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 4, 2021

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.)

233 Wilshire Blvd. Suite 280 **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. ☐

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, par value $0.001 per share	OPNT	Nasdaq Stock Market LLC

Item 8.01 Other Events

On November 4, 2021, the Company issued a press release announcing the U.S. Food and Drug Administration (“FDA”) granted Fast Track Designation to OPNT003, nasal nalmefene for the treatment of opioid overdose. The press release is filed as Exhibit 99.1 and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press release of Opiant Pharmaceuticals, Inc, dated November 4, 2021, "Opiant Receives FDA Fast Track Designation for OPNT003, Nasal Nalmefene, for Treatment of Opioid Overdose"
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

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 8, 2021 **OPIANT PHARMACEUTICALS, INC.**

By: /s/ David D. O'Toole

Name: David D. O'Toole

Title: Chief Financial Officer

Exhibit 99.1

Opiant Receives FDA Fast Track Designation for OPNT003, Nasal Nalmefene, for Treatment of Opioid Overdose

- *Fast Track Designation further underscores the potential for OPNT003 to represent a major advance in the treatment of opioid overdose as opioid overdose deaths surge*[1]

- *This designation enables early and frequent communication with the FDA, in addition to the potential for a rolling submission of NDA application*[2]

SANTA MONICA, Calif., November 4, 2021 -- Opiant Pharmaceuticals, Inc. ("Opiant") (NASDAQ: OPNT), a company advancing medicines to better treat addictions and drug overdose, today announced that the U.S. Food and Drug Administration ("FDA") has granted fast track designation for OPNT003, nasal nalmefene, its investigational treatment for opioid overdose.

In July, the Company reported positive results from a confirmatory pharmacokinetic ("PK") study comparing OPNT003 to intramuscular nalmefene injection[3]. The characteristics OPNT003 exhibited in this study, coupled with nalmefene's five-fold higher affinity compared to naloxone[4], demonstrate its promise as a potential new treatment. OPNT003 is currently being studied in an ongoing pharmacodynamic ("PD") study comparing it to nasal naloxone[5]. Both PK and PD data will form the basis of a New Drug Application ("NDA") submission using the 505(b)(2) regulatory pathway.

"Opioid overdoses in the United States are a public health crisis with rates at the highest level in history and particularly powerful synthetic opioids like fentanyl, being the main driver," said Dr. Roger Crystal, President and CEO, Opiant. "The designation of Fast Track status by the FDA underscores the potential for OPNT003 to represent a major advance in opioid overdose treatment that can help communities better respond to this escalating crisis. Opiant is focused on advancing the OPNT003 development program as rapidly as possible and the granting of Fast Track designation represents significant additional support toward this objective."

Synthetic opioids such as fentanyl are significantly more potent, have a very rapid onset, and a longer duration of action compared to heroin and prescription opioids. Synthetic opioids have created a much more dangerous environment for individuals that are using drugs, and not just those that use opioids. Fentanyl and related synthetic opioids have made their way into many substances sold illegally, including cocaine, methamphetamine and counterfeit pills, and is responsible for the deaths of thousands of Americans. Synthetic opioids have been found present in as many as 80% of overdose deaths[1]. Proving more resistant to reversal by standard doses of naloxone[6], the public health threat posed by synthetic opioids prompted leadership at the National Institutes of Health (NIH) to call for the development of "…stronger, longer-acting formulations of antagonists[7]…"

Fast Track is an FDA process designed to facilitate the development and expedite the review of potential therapies that seek to treat serious conditions and fill an unmet medical need. Programs with Fast Track designation may benefit from early and frequent communication with the FDA, in addition to a potential rolling submission of the marketing application[2]. For more information on Fast Track designation, please visit the FDA's website, available at https://www.fda.gov/patients/fast-track-breakthrough-therapy-accelerated-approval-priority-review/fast-track.

About Opiant Pharmaceuticals, Inc.
Opiant Pharmaceuticals, Inc., the company that developed NARCAN® Nasal Spray, is building a leading franchise of new medicines to combat addictions and drug overdose. For more information visit: www.opiant.com.

Forward-Looking Statements
This press release contains forward-looking statements, including statements for OPNT003's potential as an opioid overdose reversal agent. 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, and among other things, our ability to maintain cash balances and successfully commercialize or partner our product candidates currently under development. 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. Additional factors that could materially affect actual results can be found in our Form 10-K for the year ended December 31, 2020, filed with the Securities and Exchange Commission on March 4, 2021, including under the caption titled "Risk 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.

References:

1. F. Ahmad et al. Provisional drug overdose death counts. National Center for Health Statistics (2021). https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm
2. U.S. Food and Drug Administration (FDA). Fast Track. Available from: https://www.fda.gov/patients/fast-track-breakthrough-therapy-accelerated-approval-priority-review/fast-track.
3. Opiant Press Release. Link.
4. J. Cassel, et al. Alvimopan binding to the μ opioid receptor: Comparative binding kinetics of opioid antagonists. European Journal of Pharmacology, 520 (2005), pp. 29-36
5. ClinicalTrials.gov (NCT04828005) Link.
6. R. Moss, et al. Higher doses of naloxone are needed in the synthetic opioid era. Substance Abuse Treatment, Prevention, and Policy, 14 (2019), p. 6
7. Volkow N & Collins F. The role of science in addressing the opioid crisis. *N. Engl. J. Med* 377, 391–394 (2017).

For Media and Investor Inquiries:
Ben Atkins, Opiant
(310) 598-5410
batkins@opiant.com