

**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 4, 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 March 4, 2021, Opiant Pharmaceuticals, Inc. (the “Company”), issued a press release announcing the Company’s financial results for the quarter and year ended December 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.

Exhibit No. Description

[99.1 Press Release of Opiant Pharmaceuticals, Inc., dated March 4, 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: March 4, 2021

By: /s/ David D. O'Toole

Name: David D. O'Toole

Title: Chief Financial Officer

Opiant Pharmaceuticals Reports Fourth Quarter and Full-Year 2020 Financial Results and Provides Corporate Update

SANTA MONICA, Calif., March 4, 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 fourth quarter and year ended December 31, 2020 and provided a corporate update.

Pipeline Update

- *Continue to advance OPNT003, nasal nalmefene, for opioid overdose, with significant clinical and regulatory milestones expected in 2021*
 - *Confirmatory pharmacokinetic ("PK") study*
 - *Anticipate full enrollment April 2021*
 - *Top-line data anticipated in June 2021*
 - *Pharmacodynamic ("PD") study*
 - *Protocol filed with U.S. Food and Drug Administration ("FDA")*
 - *Received Institutional Review Board ("IRB") approval to initiate trial*
 - *Anticipate commencing patient dosing mid-March 2021*
 - *Top-line data expected by the start of the fourth quarter 2021*
 - *The Company remains on track to complete its New Drug Application ("NDA") submission for use of OPNT003 in opioid overdose by end 2021*
 - *In December, the Company announced an additional commitment of up to \$3.5 million from the Biomedical Advanced Research and Development Authority ("BARDA") for the development of OPNT003*
- *Pre-clinical progress on OPNT004, drinabant, for Acute Cannabinoid Overdose ("ACO")*
 - *Formulation development studies commenced December 2020 in collaboration with National Center for Advancing Translational Sciences ("NCATS")*
 - *NCATS awarded the contract for formulation activities to Irisys LLC*
- *Phase 2 study of OPNT002, nasal naltrexone, for Alcohol Use Disorder ("AUD"), remains on temporary hold due to the ongoing COVID-19 pandemic*

Financial Highlights

- *Q4 revenues of \$10.0 million and full-year net revenues of \$29.6 million driven by royalties from the sale of NARCAN® Nasal Spray ("NARCAN®")*
- *In December, Opiant entered into a strategic convertible debt financing agreement with a syndicate comprised of Pontifax Medison Finance and Kreos Capital through which the Company will have access to up to \$50 million; the first tranche of \$20 million was funded at closing on December 10, 2020*

- *\$48.3 million in cash and cash equivalents at December 31, 2020, inclusive of the first tranche of \$20 million received from the convertible debt financing closed in December 2020, compared to \$31.1 million at December 31, 2019*

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

“We are excited to start 2021 by announcing important clinical progress with OPNT003, nasal nalmefene, for opioid overdose. We are nearing completion of our confirmatory PK study and intend to begin our PD study mid-March. Importantly, we expect top-line data from both of these studies later this year, and we remain on track to complete our NDA for the use of OPNT003 in opioid overdose for FDA review by the end of 2021. Opioid overdose continues to be a growing and devastating epidemic in need of effective treatment solutions. Opiant’s purpose – to develop new medicines to treat addictions and drug overdose – has never been more relevant.”

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

“As we move into 2021, we maintain a strong cash position, driven by a focus on responsible cost containment, as well as continued royalties on net sales of NARCAN® Nasal Spray. We also locked in an attractive cost of financing with a convertible debt deal for up to \$50 million, which will increase our financial flexibility as we continue to advance OPNT003 and build toward commercialization, if we decide to pursue that path alone.”

Financial Results for the Fourth Quarter Ended December 31, 2020

For the three months ended December 31, 2020, Opiant recorded approximately \$10.0 million in revenue, compared to approximately \$7.7 million during the corresponding period of 2019. For the three months ended December 31, 2020, we recorded approximately \$8.3 million of revenue from our license agreement with EBS for the sale of NARCAN®, compared to approximately \$7.2 million in the same period of 2019. Fourth quarter 2020 sales of NARCAN® were approximately \$77.4 million, as reported by EBS.

For the three months ended December 31, 2020, general and administrative (“G&A”) expenses were approximately \$3.6 million, compared to \$2.8 million in the comparable period of 2019. The increase of \$0.8 million was due to an increase of \$1.2 million in estimated administrative expense associated with OPNT003, offset by a decrease in personnel and related expenses including stock-based compensation of \$0.4 million for the three months ended December 31, 2020, as compared to the three months ended December 31, 2019.

Research and development (“R&D”) expenses for the three months ended December 31, 2020, were approximately \$4.5 million, as compared to approximately \$2.0 million in the comparable period in 2019. The \$2.5 million increase in R&D expenses is primarily attributable to an increase for third party expenses associated with our R&D programs for the comparable periods

Sales and marketing (“S&M”) expenses for the three months ended December 31, 2020, were approximately \$0.9 million, compared to \$0.5 million in the comparable period of 2019. The

increase of \$0.4 million was attributable to government affairs expense and initial pre-commercialization market research related to OPNT003, which is under clinical development.

Royalty expense for the three months ended December 31, 2020, was approximately \$1.9 million, compared to approximately \$1.6 million in the comparable period of 2019. The increase was primarily due to payments to Net Profit Partners for the royalties received from the net sales of NARCAN® Nasal Spray.

Net loss for the three months ended December 31, 2020, was approximately \$0.6 million, or a loss of \$0.16 per basic and diluted share, compared to net income of approximately \$1.1 million, or \$0.26 per basic share and \$0.20 per diluted share, for the comparable period of 2019.

Financial Results for the Year Ended December 31, 2020

For the year ended December 31, 2020, Opiant recorded approximately \$29.6 million in revenue, compared to approximately \$40.5 million during the corresponding period of 2019. For the year ended December 31, 2020, we recorded approximately \$27.4 million of revenue from our license agreement with EBS for the sale of NARCAN®, compared to approximately \$37.6 million in the same period of 2019 which included a final milestone payment of \$13.5 million, as sales of NARCAN® Nasal Spray exceeded \$200 million for 2019. Full year 2020 sales of NARCAN® were approximately \$311.2 million, as reported by EBS.

G&A expenses for the year ended December 31, 2020, were approximately \$11.7 million, compared to approximately \$12.2 million in the comparable period of 2019. The decrease of \$0.5 million was due to a decrease in legal, investor relations and professional fees of \$1.1 million, and a decrease in personnel and related expenses including stock-based compensation of \$0.6 million, offset by an increase of \$1.2 million in estimated administrative expense associated with OPNT003 for the year ended December 31, 2020 as compared to the year ended December 31, 2019.

R&D expenses for the year ended December 31, 2020, were approximately \$9.2 million, compared to approximately \$9.1 million in the comparable period of 2019. The increase in R&D expenses is attributable to a \$0.1 million increase for third party expenses associated with our R&D programs for the comparable periods.

S&M expenses for the year ended December 31, 2020, were approximately \$4.7 million, compared to \$0.6 million in the same period of 2019. Personnel and related expense, including stock-based compensation increased by \$0.8 million and government affairs and initial pre-commercialization market research related to OPNT003, which is under clinical development, increased by \$3.3 million.

Royalty expense for the year ended December 31, 2020, was approximately \$6.2 million, compared to approximately \$7.7 million in the same period in 2019. The \$1.5 million decrease was due to lower net royalty revenue in 2020 versus 2019 which was primarily attributable to the 2019 final milestone of \$13.5 million received during 2019.

Net loss for the year ended December 31, 2020, was approximately \$1.9 million, or a loss of \$0.44 per basic and diluted share, compared to net income gain of approximately \$11.6 million, or \$2.88 per basic and \$2.17 per diluted share, for the comparable period of 2019.

In December, the Company announced that it had entered into a \$50 million convertible Note Purchase and Security Agreement with a syndicate of Pontifax Medison Finance, a healthcare-dedicated venture and debt fund, and Kreos Capital VI (Expert Fund) LP. Under the Agreement, Opiant will be able to draw up to \$50 million in three tranches. The first tranche of \$20 million was funded at closing on December 10, 2020. Subject to certain limitations, Pontifax and Kreos can elect to convert up to half of their outstanding loan into shares of Opiant's common stock at a conversion price of \$19.64 per share.

As of December 31, 2020, Opiant had cash and cash equivalents of \$48.3 million, inclusive of the first tranche of \$20 million received from the convertible debt financing closed in December 2020, compared to \$31.0 million at December 31, 2019. The current cash balance does not include the full impact of the National Institute on Drug Abuse grant of approximately \$7.4 million or the BARDA 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 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:

Thursday, March 4th at 4:30 p.m. Eastern Time/1:30 p.m. Pacific Time

Toll Free: 877-407-0792

International: 201-689-8263

Conference ID: 13715395

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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(310) 598-5410

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

	As of December 31, 2020	As of December 31, 2019
Assets		
Current Assets		
Cash & cash Equivalents	\$ 48,251	\$ 30,981
Accounts receivable	8,911	7,218
Prepaid expenses and other current assets	1,937	1,056
Total Current Assets	59,099	39,255
Long-term Assets		
Property and equipment, net	171	243
Right of use assets - operating leases	279	769
Patents and patent applications, net	13	14
Other non-current assets	1,051	-
Total Assets	\$ 60,613	\$ 40,281
Liabilities and stockholders' equity		
Current Liabilities		
Accounts payable and accrued liabilities	\$ 2,966	\$ 1,317
Accrued salaries and wages	909	1,238
Royalty payable	1,908	1,620
Deferred revenue	355	918
Operating leases - current	282	517
Total Current Liabilities	6,420	5,610
Long-Term Liabilities		
Operating leases - long term	-	255
Convertible debt, net of issuance costs	18,701	-
Total Long-Term Liabilities	18,701	255
Total Liabilities	25,121	5,865
Stockholders' equity		
Common stock, \$0.001 par value, 200,000,000 shares authorized, 4,258,105 and 4,186,438 shares issued and outstanding at December 31, 2020 and 2019, respectively	4	4
Additional paid-in-capital	100,204	97,240
Accumulated other comprehensive loss	(27)	-
Accumulated deficit	(64,689)	(62,828)
Total stockholders' equity	35,492	34,416
Total liabilities and stockholders' equity	\$ 60,613	\$ 40,281

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

	Year ended December 31, 2020	Year ended December 31, 2019	Three months ended December 31, 2020 (Unaudited)	Three months ended December 31, 2019 (Unaudited)
Revenues				
Royalty & licensing revenue	\$ 27,402	\$ 37,592	\$ 8,345	\$ 7,224
Treatment investment income	-	644	-	-
Grant and contract revenue	2,223	2,284	1,579	446
Total Revenue	29,625	40,520	9,924	7,670
Operating Expenses				
General and administrative	11,742	12,197	3,604	2,807
Research and development	9,240	9,079	4,477	2,036
Royalty expense	6,197	7,720	1,908	1,621
Sales & Marketing	4,687	612	949	471
Total expenses	31,866	29,608	10,938	6,935
Operating income (loss)	(2,241)	10,912	(1,014)	735
Other income (expense)				
Interest income, net	94	438	2	81
Interest expense	(131)	-	(131)	-
Gain (loss) on settlement of accrued liability	-	16	-	16
Gain (loss) on foreign exchange	(9)	50	(7)	115
Total other income	(46)	504	(136)	212
Net income (loss) before income taxes	(2,287)	11,416	(1,150)	947
Income tax benefit	426	177	465	121
Net income (loss)	\$ (1,861)	\$ 11,593	\$ (685)	\$ 1,068

Other comprehensive income (loss)				
Foreign currency translation adjustment	(27)	-	88	-
Total other comprehensive income (loss)	\$ (1,888)	\$ 11,593	\$ (597)	\$ 1,068
Net income (loss) per common share				
Basic	\$ (0.44)	\$ 2.88	\$ (0.16)	\$ 0.26
Diluted	\$ (0.44)	\$ 2.17	\$ (0.16)	\$ 0.20
Weighted-average common shares outstanding:				
Basic	4,249,832	4,018,464	4,258,105	4,068,417
Diluted	4,249,832	5,342,378	4,258,105	5,472,139