements
This press release contains forward-looking statements. These statements relate to future events or our future financial performance and involve known and unknown risks, uncertainties and other factors that may cause our or our industry's actual results, levels of activity, performance or achievements to be materially different from any future results, levels of activity, performance or achievements expressed, implied or inferred by these forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as "may," "will," "should," "could," "would," "expects," "plans," "intends," "anticipates," "believes," "estimates," "predicts," "projects," "potential," or "continue" or the negative of such terms and other comparable terminology. These statements are only predictions based on our current expectations and projections about future events. You should not place undue reliance on these statements. Actual events or results may differ materially. In evaluating these statements, you should specifically consider various factors. These and other factors may cause our actual results to differ materially from any forward-looking statement. We undertake no obligation to update any of the forward-looking statements after the date of this press release to conform those statements to reflect the occurrence of unanticipated events, except as required by applicable law.

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