

**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 9, 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 May 9, 2019, Opiant Pharmaceuticals, Inc. (the “**Company**”), issued a press release announcing the Company’s financial results for the first quarter ended March 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.

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release of Opiant Pharmaceuticals, Inc., dated May 9, 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: May 9, 2019 By: /s/ David D. O'Toole

Name: David D. O'Toole

Title: Chief Financial Officer

Opiant Pharmaceuticals Reports First Quarter 2019 Financial Results and Provides Corporate Update

SANTA MONICA, Calif, May 9, 2019 – Opiant Pharmaceuticals, Inc. (“Opiant”) (NASDAQ: OPNT), a specialty pharmaceutical company developing medicines for addictions and drug overdose, today reported financial results for the three months ended March 31, 2019, and provided a corporate update.

“We continue to advance our addiction and drug overdose-focused pipeline, and are committed to validating the data in peer-reviewed journals,” said Roger Crystal, M.D., Chief Executive Officer of Opiant. “Clinical pharmacokinetic (PK) data for OPNT003, nasal nalmefene, were published online in the *Journal of Pharmacology and Experimental Therapeutics*. These data further validate its potential as a rescue medication that is especially well-suited to treat an overdose of a synthetic opioid, such as fentanyl. We remain on track to conduct a pivotal PK study for OPNT003 this year. The goal of this study is to replicate the findings from the pilot PK study. Top-line data are expected later this year.”

“A second publication recently appeared online in *The Journal of Clinical Pharmacology*, supporting OPNT002, nasal naltrexone, as a potential treatment for Alcohol Use Disorder (AUD),” continued Dr. Crystal. “With a plasma half-life essentially identical to naloxone, OPNT002 is well-suited for “on-demand” dosing to treat AUD. The results and insights from this study formed the basis for our OPNT002 formulation selection study in AUD, which is expected to begin in the current quarter, followed by the enrollment of patients in a Phase 2 study later this year. We anticipate the completion of the Phase 2 trial in the second half of 2020.”

“We are very excited about our pipeline and the large market opportunities we are targeting. We truly believe that the drugs we are developing have the potential to impact thousands of lives and we look forward to continuing to advance each into the clinic. Importantly, our development plans are well-supported by our financial resources, with cash of approximately \$23.8 million at March 31, 2019, and funding from the National Institutes of Health (NIH) and Biomedical Advanced Research and Development Authority (BARDA),” concluded Dr. Crystal.

Recent Corporate Highlights

- Awarded second tranche of \$3.0 million from the total grant of approximately \$7.4 million from the NIH’s National Institute on Drug Abuse (NIDA) for the development of OPNT003, nasal nalmefene
- Clinical PK data for OPNT003, nasal nalmefene, were published online in the *Journal of Pharmacology and Experimental Therapeutics*, and presented in April at the annual meeting of the American Society for Pharmacology and Experimental Therapeutics
- Clinical PK data for OPNT002, nasal naltrexone, were published online in *The Journal of Clinical Pharmacology*

Financial Results for the First Quarter Ended March 31, 2019

For the three months ended March 31, 2019, Opiant recorded approximately \$5.4 million in revenue, compared to approximately \$1.7 million during the corresponding period of 2018. For the three months ended March 31, 2019, Opiant recognized approximately \$3.7 million of

revenue from the license agreement (the “Adapt License”) between it and Adapt Pharma Operations Limited, a subsidiary of Emergent BioSolutions Inc. (“EBS”) for the sale of NARCAN® Nasal Spray, compared to approximately \$1.6 million in the comparable period of 2018. The \$2.1 million increase in royalty revenue was attributable to a significant increase in sales of NARCAN® Nasal Spray to approximately \$65.5 million for the first quarter of 2019, as reported by EBS.

General and administrative expenses for the three months ended March 31, 2019, were approximately \$3.7 million, compared to approximately \$3.0 million in the comparable period of 2018. The increase was primarily due to a \$0.3 million increase in royalty expense and a \$0.4 million increase in legal and professional expenses.

Research and development expenses for the three months ended March 31, 2019, were approximately \$3.6 million, compared to approximately \$2.4 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.

Opiant did not record any license fees for the three months ended March 31, 2019.

Net loss for the three months ended March 31, 2019, was approximately \$1.7 million, or a loss of (\$0.44) per basic and diluted share, compared to a net loss of approximately \$9.3 million, or (\$3.68) per basic and diluted share, for the comparable period of 2018.

As of March 31, 2019, Opiant had cash and cash equivalents of \$23.8 million, compared to approximately \$24.6 million at December 31, 2018. The cash balance at March 31, 2019, 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 continues to project 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 EBS should Net Sales of NARCAN® exceed \$200 million in the 2019 calendar year. Pursuant to the Adapt License, as amended by Amendment No. 2 on March 18, 2019, in the event that this milestone is achieved, EBS 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, May 9th @ 4:30pm Eastern Time/1:30pm Pacific Time

Toll Free: 877-407-0792

International: 201-689-8263

Conference ID: 13689678

Webcast: <http://public.viavid.com/index.php?id=134030>

About Opiant Pharmaceuticals, Inc.

Opiant Pharmaceuticals, Inc. is a specialty pharmaceutical company developing medicines for addictions and drug overdose. NIDA, a division of the NIH, describes addictive disorders as chronic relapsing brain diseases which burden society at both the individual and community levels. 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, filed with the Securities and Exchange Commission on March 21, 2019, 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 share and per share data)

	As of March 31, 2019	As of December 31, 2018
	(unaudited)	
Assets		
Current Assets		
Cash & cash Equivalents	\$ 23,768	\$ 24,614
Accounts receivable	1,956	4,489
Prepaid expenses and other current assets	522	268
Total Current Assets	26,246	29,371
Other assets		
Patents and patent applications, net	15	16
Total Assets	\$ 26,261	\$ 29,387
Liabilities and stockholders' equity		
Current Liabilities		
Accounts payable and accrued liabilities	\$ 1,482	\$ 1,133
License Fees	6,300	5,400
Accrued salaries and wages	618	1,084
Royalty payable	314	998
Deferred revenue	757	1,212
Total Current Liabilities	9,471	9,827
Long-Term Liabilities		
License Fees	-	2,700
Total Long-Term Liabilities	-	2,700
Total Liabilities	9,471	12,527
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	92,943	91,276
Accumulated deficit	(76,157)	(74,421)
Total stockholders' equity	16,790	16,859
Total liabilities and stockholders' equity	\$ 26,261	\$ 29,386

Opiant Pharmaceuticals, Inc.
Condensed Consolidated Statements of Operations
(unaudited)

(In thousands, except share and per share data)

	<u>Three months ended</u> <u>March 31,</u> <u>2019</u> <u>(Unaudited)</u>	<u>Three months ended</u> <u>March 31,</u> <u>2018</u> <u>(Unaudited)</u>
Revenues		
Royalty & licensing revenue	\$ 3,746	\$ 1,649
Treatment investment income	80	54
Grant and contract revenue	<u>1,609</u>	<u>-</u>
Total Revenue	5,435	1,703
Operating Expenses		
General and administrative	3,696	2,965
Research and development	3,567	2,421
License fees	<u>-</u>	<u>5,625</u>
Total expenses	<u>7,263</u>	<u>11,011</u>
Loss from operations	(1,828)	(9,308)
Other income (expense)		
Interest income	122	5
Loss on foreign exchange	<u>(30)</u>	<u>(8)</u>
Total other income (expense)	<u>92</u>	<u>(3)</u>
Loss before provision for income taxes	(1,736)	(9,311)
Provision for income taxes	\$ -	\$ 33
Net loss	<u>\$ (1,736)</u>	<u>\$ (9,344)</u>
Net loss per common share		
Basic & Diluted	<u>\$ (0.44)</u>	<u>\$ (3.68)</u>
Weighted-average common shares outstanding:		
Basic & Diluted	<u>3,909,702</u>	<u>2,542,084</u>