

**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 12, 2020**

**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 12, 2020, Opiant Pharmaceuticals, Inc. (the “**Company**”), issued a press release announcing the Company’s financial results for the quarter and nine months ended September 30, 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

10.1	<a href="#">Press Release of Opiant Pharmaceuticals, Inc., dated November 12, 2020, Inc., dated November 12, 2020</a>
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## **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: November 12, 2020

By: /s/ David D. O'Toole

Name: David D. O'Toole

Title: Chief Financial Officer

## Opiant Pharmaceuticals Announces Third Quarter 2020 Financial Results and Corporate Update

**SANTA MONICA, Calif., Nov 12, 2020** -- 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 September 30, 2020, and provided a corporate update. Recent highlights include:

- **OPNT003 nasal nalmefene for opioid overdose**
  - *Opiant to use Aptar Pharma's Unit Dose System*
  - *Upcoming FDA meeting in December to review Pharmacodynamic study in healthy volunteers and 505(b)(2) submission strategy*
  - *Opiant continues to expect to file a New Drug Application by end of 2021*
  - *The Centers for Disease Control and Prevention reports an increase in fatal drug overdoses in the first three months of 2020 putting the U.S. on pace for record year of drug overdose deaths during coronavirus pandemic*
- **Q3 revenues of \$9.1 million driven by NARCAN® Nasal Spray ("NARCAN®") royalties**
  - *Recognized approximately \$8.6 million in royalty revenue for Q3 2020 from approximately \$88.8 million in net sales of NARCAN® Nasal Spray*
  - *Projected royalties for the full-year 2020 raised from \$26.2 million to approximately \$28 million, based on Emergent Biosolutions ("EBS") updated revenue guidance for NARCAN® sales of between \$295 million and \$315 million*
- **\$31.1 million in cash and cash equivalents and no debt at September 30, 2020**

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

"Deaths from overdoses on opioids remain a seismic crisis for communities across the United States, exacerbated by the COVID-19 pandemic. The determined deployment of opioid overdose rescue medication is essential to save lives. The trajectory of America's opioid crisis, fueled by the availability of fentanyl and related synthetic opioids, underscores the need for stronger, longer-acting formulations of opioid antagonists. To this end, we made good progress this quarter with OPNT003 nasal nalmefene, our investigational treatment for opioid overdose. I am pleased we can now use Aptar Pharma's Unit Dose System for OPNT003. It has been approved by the FDA with multiple drug products, including NARCAN® Nasal Spray. Adding to the momentum, we will meet with the FDA in December to review the design of our pharmacodynamic study in healthy volunteers and our New Drug Application plan, which is on track to be submitted by the end of next year."

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

"Royalties from net sales of NARCAN® Nasal Spray continue to fortify our already strong balance sheet. EBS reported higher sales than expected this quarter and raised their NARCAN®

revenue guidance for the year to a range of \$295 million to \$315 million. Based on this we have increased our projection of royalty revenue for the full year to approximately \$28 million. We also now expect a cash balance at the end of 2020 of approximately \$30 million.”

### **Third Quarter 2020 Results**

For the three months ended September 30, 2020, Opiant recorded approximately \$9.1 million in revenue, compared to approximately \$20.6 million during the corresponding period of 2019. For the three months ended September 30, 2020, we recorded approximately \$8.6 million of revenue from our license agreement with EBS for the sale of NARCAN®, compared to approximately \$20.5 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. Third quarter 2020 sales of NARCAN® were approximately \$88.8 million, as reported by EBS.

General and administrative expenses for the quarter were approximately \$2.7 million, compared to \$3.2 million for the same period in 2019. The \$0.5 million decrease was primarily attributable to a decrease in legal and professional fees of approximately \$0.8 million, partially offset by an increase in personnel and related expense of \$0.3 million for the three months ended September 30, 2020 compared to the three months ended September 30, 2019.

Research and development expenses were approximately \$2.8 million, as compared to approximately \$1.8 million in the third quarter of 2019. External development expense increased by \$0.8 million and personnel and related expense increased by approximately \$0.2 million during the three months ended September 30, 2020 compared to the three months ended September 30, 2019.

Sales and marketing expenses were approximately \$0.9 million, as compared to approximately \$0.1 million in the third quarter of 2019. The \$0.8 million increase was attributable to pre-commercialization efforts related to OPNT003 nasal nalmefene, which is under clinical development.

Royalty expense for the second quarter was approximately \$2 million compared to \$4.9 million for the same period in 2019. Royalty expense is for payments to Net Profit Partners for the royalties received from the net sales of NARCAN®.

Net income for the third quarter was approximately \$0.7 million, or \$0.17 per basic and \$0.15 per diluted share, compared to net income of approximately \$10.7 million, or \$2.64 per basic and \$1.97 per diluted share, for the comparable period of 2019.

### **Financial Results for the Nine Months Ended September 30, 2020**

For the nine months ended September 30, 2020, Opiant recorded approximately \$19.7 million in revenue, compared to approximately \$32.9 million during the corresponding period of 2019. For the nine months ended September 30, 2020, we recognized approximately \$19.1 million of revenue from our license agreement with EBS for the sale of NARCAN®, compared to approximately \$30.4 million in the comparable period of 2019. The decrease in revenue of approximately \$11.3 million was primarily attributable to a milestone payment of \$13.5 million earned in the third quarter of 2019, as sales of NARCAN® exceeded \$200 million for 2019, offset by an increase in royalties as a result of and increase in net sales of NARCAN® for the nine

months ended September 30, 2020. Sales of NARCAN® for the nine months ended September 30, 2020, were approximately \$233.8 million, as reported by EBS.

General and administrative expenses for the nine months ended September 30, 2020, were approximately \$8.1 million, compared to approximately \$9.4 million in the comparable period of 2019. The decrease of \$1.3 million was primarily due to a \$1.5 million decrease in legal and professional fees, partially offset by a \$0.2 million increase in personnel and related expense including stock based compensation for the nine months ended September 30, 2020 compared to the nine months ended September 30, 2019.

Research and development expenses for the nine months ended September 30, 2020, were approximately \$4.8 million, compared to approximately \$7.0 million in the comparable period of 2019. The decrease of \$2.2 million resulted from a decrease in third party clinical trial and development expense of \$2.5 million, partially offset by an increase in personnel and related expense of \$0.3 million.

Sales and marketing expenses for the nine months ended September 30, 2020, were approximately \$3.7 million, compared to \$0.1 million during the same period 2019. For the nine months ended September 30, 2020 personnel and related expense including stock based compensation was \$0.9 million, and \$2.8 million was related to third party expenses for various pre-commercial activities including market research and assessments, and strategic planning.

Royalty expenses were \$4.3 million and \$6.1 million during the nine months ended September 30, 2020 and 2019, respectively. Royalty expense is for payments to Net Profit Partners for the royalties received from the net sales of NARCAN®.

Net loss for the nine months ended September 30, 2020, was approximately \$1.2 million, or a loss of \$0.28 per basic and diluted share, compared to a net income of approximately \$10.6 million, or \$2.64 per basic share and \$1.98 per diluted share, for the comparable period of 2019.

As of September 30, 2020, Opiant had cash and cash equivalents of \$31.1 million, compared to approximately \$31 million at December 31, 2019. The current cash balance does not include the full impact of the NIDA grant of approximately \$7.4 million or the BARDA contract of approximately \$4.6 million.

***Conference Call Details:***

***Thursday, November 12<sup>th</sup> at 4:30 p.m. Eastern Time/1:30 p.m. Pacific Time***

Toll Free: 877-407-0792

International: 201-689-8263

Conference ID: 13712206

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 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, 2019, filed with the Securities and Exchange Commission on March 4, 2020, 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.

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

	As of September 30, 2020 (unaudited)	As of December 31, 2019
<b>Assets</b>		
Current Assets		
Cash & cash equivalents	\$ 31,103	\$ 30,981
Accounts receivable	8,613	7,218
Prepaid expenses and other current assets	862	1,056
Total Current Assets	40,578	39,255
Long-term Assets		
Property and equipment, net of depreciation	202	243
Right of use assets - operating leases	397	769
Patents and patent applications, net of amortization	13	14
Other non-current assets	1,052	-
Total Assets	\$ 42,242	\$ 40,281
<b>Liabilities and stockholders' equity</b>		
Current Liabilities		
Accounts payable and accrued expenses	\$ 2,553	\$ 1,317
Accrued salaries & wages	1,435	1,238
Royalty payable	1,952	1,620
Deferred revenue	360	918
Operating leases - current	401	517
Total Current Liabilities	6,701	5,610
Long-Term Liabilities		
Operating leases - long term	-	255
Total Long-Term Liabilities	-	255
Total Liabilities	6,701	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 September 30, 2020 and December 31, 2019, respectively	4	4
Additional paid-in-capital	99,655	97,239
Foreign Currency Translation Adjustment	(115)	-
Accumulated deficit	(64,003)	(62,827)
Total stockholders' equity	35,541	34,416
Total liabilities and stockholders' equity	\$ 42,242	\$ 40,281

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

	Three months ended		Nine months ended	
	September 30,		September 30,	
	2020	2019	2020	2019
Revenues				
Royalty & licensing revenue	\$ 8,601	\$ 20,494	\$ 19,057	\$ 30,368
Treatment investment revenue	-	-	-	644
Grant and contract revenue	505	147	644	1,838
Total Revenue	<u>9,106</u>	<u>20,641</u>	<u>19,701</u>	<u>32,850</u>
Operating expenses				
General and administrative	2,729	3,211	8,138	9,389
Research and development	2,784	1,843	4,763	7,044
Sales and marketing	914	141	3,738	141
Royalty expense	1,952	4,851	4,289	6,099
Total operating expenses	<u>8,379</u>	<u>10,046</u>	<u>20,928</u>	<u>22,673</u>
Income (loss) from operations	727	10,595	(1,227)	10,177
Other income (expense)				
Interest income	4	112	92	356
Gain (loss) on foreign exchange	(6)	(24)	(2)	(65)
Total other income	<u>(2)</u>	<u>88</u>	<u>90</u>	<u>291</u>
Income (loss) before income taxes	725	10,683	(1,137)	10,468
Income tax (expense) benefit	-	-	(39)	57
Net income (loss)	<u>\$ 725</u>	<u>\$ 10,683</u>	<u>\$ (1,176)</u>	<u>\$ 10,525</u>
Other comprehensive loss				
Foreign currency translation adjustment	196	-	(115)	-
Total other comprehensive loss	<u>\$ 921</u>	<u>\$ 10,683</u>	<u>\$ (1,291)</u>	<u>\$ 10,525</u>
Net income (loss) per common share				
Basic	<u>\$ 0.17</u>	<u>\$ 2.64</u>	<u>\$ (0.28)</u>	<u>\$ 2.64</u>
Diluted	<u>\$ 0.15</u>	<u>\$ 1.97</u>	<u>\$ (0.28)</u>	<u>\$ 1.98</u>
Weighted-average common shares outstanding:				
Basic	<u>4,258,105</u>	<u>4,048,635</u>	<u>4,247,045</u>	<u>3,985,112</u>
Diluted	<u>4,847,211</u>	<u>5,422,345</u>	<u>4,247,045</u>	<u>5,310,157</u>