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): July 14, 2017

OPIANT PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Nevada	**000-55330**	**46-4744124**
(State or other jurisdiction of incorporation)	(Commission File Number	(IRS Employer Identification No.)

401 Wilshire Blvd., 12th Floor, Santa Monica, CA	**90401**
(Address of Principal Executive Offices)	(Zip Cope)

(424) 252-4756
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 1.01 Entry into a Material Definitive Agreement.

On July 14, 2017 (the "Execution Date"), Opiant Pharmaceuticals, Inc., a Nevada corporation (the "Company"), and Renaissance Lakewood, LLC, a limited liability company ("Renaissance"), entered into a Research and Development Agreement (the "Agreement"). Under the Agreement, Renaissance will perform product development work on a naltrexone multi-dose nasal product for the treatment of alcohol use disorder pursuant to the terms set forth in a proposal agreed upon by the parties. Company will bear the costs of all development services, including all raw materials and packaging components, in connection with the performance of the development work under the Agreement and in accordance with financials agreed upon through the proposal. Renaissance will conduct quality control and testing, including non-stability, stability, in-use, raw material, and packaging component testing as part of the services provided to Company under the Agreement. Company shall own all formulations provided to Renaissance and any formulations developed in connection with the Agreement. Renaissance will own all know-how developed in connection with the performance of the services that is not solely related to a product. Company has the right to seek patent protection on any invention or know-how that relates solely to a product developed under the Agreement or any Company formulation, excluding general manufacturing or product development know-how of Renaissance. Company has agreed to indemnify Renaissance in connection with claims arising out of any clinical trials, ownership, testing, use, application, consumption, distribution, marketing or sale of the Product (as defined therein), or any violation or infringement of any patent, copyright or trademark from the use of a Company designated formula, component or artwork related to the Product irrespective of whether the Company had knowledge of such infringement or violation.

The Agreement is effective until terminated by either party in accordance with its terms. Renaissance or Company may terminate the project under a proposal to the Agreement due to unforeseen circumstances in the development. The Agreement may be terminated by Company, with or without cause, upon 45 days written notice. There are also mutual customary termination provisions relating to uncured breaches of material provisions. Renaissance may terminate the Agreement in the event of bankruptcy of the Company or failure of the Company for a period of 180 consecutive days to use commercially reasonable efforts to undertake or further activities to advance the possibility of the commercialization of a Product.

The Company expects to file the Agreement as exhibits to its Annual Report on Form 10-K for the fiscal year ended July 31, 2017, and intends to seek confidential treatment for certain terms and provisions of the Agreement. The foregoing description is qualified in its entirety by reference to the complete text of the Agreement when filed.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Opiant Pharmaceuticals, Inc. Press Release, dated July 19, 2017.

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: July 19, 2017

By: /s/ Roger Crystal
Name: Dr. Roger Crystal
Title: President and Chief Executive Officer

Exhibit 99.1

Opiant Pharmaceuticals, Inc. Announces Phase I Data for OPNT002 in Development for the Treatment of Alcohol Use Disorder

Intravail® Increased the Rate of Absorption of Intranasal Naltrexone

No Serious Adverse Events or Evidence of Nasal Irritation

Contract Signed with Renaissance to Advance Product Development

SANTA MONICA, California – July 19, 2017 – Opiant Pharmaceuticals, Inc. ("Opiant") (OTCQB:OPNT), a specialty pharmaceutical company developing pharmacological treatments for addictions and eating disorders, today announced results from a Phase 1 trial of OPNT002, an intranasally dosed (IN) formulation of the opioid antagonist naltrexone hydrochloride (naltrexone), in development for the treatment of Alcohol Use Disorder (AUD). This study was conducted under a clinical trial agreement between Opiant and the National Institute of Drug Abuse (NIDA), a division of the National Institutes of Health (NIH). The study examined the effects of Intravail®, an absorption enhancer, on the pharmacokinetic properties of IN naltrexone in healthy volunteers. The trial also assessed the safety of IN naltrexone, particularly with respect to nasal irritation. Opiant has also signed an agreement with Renaissance to initiate work on the product development.

Some notable Phase 1 findings include:

- Intravail®, recently licensed by Opiant from Aegis Therapeutics, increased the maximal plasma concentrations (C_{max}) of IN naltrexone by almost three-fold compared to IN naltrexone alone.
- The addition of Intravail® significantly accelerated the time (T_{max}) to reach maximum observed plasma concentrations of naltrexone, from 30 minutes to 10 minutes.
- No safety or tolerability concerns were identified; there was no evidence of nasal irritation.

"Naltrexone is a well-known treatment for AUD, and this study sheds new light on the potential clinical benefits of combining intranasally administered naltrexone with Intravail®," said Stephanie Samples O'Malley, PhD, Professor of Psychiatry; Director, Division of Substance Abuse Research in Psychiatry; Deputy Chair, Clinical Research at Yale School of Medicine and consultant to Opiant Pharmaceuticals. "Although the sample size of this study is small, these data suggest that pairing Intravail® with IN naltrexone enhances the effect of the drug which could support the development of a new method for treating AUD."

Phil Skolnick, Ph.D., D.Sc. (hon.), Chief Scientific Officer at Opiant Pharmaceuticals, Inc. added, "We are very excited by the observed changes in the pharmacokinetic properties of intranasal naltrexone when combined with Intravail®, particularly the ability of Intravail® to reduce the time needed to reach maximum plasma concentrations, which implies a more rapid onset of action. Although additional clinical work is required, the ability to rapidly deliver an intranasal dose of naltrexone on an 'as needed' basis has the potential to offer patients a much-needed innovation in the treatment of AUD."

Study Design:
This study was an in-patient, open-label, four-period, four-treatment, one-sequence, crossover design. Subjects were 14 healthy male and female volunteers ages 18 to 55 with no pre-existing nasal abnormalities. Each subject received four naltrexone treatments during the four dosing periods.

Summary of topline data:
When the IN naltrexone formulation included Intravail®, the maximum plasma concentration (C_{max}) increased 3-fold and the median time to reach the maximum observed plasma concentration (T_{max}) decreased from 30 minutes to 10 minutes. The median time to reach maximum observed plasma concentration of IN naltrexone administered with Intravail was also more rapid than an intramuscular injection. Absorption of naltrexone after oral administration of 50 mg was slower than either IN or IM administration at earlier time points.

All treatments were considered safe and well tolerated, with no severe or serious adverse events (AEs) observed.

Opiant has signed a contract manufacturing agreement with Renaissance (Lakewood, NJ) to begin work on optimizing an IN naltrexone formulation for Phase II studies. "Signing this agreement represents significant progress towards advancing this pipeline," said Roger Crystal, M.D., Chief Executive Officer of Opiant. "We worked with Renaissance (previously DPT) for commercial manufacturing of the NARCAN Nasal Spray, so we have a high degree of confidence in their ability to deliver."

About Opiant Pharmaceuticals, Inc.

Opiant Pharmaceuticals, Inc., is a specialty pharmaceutical company developing pharmacological treatments for addictions and eating disorders. 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. Its first product, NARCAN® Nasal Spray, is approved for marketing in the U.S. and Canada by the company's partner, Adapt Pharma Limited. For more information please visit: www.opiant.com.

About Intravail®

Intravail® drug delivery technology facilitates non-invasive delivery of a broad range of non-peptide and peptide drugs, as well as non-invasive delivery of protein drugs that can currently only be administered by injection, via the oral, buccal, and intranasal administration routes, with high bioavailability and increased speed of absorption.

About Naltrexone

Naltrexone is a high affinity opioid receptor antagonist. Initially approved by the FDA to treat opioid use disorders, subsequent clinical studies led to its approval to treat AUDs in 1994. Both clinical and preclinical studies have demonstrated that that alcohol consumption triggers the release of endorphins and enkephalins, naturally occurring opioid like peptides. By blocking the effects of these molecules at opioid receptors, naltrexone reduces craving for alcohol as well as the amount of alcohol consumed.

Forward-Looking Statements

This press release contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. 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, including those risks and uncertainties described in our filings with the U.S. Securities and Exchange Commission, including our most recent reports on Forms 10-K, 10-Q and 8-K, and any amendments thereto. Therefore, current and prospective security holders are cautioned that there also can be no assurance that the forward-looking statements included in this press release will prove to be accurate. In light of the significant uncertainties inherent in the forward-looking statements included herein, the inclusion of such information should not be regarded as a representation or warranty by Opiant or any other person that the objectives and plans of Opiant will be achieved in any specified time frame, if at all. 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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CONTACT INFORMATION:

Corporate Contact:
Investor.relations@opiant.com

Investors:
Sam Martin
Argot Partners
sam@argotpartners.com
212-600-1902