

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 15, 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 280, 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 March 15, 2022, Opiant Pharmaceuticals, Inc. (the “**Company**”), issued a press release announcing the Company’s financial results for the fourth quarter and full year ended December 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 March 15, 2022
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: March 15, 2022

OPIANT PHARMACEUTICALS, INC.

By: /s/ David D. O'Toole

Name: David D. O'Toole

Title: Chief Financial Officer

Opiant Pharmaceuticals Announces Fourth Quarter and Full-Year 2021 Financial Results and Provides Corporate Update

SANTA MONICA, Calif., March 15, 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 and twelve months ended December 31, 2021, and provided a corporate update. Recent highlights include:

Finance Update

- Q4 revenues of \$13.8 million, an increase of 39% compared to the same period in 2020
- Exceeded full-year 2021 royalty revenue guidance of approximately \$38 million with 2021 royalty revenue of approximately \$41 million, a 49% increase over full-year 2020
- Full-year net income of \$3.0 million
- Well capitalized, with approximately \$53.0 million in cash, cash equivalents and marketable securities, as of December 31, 2021

Pipeline Update

- OPNT003, nasal nalmefene, for opioid overdose:
 - Reported positive topline results from pharmacokinetic ("PK"), safety and tolerability multidose study
 - Completed enrollment in pharmacodynamic ("PD") study comparing nasal nalmefene and nasal naloxone, with top line data now expected in Q2 2022
 - Pre-NDA Meeting with the FDA scheduled for late March 2022
 - Targeting New Drug Application ("NDA") submission mid-year 2022; commercial preparations well underway for a potential commercial launch in 2023
- OPNT002, nasal naltrexone, for Alcohol Use Disorder ("AUD"):
 - Initiated patient dosing in Phase 2 study, with data expected in H1 2023

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

"Opiant delivered strong financial results in 2021, and continued pipeline momentum, led by OPNT003, nasal nalmefene. We believe the compelling results generated to date from our ongoing development program support OPNT003's potential to be a differentiated treatment option for the emergency treatment of opioid overdose, particularly in the community setting. In parallel, we initiated dosing in our Phase 2 study for Alcohol Use Disorder, an important advancement for our deep pipeline aimed at bringing about a paradigm shift in the treatment of addictions and drug overdose. Looking ahead, with the clinical portion of our work complete, we look forward to the upcoming top line data from the PD study and remain dedicated to progressing OPNT003 to NDA submission, as well as the continued growth of our commercial organization in preparation for a potential launch in the U.S."

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

"We ended the year with approximately \$53 million of cash and continue to prudently manage our capital resources, providing us with a strong financial foundation to support our commercial

and R&D initiatives. Based on our anticipated upcoming catalysts and product pipeline, we believe we are well-positioned to drive increasing value for all key stakeholders.”

Financial Results for the Fourth Quarter Ended December 31, 2021

For the three months ended December 31, 2021, Opiant recorded approximately \$13.8 million in revenue, compared to approximately \$10.0 million during the corresponding period of 2020. \$13.0 million of revenue was attributable to the license agreement with Emergent BioSolutions, Inc. (“EBS”) for the sale of NARCAN® Nasal Spray, compared to approximately \$8.3 million in the same period of 2020, and approximately \$0.8 million came from grant and contract revenue, compared to approximately \$1.6 million in the same period in 2020. Fourth quarter 2021 sales of NARCAN® Nasal Spray were approximately \$120.6 million, as reported by EBS.

For the three months ended December 31, 2021, general and administrative (“G&A”) expenses were approximately \$3.4 million, as compared to approximately \$3.6 million in the comparable period in 2020.

Research and development (“R&D”) expenses for the three months ended December 31, 2021, were approximately \$4.7 million, as compared to approximately \$4.5 million in the comparable period in 2020.

Sales and marketing (“S&M”) expenses for the three months ended December 31, 2021, were approximately \$1.5 million for pre-commercialization efforts related to OPNT003. Sales and marketing expense during the three months ended December 31, 2020, were approximately \$0.9 million.

Royalty expense for the three months ended December 31, 2021, was approximately \$2.9 million and \$1.9 million for the comparable period of 2020. The \$1.0 million increase was due to increased royalty revenue from net sales of NARCAN® Nasal Spray.

Net income for the three months ended December 31, 2021, was approximately \$0.8 million, or income of \$0.17 per basic share and \$0.11 per diluted share, compared to a net loss of approximately \$0.7 million, or loss of \$0.16 per basic and diluted share, for the comparable period of 2020.

Financial Results for the 12 Months Ended December 31, 2021

For the twelve months ended December 31, 2021, Opiant recorded approximately \$47.8 million in revenue, compared to approximately \$29.6 million during the corresponding period of 2020. For the twelve months ended December 31, 2021, the Company recorded approximately \$40.7 million of revenue from the sale of NARCAN® Nasal Spray, compared to approximately \$27.4 million in the same period of 2020. Sales of NARCAN® Nasal Spray for the twelve months ended December 31, 2021, were approximately \$434.3 million, as reported by EBS.

For the twelve months ended December 31, 2021, the Company recorded approximately \$7.1 million in grant and contract revenue compared to approximately \$2.2 million in the same period in 2020. The \$4.9 million increase in grant and contract revenue was due to the increased funding received from the National Institute of Drug Abuse and Biomedical Advanced Research and Development Authority for the development of OPNT003.

For the twelve months ended December 31, 2021, G&A expenses were approximately \$12.2 million, compared to approximately \$11.7 million in the comparable period in 2020.

R&D expenses for the twelve months ended December 31, 2021, were approximately \$16.8 million, as compared to approximately \$9.2 million in the comparable period in 2020. R&D expense increased by \$7.6 million primarily due to increased activity on OPNT003.

S&M expenses for the twelve months ended December 31, 2021, were approximately \$4.6 million compared to approximately \$4.7 million in the comparable period in 2020.

Royalty expense for the twelve months ended December 31, 2021, was approximately \$9.1 million, compared to approximately \$6.2 million for the comparable period of 2020. The \$2.9 million increase was due to increased royalty revenue from net sales of NARCAN® Nasal Spray.

Net income for the twelve months ended December 31, 2021, was approximately \$3.0 million, or income of \$0.68 per basic share and income of \$0.51 per diluted share, compared to net loss of approximately \$1.9 million, or a loss of \$0.44 per basic and diluted share, for the comparable period of 2020.

As of December 31, 2021, Opiant had approximately \$53.0 million in cash, cash equivalents, and marketable securities.

We are not providing royalty revenue guidance, currently, due to the uncertainty of the level of sales of NARCAN® Nasal Spray in 2022. We intend to provide guidance later in 2022, once we determine the potential impact of the launch in December of 2021 of a generic equivalent by Teva Pharmaceuticals.

The OPNT003 development project 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, March 15th 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: 13726931
 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, including anticipated results and timing of the receipt of data from our PD study and timing of filing of an NDA. 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, 2021, filed with the Securities and Exchange Commission on March 15, 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

Batkins@opiant.com

(310) 598-5410

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

	Year ended December 31, 2021	Year ended December 31, 2020	Three months ended December 31, 2021 (Unaudited)	Three months ended December 31, 2020 (Unaudited)
	Revenues			
Royalty revenue	\$ 40,725	\$ 27,402	\$ 13,036	\$ 8,345
Grant and contract revenue	7,060	2,223	764	1,579
Total revenue	<u>47,785</u>	<u>29,625</u>	<u>13,800</u>	<u>9,924</u>
Operating expenses				
General and administrative	12,153	11,742	3,394	3,604
Research and development	16,834	9,240	4,715	4,477
Sales & marketing	4,576	4,687	1,496	949
Royalty expense	9,066	6,197	2,921	1,908
Total expenses	<u>42,629</u>	<u>31,866</u>	<u>12,526</u>	<u>10,938</u>
Operating income (loss)	5,156	(2,241)	1,274	(1,014)
Other income (expense)				
Interest income, net	11	94	1	2
Interest expense	(2,129)	(131)	(503)	(131)
Gain (loss) on foreign exchange	(5)	(9)	4	(7)
Total other income	<u>(2,123)</u>	<u>(46)</u>	<u>(498)</u>	<u>(136)</u>
Net income (loss) before income taxes	3,033	(2,287)	776	(1,150)
Income tax benefit (expense)	(24)	426	27	465
Net income (loss)	<u>\$ 3,009</u>	<u>\$ (1,861)</u>	<u>\$ 803</u>	<u>\$ (685)</u>
Other comprehensive income (loss)				
Foreign currency translation adjustment	(28)	(27)	(27)	88
Total other comprehensive income (loss)	<u>\$ 2,981</u>	<u>\$ (1,888)</u>	<u>\$ 776</u>	<u>\$ (597)</u>
Net income (loss) per common share				
Basic	<u>\$ 0.68</u>	<u>\$ (0.44)</u>	<u>\$ 0.17</u>	<u>\$ (0.16)</u>
Diluted	<u>\$ 0.51</u>	<u>\$ (0.44)</u>	<u>\$ 0.11</u>	<u>\$ (0.16)</u>
Weighted-average common shares outstanding:				
Basic	<u>4,456,162</u>	<u>4,249,832</u>	<u>4,742,530</u>	<u>4,258,105</u>
Diluted	<u>5,920,069</u>	<u>4,249,832</u>	<u>7,111,376</u>	<u>4,258,105</u>

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

	As of December 31, 2021	As of December 31, 2020
Assets		
Current Assets		
Cash & cash equivalents	\$ 37,854	\$ 48,251
Marketable securities	15,015	-
Accounts receivable	13,327	8,911
Prepaid expenses and other current assets	2,963	1,937
Total Current Assets	69,159	59,099
Long-term Assets		
Property and equipment, net	78	171
Right of use assets - operating leases	1,000	279
Patents and patent applications, net	12	13
Other non-current assets	179	1,051
Total Assets	\$ 70,428	\$ 60,613
Liabilities and stockholders' equity		
Current Liabilities		
Accounts payable and accrued liabilities	\$ 3,370	\$ 2,966
Accrued salaries and wages	201	909
Royalty payable	2,920	1,908
Deferred revenue	17	355
Operating leases - current	338	282
Total Current Liabilities	6,846	6,420
Long-Term Liabilities		
Operating leases - long term	673	-
Convertible debt, net of issuance costs	16,069	18,701
Total Long-Term Liabilities	16,742	18,701
Total Liabilities	23,588	25,121
Stockholders' equity		
Common stock, \$0.001 par value, 200,000,000 shares authorized, 4,909,846 and 4,258,105 shares issued and outstanding at December 31, 2021 and 2020, respectively	5	4
Additional paid-in-capital	108,570	100,204
Accumulated other comprehensive loss	(55)	(27)
Accumulated deficit	(61,680)	(64,689)
Total stockholders' equity	46,840	35,492
Total liabilities and stockholders' equity	\$ 70,428	\$ 60,613