

**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 11, 2021

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 May 11, 2021, Opiant Pharmaceuticals, Inc. (the “**Company**”), issued a press release announcing the Company’s financial results for the quarter ended March 31, 2021 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 May 11, 2021](#)

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 11, 2021

By: /s/ David D. O'Toole

Name: David D. O'Toole

Title: Chief Financial Officer

Opiant Pharmaceuticals Announces First Quarter 2021 Financial Results and Corporate Update

SANTA MONICA, Calif., May 11, 2021 -- 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, 2021, and provided a corporate update. Recent highlights include:

Pipeline and Corporate Update

- *OPNT003, nasal nalmefene, for opioid overdose:*
 - *Confirmatory pharmacokinetic ("PK") study close to completing enrollment and on track to report data in early Q3*
 - *First subjects dosed in head-to-head clinical pharmacodynamic ("PD") study comparing the effectiveness of OPNT003, nasal nalmefene, with nasal naloxone; data anticipated in the fourth quarter*
 - *Other drug development activities necessary for NDA filing on track to deliver data by year-end*
 - *The Center for Disease Control released provisional data for the year ending September 2020:*
 - *66,813 overdose were caused by opioids (predicted)*
 - *80% or 53,877 opioid overdose deaths (predicted) were linked to illicit synthetic opioids, and particularly fentanyl*
 - *Awarded third and final tranche of \$1.8 million from the total grant of approximately \$7.4 million from the National Institute on Drug Abuse ("NIDA"), part of the National Institutes of Health, to support the development of OPNT003*
- *OPNT004, drinabant, for Acute Cannabinoid Overdose:*
 - *Preclinical activities and formulation development on track to support an IND for parenteral administration*
- *OPNT002, nasal naltrexone, for Alcohol Use Disorder:*
 - *Start of Phase 2 study, which was paused due to the ongoing COVID-19 pandemic, remains on pause; Company is assessing optimal time to proceed*
- *Strengthened board of directors with the addition of seasoned clinical development executive, Lorianne Masuoka, M.D., in March 2021*

Financial Highlights

- Q1 revenues of \$6.4 million driven by royalties from the sale of NARCAN® Nasal Spray ("NARCAN®")
- As of March 31, 2021, \$50.6 million in cash, cash equivalents, and marketable securities

Commenting, Roger Crystal, M.D., President and Chief Executive Officer of Opiant, said:

“Opiant had a strong start to 2021, including the commencement of our confirmatory PK and PD studies for OPNT003, nasal nalmefene, for opioid overdose. Our comprehensive development of OPNT003 is indicative of our firm commitment to delivering new medicines to save lives from addictions and drug overdose and support public health in the face of a worsening drug overdose crisis driven primarily by opioids. We believe OPNT003 may be particularly effective for the treatment of overdoses from synthetic opioids, like fentanyl, which is the leading cause of drug overdose death in America.”

David O’Toole, Chief Financial Officer of Opiant, said:

“We remain in a strong financial position to support our ongoing drug development activities and clinical studies, as well as to ramp up pre-commercial efforts for our lead program, OPNT003.”

First quarter 2021 results

For the three months ended March 31, 2021, Opiant recorded approximately \$6.4 million in revenue, compared to approximately \$4.3 million during the corresponding period of 2020. For the three months ended March 31, 2021, we recorded approximately \$4.3 million of revenue from our license agreement with Emergent BioSolutions, Inc. (“EBS”) for the sale of NARCAN®, compared to approximately \$4.2 million in the same period of 2020. First quarter 2021 sales of NARCAN® were approximately \$74.2 million, as reported by EBS.

For the three months ended March 31, 2021, general and administrative expenses were approximately \$2.6 million, the same as the comparable period of 2020.

Research and development expenses for the three months ended March 31, 2021, were approximately \$4.1 million, as compared to approximately \$1.4 million in the comparable period in 2020. External development expense increased by \$2.6 million due to increased activity on our lead product candidate, OPNT003 - Nasal Nalmefene. In addition, personnel and related expense increased by approximately \$0.1 million during the three months ended March 31, 2021 compared to the three months ended March 31, 2020.

Sales and marketing expenses for the three months ended March 31, 2021, were approximately \$1.0 million for pre-commercialization efforts related to OPNT003, nasal nalmefene. Sales and marketing expense during the three months ended March 31, 2020 was approximately \$1.1 million.

Royalty expense for the three months ended March 31, 2021, was approximately \$1 million, compared to \$0.9 million for the comparable period of 2020.

Net loss for the three months ended March 31, 2021, was approximately \$2.8 million, or a loss of \$0.66 per basic and diluted share, compared to net loss of approximately \$1.7 million, or a loss of \$0.40 per basic and diluted share, for the comparable period of 2020.

As of March 31, 2021, Opiant had \$50.6 million in cash, cash equivalents, and marketable securities. Current cash balance does not include the full impact of the NIDA grant of

approximately \$7.4 million or the Biomedical Advanced Research and Development Authority contract of approximately \$8.1 million.

Based on the mid-range of the full-year 2021 guidance for sales of NARCAN® Nasal Spray provided by EBS, of \$315 million, we continue to expect full-year 2021 royalty revenue from the sale of NARCAN® Nasal Spray of approximately \$27.8 million. We also expect to end 2021 with cash and cash equivalents of approximately \$40 million, which will not include any receipt of additional tranches of the convertible debt deal.

Conference Call Details:

Tuesday, May 11th at 4:30 p.m. Eastern Time/1:30 p.m. Pacific Time

Toll Free: 877-407-0792

International: 201-689-8263

Conference ID: 13718590

Webcast: <http://ir.opiant.com/>

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, 2020, filed with the Securities and Exchange Commission on March 4, 2021, 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:

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VP of Corporate Communications and Investor Relations

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(310) 598-5410

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

	As of March 31, 2021 <small>(unaudited)</small>	As of December 31, 2020
Assets		
Current assets		
Cash & cash Equivalents	\$ 35,450	\$ 48,251
Marketable securities	12,598	-
Accounts receivable	5,609	8,911
Prepaid expenses and other current assets	2,447	1,937
Total current assets	56,104	59,099
Other assets		
Marketable securities	2,501	-
Property and equipment, net	140	171
Right of use assets - operating leases	146	279
Patents and patent applications, net	12	13
Other non-current assets	-	1,051
Total assets	\$ 58,903	\$ 60,613
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable and accrued liabilities	\$ 3,680	\$ 2,966
Accrued salaries and wages	481	909
Royalty payable	980	1,908
Deferred revenue	859	355
Operating leases	149	282
Total current liabilities	6,149	6,420
Long-term liabilities		
Convertible debt, net of unamortized discount	18,769	18,701
Total long-term liabilities	18,769	18,701
Total liabilities	24,918	25,121
Stockholders' equity		
Common stock, \$0.001 par value, 200,000,000 shares authorized, 4,330,594 and 4,258,105 shares issued and outstanding at March 31, 2021 and December 31, 2020, respectively	4	4
Additional paid-in-capital	101,529	100,204
Accumulated other comprehensive loss	(15)	(27)
Accumulated deficit	(67,533)	(64,689)
Total stockholders' equity	33,985	35,492
Total liabilities and stockholders' equity	\$ 58,903	\$ 60,613

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>2021</u> <u>(Unaudited)</u>	<u>Three months ended</u> <u>March 31,</u> <u>2020</u> <u>(Unaudited)</u>
Revenues		
Royalty revenue	\$ 4,334	\$ 4,199
Grant and contract revenue	2,053	84
Total Revenue	<u>6,387</u>	<u>4,283</u>
Operating expenses		
General and administrative	2,646	2,573
Research and development	4,088	1,421
Sales & marketing	998	1,077
Royalty expense	980	934
Total expenses	<u>8,712</u>	<u>6,005</u>
Loss from operations	(2,325)	(1,722)
Other income (expense)		
Interest income	3	76
Interest expense	(537)	-
Loss on foreign exchange	14	-
Total other income (expense)	<u>(520)</u>	<u>76</u>
Loss before provision for income taxes	(2,845)	(1,646)
Income tax expense	-	39
Net loss	<u>\$ (2,845)</u>	<u>\$ (1,685)</u>
Other comprehensive loss:		
Foreign currency translation adjustment	13	(293)
Comprehensive loss	<u>\$ (2,832)</u>	<u>\$ (1,978)</u>
Net loss per common share		
Basic & Diluted	<u>\$ (0.66)</u>	<u>\$ (0.40)</u>
Weighted-average common shares outstanding:		
Basic & Diluted	<u>4,282,923</u>	<u>4,224,555</u>