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): April 27, 2022

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 400 **Santa Monica, CA**	**90401**
(Address of Principal Executive Offices)	(Zip Code)

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

233 Wilshire Blvd. Suite 280, Santa Monica, CA 90401
(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 April 27, 2022, Opiant Pharmaceuticals, Inc. issued a press release announcing positive top-line results from its confirmatory pharmacodynamic ("PD") study for its investigational treatment OPNT003, nasal nalmefene, for opioid overdose. A copy of the press release is filed herewith as Exhibit 99.1.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release of Opiant Pharmaceuticals, Inc., dated April 27, 2022

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: April 27, 2022 **OPIANT PHARMACEUTICALS, INC.**

By: /s/ David D. O'Toole

Name: David D. O'Toole

Title: Chief Financial Officer

Exhibit 99.1

Opiant Pharmaceuticals Announces Positive Topline Results from Head-to-Head Pharmacodynamic Study Comparing OPNT003, Nasal Nalmefene, to Nasal Naloxone

- *Study compared OPNT003, nasal nalmefene, with 4 mg nasal naloxone hydrochloride in reversing the respiratory depression produced by remifentanil, a synthetic opioid*
- *OPNT003 met the primary endpoint of non-inferiority, which was designed to assess whether nasal nalmefene performed as well or better than nasal naloxone*
- *OPNT003 produced, at the primary end point of five minutes, a greater reversal in remifentanil-induced respiratory depression that was nearly twice that produced by nasal naloxone*
- *Completion of the PD study concludes the planned clinical development program for OPNT003; Company expects to complete an NDA filing for OPNT003 in the second half of 2022*
- *Company to discuss top-line data on its scheduled first quarter earnings and corporate update conference call May 10 at 4:30 p.m. ET*

SANTA MONICA, Calif., April 27, 2022 -- Opiant Pharmaceuticals, Inc. (“Opiant”) (NASDAQ: OPNT) today announced positive topline results from a pharmacodynamic (“PD”) study for OPNT003, nasal nalmefene, (3mg nalmefene hydrochloride), an investigational treatment for opioid overdose.

This crossover study conducted in healthy volunteers compared 3mg nasal nalmefene hydrochloride with 4 mg nasal naloxone hydrochloride in reversing respiratory depression produced by remifentanil, a synthetic opioid. The two study drugs were assessed by measuring changes in minute ventilation following administration of the respective study drug, with the primary endpoint at five minutes post administration.

A preliminary analysis on the 50 subjects completing the study found that treatment with OPNT003, nasal nalmefene, produced a greater reversal of respiratory depression that was nearly twice that produced by nasal naloxone at five minutes. The increases in minute ventilation were 5.745 L/min and 3.011 L/min, with nalmefene and naloxone, respectively. OPNT003 met the primary endpoint of non-inferiority, which was designed to assess whether nasal nalmefene performed as well or better than nasal naloxone.

“The findings from this PD study are compelling and add to a body of non-clinical and clinical evidence demonstrating the potential of OPNT003, nasal nalmefene, to offer an important treatment option for opioid overdose,” said Richard C. Dart, M.D., Ph.D., Director of the Rocky Mountain Poison & Drug Center, Denver Health and Hospital Authority, and a member of Opiant’s Scientific Advisory Board. “Synthetic opioids, such as fentanyl, are responsible for the great majority of overdoses today, are far more potent, have a more rapid onset, and can have a long duration of action. They can quickly depress respiration and can continue to deprive the brain of oxygen even after administration of naloxone, the only current FDA-approved treatment for opioid overdose. Unless quickly reversed, this can cause severe hypoxic injury to the victim’s organs and brain, and potentially death.”

“We are thrilled to be sharing positive topline data from our head-to-head PD study comparing OPNT003, nasal nalmefene, with nasal naloxone,” said Roger Crystal, M.D., President and Chief

Executive Officer of Opiant. “These data, taken together with our prior PK studies, suggest that OPNT003 could be well suited to address the challenges in treating today’s opioid overdoses, which are driven by synthetic opioids, like fentanyl. It is extremely rewarding to see this program yield clear, consistent, results, and we look forward to continuing to work towards submitting our New Drug Application (“NDA”), which we anticipate occurring in the second half of this year."

Positive results were previously reported in two separate pharmacokinetic (“PK”) studies. OPNT003-PK-001 evaluated the PK behavior of nasal nalmefene compared to nalmefene intramuscular injection. Nasal nalmefene exhibited both rapid absorption (T_{max} 15 min) and high plasma concentrations (C_{max} 12.2 ng/ml) that surpassed an approved dose of intramuscular nalmefene, as well as having a comparable long plasma half-life. OPNT003-PK-002 compared the effect of a single dose of nasal nalmefene in one nostril, one dose in each nostril, and two doses in one nostril. OPNT003 demonstrated dose proportional plasma concentrations to a single dose, whether administered as a single dose in each nostril or as two doses in a single nostril, and was safe and well tolerated. Completion of the PD study concludes the planned clinical development program for OPNT003.

OPNT003, nasal nalmefene, is being developed using a 505(b)(2) pathway. The U.S. Food and Drug Administration (“FDA”) granted Opiant Fast Track Designation for OPNT003 in November 2021. The Company expects to complete an NDA filing in the second half of 2022.

This project has been funded in whole or in part with federal funds from the Department of Health and Human Services; Office of the Assistant Secretary for Preparedness and Response; Biomedical Advanced Research and Development Authority, under Contract number HHSO100201800029C; and the National Institute on Drug Abuse (“NIDA”).

Conference Call

Opiant will discuss OPNT003 top line data on its first quarter 2022 financial results and corporate update conference call with slides, Tuesday, May 10, 2022, at 4:30 p.m. Eastern Time. To listen to the conference call, please dial 1-877-407-0792 (domestic) or 1-201-689-8263 (international) using conference ID number 13728852. The call will also be webcast LIVE with slides and can be accessed via the Investors section of the Company's website at: www.opiant.com.

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. 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 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, submit a New Drug Application in the second half of 2022. 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, 2021, filed with the Securities and Exchange Commission on March 4, 2022, 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.

For Media and Investor Inquiries:
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