

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): March 21, 2019

OPIANT PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of
incorporation)

001-38193

(Commission File Number)

46-4744124

(IRS Employer Identification No.)

**201 Santa Monica Boulevard, Suite 500
Santa Monica, CA**

(Address of Principal Executive Offices)

90401

(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 2.02. Results of Operations and Financial Condition.

On March 21, 2019, Opiant Pharmaceuticals, Inc. (the “**Company**”), issued a press release announcing the Company’s financial results for the fourth quarter and year ended December 31, 2018 and recent corporate highlights. A copy of the press release is furnished herewith as Exhibit 99.1.*

* The information in Item 2.02 of this Form 8-K shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934 (the “Exchange Act”) or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933 or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release of Opiant Pharmaceuticals, Inc., dated March 21, 2019.

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.

OPIANT PHARMACEUTICALS, INC.

Dated: March 21, 2019 By: /s/ David D. O'Toole

Name: David D. O'Toole
Title: Chief Financial Officer

Opiant Pharmaceuticals, Inc. Reports Fourth Quarter and Full-Year 2018 Financial Results and Provides Corporate Update

Addiction and Drug Overdose Pipeline Supported by Strong Cash Position; Expected to be in Range of \$17M-\$20M at End of 2019

SANTA MONICA, Calif, March 21, 2019 – Opiant Pharmaceuticals, Inc. (“Opiant”) (NASDAQ: OPNT), a specialty pharmaceutical company developing medicines for addictions and drug overdose, today reported financial results for the quarter and year ended December 31, 2018, and provided a corporate update.

“The opioid epidemic has worsened with increased fentanyl abuse,” said Roger Crystal, M.D., Chief Executive Officer of Opiant. “Opiant’s pipeline, led by OPNT003, nasal nalmefene, for the treatment of opioid overdose, is making good progress. OPNT003 is funded through to a potential New Drug Application submission via our contract of up to \$4.6 million with the Biomedical Advanced Research and Development Authority (“BARDA”) to support its development as a medical countermeasure in the event of a fentanyl chemical attack. We also received a \$7.4 million grant from the National Institute on Drug Abuse (“NIDA”). In 2019 we intend to conduct a pivotal pharmacokinetic study of OPNT003 with top-line data expected later this year.”

“We recently in-licensed drinabant, OPNT004 from Sanofi, a cannabinoid receptor antagonist, for the emergency treatment of Acute Cannabinoid Overdose (“ACO”). With an increasing number of states legalizing marijuana, ACO rates are expected to rise. In 2019, our focus will be on reformulating oral OPNT004 into an injectable. We intend to commence clinical studies in 2020,” concluded Dr. Crystal.

“Our pipeline is supported by a strong financial position. We anticipate a growing revenue stream from royalties from NARCAN® Nasal Spray. Moreover, with a projected cash position of approximately \$17 million to \$20 million at the end of 2019, we expect our balance sheet to support us through key milestones” said David O’Toole, Chief Financial Officer of Opiant.

Recent Corporate Highlights

- Acquired an exclusive global license from Sanofi for the development and commercialization of drinabant (OPNT004) for the treatment ACO
- Additional patent of NARCAN® Nasal Spray now listed in the U.S. Food and Drug Administration publication, *Approved Drug Products with Therapeutic Equivalence Evaluations*, commonly known as the “Orange Book”
- Announced that a Phase 2 clinical trial evaluating OPNT001, a naloxone nasal spray for the treatment of bulimia nervosa (BN), did not meet its primary endpoint. Opiant is discontinuing its BN development program

Financial Results for the Fourth Quarter Ended December 31, 2018

For the three months ended December 31, 2018, Opiant recorded approximately \$4.8 million in revenue, compared to approximately \$11.7 million during the corresponding period of 2017. For the three months ended December 31, 2018, Opiant recognized approximately \$4.4 million of revenue from the license agreement (the “Adapt License”) between it and Adapt Pharma

Operations Limited, a subsidiary of Emergent BioSolutions Inc. (“Adapt”) for the sale of NARCAN® Nasal Spray.

General and administrative expenses for the three months ended December 31, 2018, were approximately \$2.6 million, compared to approximately \$4.4 million in the comparable period of 2017. The decrease was primarily due to decreased personnel and related expenses of \$1.3 million, and decreased stock-based compensation expense of \$0.7 million, which was partially offset by an increase in corporate overhead of \$0.2 million.

Research and development expenses for the three months ended December 31, 2018, were approximately \$2.5 million, compared to approximately \$1.9 million in the comparable period of 2017. The increase was primarily attributable to a \$0.4 million increase in stock-based compensation expense, and a \$0.7 million increase in third-party expenses associated with Opiant’s research and development programs, which was partially offset by a decrease of \$0.5 million in personnel and related expense.

License fees for the three months ended December 31, 2018, were approximately \$8.1 million. The license fees relate to royalties from the Adapt License.

Net loss for the three months ended December 31, 2018, was approximately \$9.5 million, or a loss of (\$2.49) per basic share, compared to net income of approximately \$3.4 million, or \$1.59 per basic share, for the comparable period of 2017.

Year Ended December 31, 2018 Financial Results

For the year ended December 31, 2018, Opiant recorded approximately \$14.0 million in revenue, compared to approximately \$15.6 million in the year ended December 31, 2017. During the year ended December 31, 2018, Opiant recognized approximately \$13.3 million of revenue from the Adapt license for the sale of NARCAN® Nasal Spray. During the year ended December 31, 2017, Opiant recorded approximately \$11.7 million of revenue from the Adapt license and \$3.8 million from the sale of a certain portion of the Adapt license royalty streams to SWK Capital (“SWK”). This \$3.8 million payment from SWK was a one-time milestone payment, as provided under a royalty monetization agreement between Opiant and SWK.

General and administrative expenses for the year ended December 31, 2018, were approximately \$11.3 million, compared to approximately \$10.3 million for the year ended December 31, 2017. The increase was primarily attributable to a \$1.6 million increase in stock-based compensation expense, and a \$0.7 million increase in corporate overhead, which was partially offset by a \$1.3 million decrease in personnel and related expense.

Research and development expenses for the year ended December 31, 2018, were approximately \$8.5 million, compared to approximately \$4.9 million for the same period in 2017. The increase was primarily attributable to a \$1.5 million increase in third-party expenses associated with Opiant’s research and development programs, a \$1.5 million increase in stock-based compensation expense and a \$0.6 million increase in personnel and related expense.

Third-party license fees for the year ended December 31, 2018, were approximately \$13.7 million. The third-party license fees relate to the Adapt License. There were no third-party license fees for the year ended December 31, 2017.

Net loss for the year ended December 31, 2018, was approximately \$21.2 million, or a loss of (\$7.10) per basic and diluted share, compared to a net loss of approximately \$2.6 million, or (\$1.28) per basic and diluted share, for the year ended December 31, 2017. The significant increase in net loss for the year ended December 31, 2018, compared to the year ended December 31, 2017, was primarily due to the third-party license fees of \$5.6 million paid to Adapt in February of 2018 and \$8.1 million payable to Adapt under Amendment No. 2, dated March 18, 2019, to the Adapt License (“Amendment No. 2”).

At December 31, 2018, Opiant had cash and cash equivalents of approximately \$24.6 million, compared to approximately \$8.1 million at December 31, 2017. The cash balance at December 31, 2018, does not include the full impact of the NIDA grant of approximately \$7.4 million or the BARDA contract of approximately \$4.6 million. Opiant projects a cash balance of approximately \$17 million to \$20 million at the end of 2019. This anticipated range does not include the potential one-time milestone payment of \$13.5 million due to Opiant from Adapt should Net Sales of NARCAN® exceed \$200 million, pursuant to the Adapt License. Pursuant to the Adapt License, as amended by Amendment No. 2, in the event that this milestone is achieved, Adapt may reduce the amount payable to Opiant by the remaining \$2.7 million of the maximum \$8.1 million license fees payable.

Conference Call Details

Thursday, March 21st @ 4:30pm Eastern Time/1:30pm Pacific Time

Toll Free: 877-407-0792

International: 201-689-8263

Conference ID: 13688872

Webcast: <http://public.viavid.com/index.php?id=133676>

About Opiant Pharmaceuticals, Inc.

Opiant Pharmaceuticals, Inc. is a specialty pharmaceutical company developing medicines for addictions and drug overdose. NIDA, a division of the National Institutes of Health, describes addictive 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 drug overdose product, NARCAN® Nasal Spray, is approved for marketing in the U.S. and Canada by its licensee, Adapt Pharmaceuticals, now owned by Emergent BioSolutions, Inc. 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 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, 2018 and Form 10-KT for the transition period August 1 to December 31, 2017, filed with the Securities and Exchange Commission on March 21, 2019 and March 7, 2018, respectively, 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.

CONTACTS:

For Investor Relations:

Dan Ferry
Managing Director
LifeSci Advisors, LLC
Daniel@lifesciadvisors.com
(617) 535-7746

For Media Inquiries:

Julie Normart
W2O Group
jnormart@w2ogroup.com
(415) 946-1087

Opiant Pharmaceuticals, Inc.
Consolidated Balance Sheets
(in thousands, except shares and per share amounts)

	As of December 31, 2018	As of December 31, 2017
Assets		
Current Assets		
Cash & cash Equivalents	\$ 24,614	\$ 8,116
Accounts receivable	4,489	11,697
Deferred financing costs	-	209
Prepaid expenses and other current assets	267	733
Total Current Assets	29,370	20,755
Long-term Assets		
Computer equipment, net	-	1
Patents and patent applications, net	16	17
Total Assets	\$ 29,386	\$ 20,773
Liabilities and stockholders' equity		
Current Liabilities		
Accounts payable and accrued liabilities	\$ 1,133	\$ 3,157
License Fees	5,400	-
Accrued salaries and wages	1,084	713
Royalty payable	998	1,408
Deferred revenue	1,212	379
Total Current Liabilities	9,827	5,657
Long-Term Liabilities		
Deferred revenue	-	2,116
License Fees	2,700	-
Total Long-Term Liabilities	2,700	2,116
Total Liabilities	12,527	7,773
Stockholders' equity		
Common stock, \$0.001 par value, 200,000,000 shares authorized, 3,845,361 and 2,535,766 shares issued and outstanding at December 31, 2018 and 2017, respectively	4	2
Additional paid-in-capital	91,276	66,223
Accumulated deficit	(74,421)	(53,225)
Total stockholders' equity	16,859	13,000
Total liabilities and stockholders' equity	\$ 29,386	\$ 20,773

Opiant Pharmaceuticals Inc.
Consolidated Statements of Operations
(in thousands, except shares and per share amounts)

	Year ended December 31, 2018	Year ended December 31, 2017 (Unaudited)	Three months ended December 31, 2018 (Unaudited)	Three months ended December 31, 2017 (Unaudited)
Revenues				
Royalty & licensing revenue	\$ 13,262	\$ 15,447	\$ 4,375	\$ 11,697
Treatment investment income	251	105	81	51
Grant and contract revenue	469	-	307	-
Total Revenue	<u>13,982</u>	<u>15,552</u>	<u>4,763</u>	<u>11,748</u>
Operating Expenses				
General and administrative	11,264	10,313	2,647	4,430
Research and development	8,479	4,857	2,534	1,894
Royalty expense	1,491	1,408	954	1,408
License fees	13,725	-	-	-
Selling expense	214	851	148	439
Total expenses	<u>35,173</u>	<u>17,429</u>	<u>6,283</u>	<u>8,171</u>
Operating loss	(21,191)	(1,877)	(1,520)	3,577
Other income (expense)				
Interest income, net	145	34	114	5
Loss on settlement of accrued liability	(50)	48	-	81
Income (loss) on foreign exchange	(48)	(14)	(13)	(55)
Total other income	<u>47</u>	<u>68</u>	<u>101</u>	<u>31</u>
Net income (loss) before provision for income taxes	(21,144)	(1,809)	(1,419)	3,608
Provision for income taxes	\$ 51	\$ 797	\$ 18	\$ 246
Net income (loss)	<u>\$ (21,195)</u>	<u>\$ (2,606)</u>	<u>\$ (1,437)</u>	<u>\$ 3,362</u>
Net income (loss) per common share				
Basic & Diluted	<u>\$ (7.10)</u>	<u>\$ (1.28)</u>	<u>\$ (0.37)</u>	<u>\$ 1.59</u>
Weighted-average common shares outstanding:				
Basic & Diluted	<u>2,985,335</u>	<u>2,041,752</u>	<u>3,833,691</u>	<u>2,109,841</u>