

**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): May 12, 2020

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 2.02. Results of Operations and Financial Condition.

On May 12, 2020, Opiant Pharmaceuticals, Inc. (the “**Company**”), issued a press release announcing the Company’s financial results for the quarter ended March 31, 2020 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>
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<u>99.1</u>	<u>Press Release of Opiant Pharmaceuticals, Inc., dated May 12, 2020.</u>
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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: May 12, 2020 By: /s/ David D. O'Toole

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

Opiant Pharmaceuticals Announces First Quarter 2020 Financial Results and Corporate Update

SANTA MONICA, Calif., May 12, 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 three months ended March 31, 2020, and provided a corporate update. Recent highlights include:

- *Strong financial position:*
 - o *Q1 2020 revenues of \$4.3 million driven by NARCAN® Nasal Spray ("NARCAN®") royalties of \$4.2 million, an increase of 12 percent year-over-year*
 - o *Projected royalties for the full-year 2020 of approximately \$26.2 million, reiterated based on Emergent BioSolutions Inc. ("EBS") revenue guidance for NARCAN®*
 - o *Cash and cash equivalents of \$32.2 million and no debt as of March 31, 2020*
- *Update on submission of a New Drug Application ("NDA") to the U.S. Food and Drug Administration ("FDA") for Opiant's lead development program, OPNT003, nasal nalmefene, for opioid overdose:*
 - o *FDA removed its clinical hold on OPNT003, allowing Opiant to proceed with pharmacokinetic ("PK") study*
 - o *Reached agreement with the FDA on the design of a pharmacodynamic ("PD") study in healthy volunteers to support the OPNT003 NDA application*
 - o *OPNT003 development program impacted by prolonged COVID-19 related travel restrictions on manufacturing equipment engineers in Europe*
 - o *Opiant now expects to file an NDA in early 2021*
- *Executed a cooperative research and development agreement with the National Center for Advancing Translational Sciences ("NCATS") to formulate OPNT004 for human studies in Acute Cannabinoid Overdose*
- *Paused initiation of recruitment for planned Phase 2 study of OPNT002 for Alcohol Use Disorder due to ongoing COVID-19 global health pandemic*

"These results highlight our unique position: cash-strong, no debt, and with an increasing royalty stream from sales of NARCAN® supporting our robust pipeline across multiple compelling therapy areas in addiction and overdose," said Roger Crystal, M.D., President and Chief Executive Officer of Opiant. "We also have the financial support and collaboration of multiple government agencies, including the National Institute on Drug Abuse ("NIDA"), NCATS, and the Biomedical Advanced Research and Development Authority ("BARDA")."

Speaking about OPNT003, Dr. Crystal added: "We are pleased that the FDA has removed its clinical hold on OPNT003 for opioid overdose reversal. As we previously reported in January, the FDA placed our development of OPNT003 on hold as it reviewed certain characteristics of the intranasal delivery device. After reviewing our response, the FDA removed its clinical hold based on our agreement to amend slightly our PK study protocol. Therefore, we can move

forward with our study as soon as feasible. Separately, we have agreed with the FDA on the design of a short PD study in healthy volunteers that we believe will enhance the clinical profile of OPNT003. As we progress towards our regulatory filing for OPNT003, we are also having to factor into our timeline the impact of prolonged COVID-19 related travel restrictions on our equipment engineers in Europe. Based on these collective modifications to our OPNT003 development program, our NDA filing is now likely to occur in early 2021.”

David O’Toole, Chief Financial Officer of Opiant, said: “We are well-positioned financially with significant cash, no debt and no need to access government programs in the United States or United Kingdom for COVID-19-related financial assistance or relief. Our pipeline investments and overall financial position continue to benefit from a resilient stream of revenue from the sales of NARCAN®.”

First quarter 2020 results

For the three months ended March 31, 2020, Opiant recorded approximately \$4.3 million in revenue, compared to approximately \$5.4 million during the corresponding period of 2019. The first quarter of 2019 included \$1.7 million in revenue from the NIDA grant and the contract from BARDA. For the three months ended March 31, 2020, we recorded approximately \$4.2 million of revenue from our license agreement with EBS for the sale of NARCAN®, compared to approximately \$3.7 million in the same period of 2019. First-quarter 2020 sales of NARCAN® were approximately \$72.2 million, as reported by EBS.

General and administrative expenses for the quarter were approximately \$2.6 million, compared to approximately \$3.4 million for the same period of 2019. The \$0.8 million decrease is primarily attributable to a decrease in stock-based compensation and legal expenses.

Research and development expenses were approximately \$1.4 million, as compared to approximately \$3.6 million in the first three months of 2019. The \$2.2 million decrease was primarily attributable to a reduction in third-party clinical trial and development expense.

Sales and marketing expenses were approximately \$1.1 million, compared to none during the first three months in 2019. As Opiant continues to advance OPNT003 towards potential market approval, we anticipate that our sales and marketing expenses will increase in several areas to support the development of a commercial platform that would allow Opiant to potentially commercialize OPNT003, as well as future pipeline products.

Royalty expense for the first quarter was approximately \$0.9 million due for payments to Net Profit Partners for the royalties received from the net sales of NARCAN®.

Net loss for the first quarter was approximately \$1.7 million, or a loss of \$0.40 per basic and diluted share, compared to a net loss of approximately \$1.7 million, or a loss of \$0.44 per basic and diluted share, for the comparable period of 2019.

As of March 31, 2020, Opiant had cash and cash equivalents of \$32.2 million, compared to approximately \$31 million at December 31, 2019. The current cash balance does not include the full impact of the NIDA grant of approximately \$7.4 million or the BARDA contract of approximately \$4.6 million.

Conference Call Details:**Tuesday, May 12th at 4:30 p.m. Eastern Time/1:30 p.m. Pacific Time**

Toll Free: 877-407-0792

International: 201-689-8263

Conference ID: 13702897

Webcast: <http://public.viavid.com/index.php?id=139556>**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.

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

	As of March 31, 2020	As of December 31, 2019
	(unaudited)	
Assets		
Current Assets		
Cash & cash Equivalents	\$ 32,198	\$ 30,981
Accounts receivable	4,205	7,218
Prepaid expenses and other current assets	1,023	1,056
Total Current Assets	37,426	39,255
Other assets		
Property and equipment, net	199	243
Right of use assets - operating leases	628	769
Patents and patent applications, net	14	14
Total Assets	\$ 38,267	\$ 40,281
Liabilities and stockholders' equity		
Current Liabilities		
Accounts payable and accrued liabilities	\$ 1,450	\$ 1,317
Accrued salaries and wages	599	1,238
Royalty payable	934	1,620
Deferred revenue	843	918
Operating leases - current	500	517
Total Current Liabilities	4,326	5,610
Long-Term Liabilities		
Operating leases - long term	131	255
Total Long-Term Liabilities	131	255
Total Liabilities	4,457	5,865
Stockholders' equity		
Common stock, \$0.001 par value, 200,000,000 shares authorized, 3,925,361 and 3,845,361 shares issued and outstanding at March 31, 2019 and December 31, 2018, respectively	4	4
Additional paid-in-capital	98,611	97,240
Foreign Currency Translation Adjustment	(293)	-
Accumulated deficit	(64,512)	(62,828)
Total stockholders' equity	33,810	34,416
Total liabilities and stockholders' equity	\$ 38,267	\$ 40,281

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

	<u>Three months ended</u> <u>March 31,</u> <u>2020</u> <u>(Unaudited)</u>	<u>Three months ended</u> <u>March 31,</u> <u>2019</u> <u>(Unaudited)</u>
Revenues		
Royalty & licensing revenue	\$ 4,199	\$ 3,746
Treatment investment income	-	80
Grant and contract revenue	84	1,609
Total Revenue	<u>4,283</u>	<u>5,435</u>
Operating Expenses		
General and administrative	2,573	3,382
Research and development	1,421	3,567
Sales & marketing	1,077	-
Royalty expense	934	314
Total expenses	<u>6,005</u>	<u>7,263</u>
Loss from operations	(1,722)	(1,828)
Other income (expense)		
Interest income, net	76	122
Loss on foreign exchange	-	(30)
Total other income (expense)	<u>76</u>	<u>92</u>
Loss before provision for income taxes	(1,646)	(1,736)
Income tax expense	(39)	-
Net loss	<u>\$ (1,685)</u>	<u>\$ (1,736)</u>
Other comprehensive loss:		
Foreign currency translation loss adjustment	(293)	-
Comprehensive loss	<u>\$ (1,978)</u>	<u>\$ (1,736)</u>
Net loss per common share		
Basic & Diluted	<u>\$ (0.40)</u>	<u>\$ (0.44)</u>
Weighted-average common shares outstanding:		
Basic & Diluted	<u>4,224,555</u>	<u>3,909,702</u>