

**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): November 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 November 11, 2021, Opiant Pharmaceuticals, Inc. (the “**Company**”), issued a press release announcing the Company’s financial results for the quarter ended September 30, 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 November 11, 2021
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: November 12, 2021

OPIANT PHARMACEUTICALS, INC.

By: /s/ David D. O'Toole

Name: David D. O'Toole

Title: Chief Financial Officer

Opiant Pharmaceuticals Announces Third Quarter 2021 Financial Results and Provides Corporate Update

SANTA MONICA, Calif., November 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 and nine months ended September 30, 2021, and provided a corporate update. Recent highlights include:

Finance Update

- **Q3 revenues of \$16.3 million**, a 79% increase over the same period in 2020, driven by NARCAN® Nasal Spray royalties
- **Nine-month revenues of \$34 million**
- **\$50.3 million in cash, cash equivalents and marketable securities** (as of September 30, 2021)
- **Raises full-year 2021 revenue and cash guidance**
 - *Royalty revenue from the sale of NARCAN® Nasal Spray now anticipated to be approximately \$38 million*
 - *Cash, cash equivalents and marketable securities now expected to be in the range of approximately \$50 million to \$52 million, an increase of approximately \$8 million greater than 2nd quarter guidance*

Pipeline Update

- **OPNT003, nasal nalmefene, for opioid overdose:**
 - *Obtained U.S. Food and Drug Administration (“FDA”) Fast-Track Designation for OPNT003*
 - *Enrollment and dosing of subjects in Pharmacodynamic (“PD”) study is progressing. The PD study is designed as a non-inferiority study comparing OPNT003 to nasal naloxone to reverse the respiratory depression produced by the synthetic opioid remifentanyl, by measuring change in minute ventilation. Company is on track to complete the clinical phase of the study by the end of 2021 with top-line data now anticipated in Q1 2022*
 - *Targeting NDA submission under Fast-Track designation during the first half of 2022, with commercial preparations underway for a potential launch in Q4 2022*
- **OPNT002, nasal naltrexone, for Alcohol Use Disorder (“AUD”):** *Announces its plans to initiate patient recruitment for Phase 2 clinical study in Q4 2021*

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

“Opiant demonstrated strong performance again this quarter with continued positive momentum for OPNT003, nasal nalmefene, for opioid overdose. Following positive PK data, we were pleased

this month to receive FDA Fast-Track designation. We are making good progress in our PD study and anticipate top-line results in the first quarter of 2022. In parallel, we continue to invest in and advance preparations for a potential commercial launch in 2022, if approved. We are also looking forward in Q4 this year to initiating our Phase 2 study of OPNT002, nasal naltrexone, for Alcohol Use Disorder, which we had put on hold due to COVID.”

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

“During Q3, we saw continued and strong revenue growth attributable to our royalties on significant net sales this quarter of NARCAN® Nasal Spray, a further indicator of the demand for opioid overdose treatment in the U.S. As we look forward to a potential launch of OPNT003 in the latter half of 2022, our expected strong cash position at the end of 2021, will support the commercial plan and the progression of the pipeline.”

Financial Results for the Three Months Ended September 30, 2021

For the three months ended September 30, 2021, Opiant recorded approximately \$16.3 million in revenue, compared to approximately \$9.1 million during the corresponding period of 2020. For the three months ended September 30, 2021, the Company recorded approximately \$14 million of revenue from its license agreement with Emergent BioSolutions, Inc. (“EBS”) for the sale of NARCAN® Nasal Spray, compared to approximately \$8.6 million in the same period of 2020. Third quarter 2021 sales of NARCAN® Nasal Spray were approximately \$133.3 million, as reported by EBS. For the three months ended September 30, 2021, the Company recorded approximately \$2.3 million in grant and contract revenue compared to approximately \$0.5 million in the same period in 2020. The \$5.4 million increase in revenue from our license agreement with EBS was primarily due to a \$44.5 million increase in net NARCAN® Nasal Spray sales in the three months ended September 30, 2021, compared to the three months ended September 30, 2020. The \$1.8 million increase in grant and contract revenue was due to the increased funding received from the National Institute of Drug Abuse (“NIDA”) and Biomedical Advanced Research and Development Authority (“BARDA”) for the development of OPNT003.

For the three months ended September 30, 2021, general and administrative (“G&A”) expenses were approximately \$3.4 million, as compared to approximately \$2.7 million in the comparable period in 2020.

Research and development (“R&D”) expenses for the three months ended September 30, 2021, were approximately \$4.9 million, as compared to approximately \$2.8 million in the comparable period in 2020. Development expense increased by \$2.1 million primarily due to increased activity on OPNT003.

Sales and marketing (“S&M”) expenses for the three months ended September 30, 2021, were approximately \$1.1 million for pre-commercialization efforts related to OPNT003. Sales and marketing expense during the three months ended September 30, 2020, were approximately \$0.9 million.

Royalty expense for the three months ended September 30, 2021, was approximately \$3.1 million and \$2.0 million for the comparable period of 2020. The \$1.1 million increase was due to increased royalty revenue from net sales of NARCAN® Nasal Spray.

Net income for the three months ended September 30, 2021, was approximately \$3.4 million, or income of \$0.77 per basic share and \$0.56 diluted share, compared to net income of

approximately \$0.7 million, or income of \$0.17 per basic and \$0.15 per diluted share, for the comparable period of 2020.

Financial Results for the Nine Months Ended September 30, 2021

For the nine months ended September 30, 2021, Opiant recorded approximately \$34 million in revenue, compared to approximately \$19.7 million during the corresponding period of 2020. For the nine months ended September 30, 2021, the Company recorded approximately \$27.7 million of revenue from the sale of NARCAN® Nasal Spray, compared to approximately \$19.1 million in the same period of 2020. Sales of NARCAN® Nasal Spray for the nine months ended September 30, were approximately \$313.7 million, as reported by EBS. For the nine months ended September 30, 2021, the Company recorded approximately \$6.3 million in grant and contract revenue compared to approximately \$0.6 million in the same period in 2020. The \$8.6 million increase in revenue from our license agreement with EBS was primarily due to a \$80.0 million increase in net NARCAN® Nasal Spray sales in the nine months ended September 30, 2021, compared to the nine months ended September 30, 2020. The \$5.7 million increase in grant and contract revenue was due to the increased funding received from NIDA and BARDA for the development of OPNT003.

For the nine months ended September 30, 2021, G&A expenses were approximately \$8.7 million, compared to approximately \$8.1 million in the comparable period in 2020.

R&D expenses for the nine months ended September 30, 2021, were approximately \$12.1 million, as compared to approximately \$4.8 million in the comparable period in 2020. Development expense increased by \$7.3 million primarily due to increased activity on OPNT003.

S&M expenses for the nine months ended September 30, 2021, were approximately \$3.0 million compared to approximately \$3.7 million in the comparable period in 2020.

Royalty expense for the nine months ended September 30, 2021, was approximately \$6.1 million, compared to approximately \$4.3 million for the comparable period of 2020. The \$1.8 million increase was due to increased royalty revenue from net sales of NARCAN®.

Net income for the nine months ended September 30, 2021, was approximately \$2.3 million, or income of \$0.52 per basic share and income of \$0.41 per diluted share, compared to net loss of approximately \$1.2 million, or a loss of \$0.28 per basic and diluted share, for the comparable period of 2020.

As of September 30, 2021, Opiant had \$50.3 million in cash, cash equivalents, and marketable securities.

Opiant is raising its 2021 financial guidance, reflecting higher than expected sales of NARCAN® Nasal Spray. Aligning its guidance to the upper-range of the full-year 2021 guidance for sales of NARCAN® Nasal Spray provided by EBS, of \$420 million, Opiant expects full-year 2021 royalty revenue from the sale of NARCAN® Nasal Spray of approximately \$38 million. The Company is also updating its guidance for ending cash and now expects to end 2021 with cash, cash equivalents and marketable securities in the range of approximately \$50 million to \$52 million, not including potential receipt of any additional tranches from the convertible debt deal.

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:

Thursday, November 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: 13723604
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 and statements regarding updated royalty revenue guidance and ending cash target in 2021. 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:

Ben Atkins

VP of Corporate Communications and Investor Relations

Batkins@opiant.com

(310) 598-5410

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

	As of September 30, 2021	As of December 31, 2020
	(unaudited)	
Assets		
Current assets		
Cash & cash equivalents	\$ 35,285	\$ 48,251
Marketable securities	15,045	-
Accounts receivable	15,426	8,911
Prepaid expenses and other current assets	2,121	1,937
Total current assets	67,877	59,099
Other assets		
Property and equipment, net	93	171
Right of use assets - operating leases	998	279
Patents and patent applications, net	12	13
Other non-current assets	-	1,051
Total assets	\$ 68,980	\$ 60,613
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable and accrued liabilities	\$ 2,581	\$ 2,966
Accrued salaries and wages	1,347	909
Royalty payable	3,137	1,908
Deferred revenue	-	355
Operating leases	287	282
Total current liabilities	7,352	6,420
Long-term liabilities		
Operating leases	716	-
Convertible debt, net of unamortized discount	18,906	18,701
Total long-term liabilities	19,622	18,701
Total liabilities	26,974	25,121
Stockholders' equity		
Common stock, \$0.001 par value, 200,000,000 shares authorized, 4,349,599 and 4,258,105 shares issued and outstanding at June 30, 2021 and December 31, 2020, respectively	5	4
Additional paid-in-capital	104,460	100,204
Accumulated other comprehensive loss	(27)	(27)
Accumulated deficit	(62,432)	(64,689)
Total stockholders' equity	42,006	35,492
Total liabilities and stockholders' equity	\$ 68,980	\$ 60,613

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

	Three months ended September 30 2021 (Unaudited)	Three months ended September 30 2020 (Unaudited)	Nine months ended September 30 2021 (Unaudited)	Nine months ended September 30 2020 (Unaudited)
Revenues				
Royalty revenue	\$ 14,041	\$ 8,601	\$ 27,689	\$ 19,057
Grant and contract revenue	2,298	505	6,296	644
Total Revenue	<u>16,339</u>	<u>9,106</u>	<u>33,985</u>	<u>19,701</u>
Operating expenses				
General and administrative	3,379	2,729	8,759	8,138
Research and development	4,881	2,784	12,119	4,763
Sales & marketing	1,060	914	3,080	3,738
Royalty expense	3,059	1,952	6,145	4,289
Total expenses	<u>12,379</u>	<u>8,379</u>	<u>30,103</u>	<u>20,928</u>
Income (loss) from operations	3,960	727	3,882	(1,227)
Other income (expense)				
Interest income	4	4	10	92
Interest expense	(547)	-	(1,626)	-
Gain (loss) on foreign exchange	-	(6)	(10)	(2)
Total other income (expense)	<u>(543)</u>	<u>(2)</u>	<u>(1,626)</u>	<u>90</u>
Income (loss) before provision for income taxes	3,417	725	2,256	(1,137)
Income tax expense	-	-	-	39
Net income (loss)	<u>\$ 3,417</u>	<u>\$ 725</u>	<u>\$ 2,256</u>	<u>\$ (1,176)</u>
Other comprehensive income (loss):				
Foreign currency translation adjustment	8	196	1	(115)
Comprehensive income (loss)	<u>\$ 3,425</u>	<u>\$ 921</u>	<u>\$ 2,257</u>	<u>\$ (1,291)</u>
Net income (loss) per common share				
Basic	<u>\$ 0.77</u>	<u>\$ 0.17</u>	<u>\$ 0.52</u>	<u>\$ (0.28)</u>
Diluted	<u>\$ 0.56</u>	<u>\$ 0.15</u>	<u>\$ 0.41</u>	<u>\$ (0.28)</u>
Weighted-average common shares outstanding:				
Basic	<u>4,462,236</u>	<u>4,258,105</u>	<u>4,359,759</u>	<u>4,247,045</u>
Diluted	<u>6,065,044</u>	<u>4,847,211</u>	<u>5,565,065</u>	<u>4,247,045</u>