

**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 10, 2022**

**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 400  
Santa Monica, CA**

(Address of Principal Executive Offices)

**90401**

(Zip Code)

**(310) 598 5410**

Registrant's telephone number, including area code

**233 Wilshire Blvd. Suite 400, Santa Monica, CA 90401**

(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 10, 2022, Opiant Pharmaceuticals, Inc. (the “**Company**”), issued a press release announcing the Company’s financial results for the first quarter ended March 31, 2022 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

<a href="#">99.1</a>	<a href="#">Press Release of Opiant Pharmaceuticals, Inc., dated May 10, 2022</a>
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

## 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.

Dated: May 10, 2022

**OPIANT PHARMACEUTICALS, INC.**

By: /s/ David D. O'Toole

Name: David D. O'Toole

Title: Chief Financial Officer

## Opiant Pharmaceuticals Announces First Quarter 2022 Financial Results and Provides Corporate Update

**SANTA MONICA, Calif., May 10, 2022** -- 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, 2022, and provided a corporate update. Recent highlights include:

### Finance Update

- *Q1 revenues of \$4.5 million; \$2.2 million of revenue was attributable to the license agreement with Emergent BioSolutions, Inc. ("EBS") for the sale of NARCAN® Nasal Spray*
  - *The royalty rate reduced in Q1 due to EBS applying the "Generic Reduction Clause" contained in the License Agreement*
- *Well capitalized, with approximately \$50.8 million in cash, cash equivalents and marketable securities, as of March 31, 2022*

### Pipeline Update

- *OPNT003, nasal nalmefene, for opioid overdose:*
  - *Reported positive topline results from a pharmacodynamic ("PD") study for OPNT003, nasal nalmefene*
    - *OPNT003 met the primary endpoint of non-inferiority, which was designed to assess whether nasal nalmefene performed at least as well as nasal naloxone*
    - *OPNT003 produced, at the primary end point of five minutes, a greater reversal in remifentanyl-induced respiratory depression that was nearly twice that produced by nasal naloxone*
    - *Additional analyses of select secondary endpoints show that at 5 minutes after administration, nasal nalmefene achieved a reversal of remifentanyl-induced respiratory depression to values that were within the 95% confidence interval ("CI") of the minute ventilation observed just prior to remifentanyl infusion. This reversal was maintained through 20 minutes. Nasal naloxone achieved a similar reversal of minute ventilation only at 20 minutes*
    - *Completion of the PD study concludes the planned clinical development program for OPNT003*
  - *On track to complete New Drug Application ("NDA") for OPNT003 in H2 2022, following completion of recent pre-NDA meeting*
  - *Commercial preparations continue to advance for a potential commercial launch in 2023; Centers for Disease Control and Prevention ("CDC") provisional data confirms more than 80,000 people died of opioid overdose in 2021, a 16% increase over 2020*
- *OPNT002, nasal naltrexone, for Alcohol Use Disorder ("AUD"):*
  - *Continued patient enrollment and dosing in Phase 2 study; data expected in H1 2023*

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

“The latest CDC data have put a spotlight on the continued worsening of the opioid crisis. The need for new safe and effective opioid overdose reversal treatments is greater than ever, and at Opiant we’ve made strong progress advancing the OPNT003, nasal nalmeferene, development program. The compelling results of the recently completed PD study versus nasal naloxone add to the significant body of clinical and non-clinical evidence demonstrating the potential of our late-stage product candidate to offer an important treatment option for opioid overdose. With the planned clinical development program for OPNT003 now concluded, we have met with the FDA, and feel we are well-positioned to submit our NDA for OPNT003, which we anticipate occurring in the second half of this year. On the commercial front, preparations continue at pace. Beyond OPNT003, our robust pipeline also continues to progress, as patient enrollment and dosing ramp up in our ongoing Phase 2 study of OPNT002, nasal naltrexone, for alcohol use disorder.”

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

“From a capital resource perspective, we ended the first quarter with approximately \$51 million of cash and continue to prudently manage our expenses, enabling us to execute on our key commercial and R&D initiatives. We look forward to multiple potentially value enhancing regulatory, commercial and clinical catalysts in the quarters ahead.”

#### **Financial Results for the First Quarter Ended March 31, 2022**

For the three months ended March 31, 2022, Opiant recorded approximately \$4.5 million in revenue, compared to approximately \$6.4 million during the corresponding period of 2021. \$2.2 million of revenue was attributable to the license agreement with Emergent BioSolutions, Inc., (“EBS”) for the sale of NARCAN® Nasal Spray, compared to approximately \$4.3 million in the same period of 2021. Approximately \$2.3 million came from grant and contract revenue, compared to approximately \$2.1 million in the same period in 2021. First quarter 2022 sales of NARCAN® Nasal Spray were approximately \$93.1 million, as reported by EBS.

The decrease in royalty rate was due to EBS applying the “Generic Reduction Clause,” which is provided for in the License Agreement between Opiant and Adapt Pharma. Since the generic entry of nasal naloxone into the U.S. marketplace in December of 2021, to the extent the clause is rightfully triggered, EBS can reduce royalties payable to Opiant to 2% for the quarter in the event U.S. net sales decrease by greater than 30% during the quarter when compared to the net NARCAN® sales in the quarter before the launch of the generic. The clause states that this calculation is completed separately each quarter, which means that the application of the Generic Reduction Clause this quarter has no bearing on whether it is triggered in the remaining quarters of 2022.

For the three months ended March 31, 2022, general and administrative (“G&A”) expenses were approximately \$4.4 million, as compared to approximately \$2.6 million in the comparable period in 2021. The \$1.9 million increase was due to a \$1.2 million increase in employee costs, including stock-based compensation and a \$0.7 million increase in legal fees.

Research and development (“R&D”) expenses for the three months ended March 31, 2022, were approximately \$8.8 million, as compared to approximately \$4.1 million in the comparable period in 2021. The \$4.7 million increase was primarily due to expenses associated with the completion of the clinical work for OPNT003. Approximately \$2.2 million of the increase was offset by reimbursement by the contract with Biomedical Advanced Research and Development Authority (“BARDA”).

Sales and marketing (“S&M”) expenses for the three months ended March 31, 2022, were approximately \$2.7 million for pre-commercialization efforts related to OPNT003.

Royalty expense for the three months ended March 31, 2022, was approximately \$0.4 million and \$1.0 million for the comparable period of 2021. The \$0.6 million decrease was due to decreased royalty revenue from net sales of NARCAN® Nasal Spray.

Net loss for the three months ended March 31, 2022, was approximately \$12.2 million, or a loss of \$2.43 per basic and diluted share, compared to a net loss of approximately \$2.8 million, or loss of \$0.66 per basic and diluted share, for the comparable period of 2021.

As of March 31, 2022, Opiant had approximately \$50.8 million in cash, cash equivalents, and marketable securities.

The OPNT003 development program has been funded in part with Federal funds from the Department of Health and Human Services; Office of the Assistant Secretary for Preparedness and Response; Biomedical Advanced Research and Development Authority, under Contract No. HHSO100201800029C.

**Conference Call Details:**

**Tuesday, May 10th at 4:30 p.m. Eastern Time/1:30 p.m. Pacific Time**

Toll Free: 1-877-407-0792

International: 1-201-689-8263

Conference ID: 13728852

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](http://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 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, submit a New Drug Application in the second half of 2022. 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, 2021, filed with the Securities and Exchange Commission on March 4, 2022, 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

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(310) 598-5410

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

	Three months ended March 31,	
	2022	2021
Revenues		
Royalty revenue	\$ 2,193	\$ 4,334
Grant and contract revenue	2,277	2,053
Total revenue	<u>4,470</u>	<u>6,387</u>
Operating expenses		
General and administrative	4,332	2,646
Research and development	8,823	4,088
Sales and marketing	2,677	998
Royalty expense	426	979
Total operating expenses	<u>16,258</u>	<u>8,711</u>
Loss from operations	(11,788)	(2,324)
Other income (expense)		
Interest income	5	3
Interest expense	(421)	(537)
Gain on foreign exchange	16	14
Total other income (expense)	<u>(400)</u>	<u>(520)</u>
Loss before income taxes	(12,188)	(2,844)
Income tax expense	-	-
Net loss	<u>\$ (12,188)</u>	<u>\$ (2,844)</u>
Other comprehensive loss		
Foreign currency translation adjustment	(27)	13
Total other comprehensive loss	<u>\$ (12,215)</u>	<u>\$ (2,831)</u>
Net loss per common share		
Basic and Diluted	<u>\$ (2.43)</u>	<u>\$ (0.66)</u>
Weighted-average common shares outstanding:		
Basic and Diluted	<u>5,015,262</u>	<u>4,282,923</u>

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

	As of March 31 2022 (unaudited)	As of December 31, 2021
<b>Assets</b>		
Current Assets		
Cash & cash equivalents	\$ 48,325	\$ 37,854
Marketable securities	2,500	\$ 15,015
Accounts receivable	4,454	13,327
Prepaid and other current assets	3,881	2,963
Total Current Assets	59,160	69,159
Other Assets		
Property and equipment, net	71	78
Right of use assets - operating leases	875	1,000
Patents and patent applications, net	11	12
Other non-current assets	202	179
Total Assets	\$ 60,319	\$ 70,428
<b>Liabilities and stockholders' equity</b>		
Current Liabilities		
Accounts payable and accrued expenses	\$ 5,319	\$ 3,370
Accrued salaries & wages	760	202
Royalty payable	426	2,920
Deferred revenue	-	17
Operating leases	283	338
Total Current Liabilities	6,788	6,847
Long-Term Liabilities		
Operating leases - long term	608	673
Convertible debt - net of unamortized discount	13,660	16,069
Total Long-Term Liabilities	14,268	16,742
Total Liabilities	21,056	23,589
Stockholders' equity		
Common stock, \$0.001 par value, 200,000,000 shares authorized, 5,079,605 and 4,909,846 shares issued and outstanding at March 31, 2022 and December 31, 2021, respectively	5	4
Additional paid-in-capital	113,208	108,570
Accumulated other comprehensive loss	(82)	(55)
Accumulated deficit	(73,868)	(61,680)
Total stockholders' equity	39,263	46,839
Total liabilities and stockholders' equity	\$ 60,319	\$ 70,428