

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 4, 2020

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.)

233 Wilshire Blvd. Suite 280
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.

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 2.02. Results of Operations and Financial Condition.

On March 4, 2020, Opiant Pharmaceuticals, Inc. (the “**Company**”), issued a press release announcing the Company’s financial results for the quarter and year ended December 31, 2019 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.

Exhibit No. Description

99.1 [Press Release of Opiant Pharmaceuticals, Inc., dated March 4, 2020.](#)

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 4, 2020 By: /s/ David O'Toole

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

Opiant Pharmaceuticals Reports Fourth Quarter and Full-Year 2019 Financial Results and Provides Corporate Update

SANTA MONICA, Calif., March 4, 2020 -- Opiant Pharmaceuticals, Inc. (“Opiant”) (NASDAQ: OPNT), a specialty pharmaceutical company developing medicines to treat addictions and drug overdose, today reported financial results for the fourth quarter and year ended December 31, 2019, and provided a corporate update.

“We continue to make good progress advancing our pipeline, and are excited about our expected 2020 milestones,” stated Roger Crystal, M.D., President and Chief Executive Officer of Opiant. “There is a large commercial opportunity for each of our products under development, including the market for opioid reversal agents, which we expect to reach approximately \$1 billion in 2022. While access to naloxone is critical to save lives, a substantial need continues to exist for stronger, longer-acting opioid antagonists due to the rapid increase in fentanyl-related overdoses. A new report from the Centers for Disease Control and Prevention showed that fentanyl-related drug overdose deaths in 2018 increased 10 percent from 2017.”

David O’Toole, Chief Financial Officer, added: “We are in a strong financial position as we begin 2020, including having our pipeline funded through government sources, and a royalty revenue stream from net sales of NARCAN® Nasal Spray.”

Corporate Highlights and Near-Term Milestones

- Signed a Letter of Intent with the National Center for Advancing Translational Sciences to collaborate on the development of OPNT004 (drinabant), a novel cannabinoid receptor antagonist, for the treatment of Acute Cannabinoid Overdose.
- Awarded the second tranche of approximately \$2.4 million from the total contract award of up to a maximum of approximately \$4.6 million from the Biomedical Advanced Research & Development Authority (BARDA), to accelerate Opiant’s development of OPNT003, nasal nalmefene.
- Entered into, in conjunction with Emergent BioSolutions Inc., through its Adapt Pharma subsidiaries, a settlement agreement to resolve the 2018 lawsuit filed against Perrigo UK FINCO Limited Partnership (Perrigo), related to Perrigo’s abbreviated new drug application (ANDA) seeking to market a generic version of NARCAN® (naloxone hydrochloride) Nasal Spray 4mg/spray.
- As of December 31, 2019, Opiant had cash and cash equivalents of \$31.9 million, compared to \$24.6 million at December 31, 2018.

Financial Results for the Fourth Quarter Ended December 31, 2019

For the three months ended December 31, 2019, Opiant recorded approximately \$7.7 million in revenue, compared to approximately \$4.8 million during the corresponding period of 2018. For the three months ended December 31, 2019, Opiant recognized approximately \$7.2 million of revenue from the license agreement (the Adapt License) between it and Adapt Pharma Operations Limited, now a subsidiary of Emergent BioSolutions Inc. (EBS), for the sale of NARCAN® Nasal Spray, compared to approximately \$4.4 million in the same period of 2018. The \$7.2 million of revenue from the license agreement between us and Adapt was attributable to

sales of NARCAN® Nasal Spray of approximately \$66.8 million for the three months ended December 31, 2019, as reported by EBS.

General and administrative expenses for the three months ended December 31, 2019, were approximately \$2.8 million, the same amount in the comparable period of 2018.

Research and development expenses for the three months ended December 31, 2019, were approximately \$2.0 million, as compared to approximately \$2.5 million in the comparable period in 2018. The decrease was primarily due to a \$0.5 million decrease in third-party expenses associated with Opiant's research and development programs.

Sales and marketing expenses for the three months ended December 31, 2019, were approximately \$471,000, compared to none in the comparable period of 2018. The increase was primarily due to compensation-related expenses and third-party consulting expense.

Royalty expense for the three months ended December 31, 2019, was approximately \$1.7 million, compared to approximately \$1.0 million in the comparable period of 2018. The increase was primarily due to payments to Net Profit Partners for the royalties received from the net sales of NARCAN® Nasal Spray.

Net income for the three months ended December 31, 2019, was approximately \$1.1 million, or \$0.26 per basic and \$0.20 per diluted share, compared to a net loss of approximately \$9.5 million, or a loss of (\$2.49) per basic and diluted share, for the comparable period of 2018.

Financial Results for the Year Ended December 31, 2019

For the year ended December 31, 2019, Opiant recorded approximately \$40.5 million in revenue, compared to approximately \$14.0 million during the corresponding period of 2018. For the year ended December 31, 2019, Opiant recognized approximately \$37.6 million of revenue the Adapt License for the sale of NARCAN® Nasal Spray, compared to approximately \$13.3 million in the comparable period of 2018. The \$24.3 million increase was attributable to \$10.8 million of royalty revenue from an increase in sales of NARCAN® Nasal Spray to approximately \$280 million for the 12 months ended December 31, 2019, as reported by EBS, and \$13.5 million from a one-time milestone payment, as sales of Narcan exceeded \$200 million through the third quarter of 2019.

General and administrative expenses for the year ended December 31, 2019, were approximately \$12.2 million, compared to approximately \$11.5 million in the comparable period of 2018. The increase was primarily due to a \$1.4 million increase in personnel and related expense, including recruiting, and an increase of \$0.9 million in legal and professional fees, partially offset by a \$1.6 million decrease in stock-based compensation expense.

Research and development expenses for the year ended December 31, 2019, were approximately \$9.1 million, compared to approximately \$8.5 million in the comparable period of 2018. The increase was primarily attributable to a \$1.1 million increase in third-party expenses associated with Opiant's research and development programs, and a \$0.6 million increase in employee-related compensation, partially offset by a decrease in stock-based compensation expense of \$1.1 million.

Sales and marketing expenses for the year ended December 31, 2019, were approximately \$612,000, compared to none in the same period of 2018. The increase was primarily due to compensation-related expense and third-party consulting expense.

Royalty expense for the year ended December 31, 2019, was approximately \$7.7 million, compared to approximately \$1.5 million in the same period in 2018. The increase was primarily due to a \$4.9 million increase in payments due to Net Profit Partners for the royalties and sales milestone received from the net sales of NARCAN® Nasal Spray and \$1.3 million for payments made to buyout the net profit interests in Nasal Nalmefene held by investors who had initially supported the development of NARCAN® Nasal Spray.

There were no license fees recorded for the year ended December 31, 2019. Opiant recorded \$13.7 million of license fees during the year ended December 31, 2018. The license fees related to Opiant's obligations under the Adapt License.

Net income for the year ended December 31, 2019, was approximately \$11.6 million, or \$2.88 per basic and \$2.17 per diluted share, compared to a net loss of approximately \$21.2 million, or a loss of (\$7.10) per basic and diluted share, for the comparable period of 2018.

As of December 31, 2019, Opiant had cash and cash equivalents of \$31.9 million, compared to \$24.6 million at December 31, 2018. The current cash balance does not include the full impact of the National Institute on Drug Abuse grant of approximately \$7.4 million or the BARDA contract of approximately \$4.6 million.

Based on the mid-range of the full-year 2020 guidance for sales of NARCAN® Nasal Spray provided by EBS, of \$300 million, we expect full-year 2020 royalty revenue from the Adapt License for the sale of NARCAN® Nasal Spray of approximately \$26.2 million.

Conference Call Details:

Wednesday, March 4th at 4:30 p.m. Eastern Time/1:30 p.m. Pacific Time

Toll Free: 877-407-0792

International: 201-689-8263

Conference ID: 13698569

Webcast: <http://public.viavid.com/index.php?id=137874>

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 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 same 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 filed quarterly reports on Form 10-Q and our annual report on Form 10-K for the year ended December 31, 2019, filed with the Securities and Exchange Commission on March 4, 2020, 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.

Investor Relations Contacts:

Ben Atkins

VP of Corporate Communications and Investor Relations

Batkins@opiant.com

Dan Ferry

Managing Director

LifeSci Advisors, LLC

Daniel@lifesciadvisors.com

(617) 430-7576

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

	As of December 31, 2019	As of December 31, 2018
Assets		
Current Assets		
Cash & cash Equivalents	\$ 30,981	\$ 24,614
Accounts receivable	7,218	4,489
Prepaid expenses and other current assets	1,056	267
Total Current Assets	39,255	29,370
Long-term Assets		
Property and equipment, net	243	-
Right of use assets - operating leases	769	-
Patents and patent applications, net	14	16
Total Assets	\$ 40,281	\$ 29,386
Liabilities and stockholders' equity		
Current Liabilities		
Accounts payable and accrued liabilities	\$ 1,317	\$ 1,133
License Fees	-	5,400
Accrued salaries and wages	1,238	1,084
Royalty payable	1,620	998
Deferred revenue	918	1,212
Operating leases - current	517	-
Total Current Liabilities	5,610	9,827
Long-Term Liabilities		
Operating leases - long term	255	-
License Fees	-	2,700
Total Long-Term Liabilities	255	2,700
Total Liabilities	5,865	12,527
Stockholders' equity		
Common stock, \$0.001 par value, 200,000,000 shares authorized, 4,186,438 and 3,845,361 shares issued and outstanding at December 31, 2019 and 2018, respectively	4	4
Additional paid-in-capital	97,240	91,276
Accumulated deficit	(62,828)	(74,421)
Total stockholders' equity	34,416	16,859
Total liabilities and stockholders' equity	\$ 40,281	\$ 29,386

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

	Year ended December 31, 2019	Year ended December 31, 2018	Three months ended December 31, 2019 (Unaudited)	Three months ended December 31, 2018 (Unaudited)
Revenues				
Royalty & licensing revenue	\$ 37,592	\$ 13,262	\$ 7,224	\$ 4,375
Treatment investment income	644	251	-	81
Grant and contract revenue	2,284	469	446	307
Total Revenue	40,520	13,982	7,670	4,763
Operating Expenses				
General and administrative	12,197	11,478	2,807	2,795
Research and development	9,079	8,479	2,036	2,534
Royalty expense	7,720	1,491	1,621	954
License fees	-	13,725	-	8,100
Sales & Marketing	612	-	471	-
Total expenses	29,608	35,173	6,935	14,383
Operating income (loss)	10,912	(21,191)	735	(9,620)
Other income (expense)				
Interest income, net	438	145	81	114
Gain (loss) on settlement of accrued liability	16	(50)	16	-
Gain (loss) on foreign exchange	50	(48)	115	(13)
Total other income	504	47	212	101
Net income (loss) before income taxes	11,416	(21,144)	947	(9,519)
Income tax (expense) benefit	177	(51)	121	(18)
Net income (loss)	\$ 11,593	\$ (21,195)	\$ 1,068	\$ (9,537)
Net income (loss) per common share				
Basic	\$ 2.88	\$ (7.10)	\$ 0.26	\$ (2.49)
Diluted	\$ 2.17	\$ (7.10)	\$ 0.20	\$ (2.49)
Weighted-average common shares outstanding:				
Basic	4,018,464	2,985,335	4,068,417	3,833,691
Diluted	5,342,378	2,985,335	5,472,139	3,833,691