

**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): August 5, 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 August 5, 2021, Opiant Pharmaceuticals, Inc. (the “**Company**”), issued a press release announcing the Company’s financial results for the quarter ended June 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 August 5, 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.

Dated: August 5, 2021

**OPIANT PHARMACEUTICALS, INC.**

By: /s/ David D. O'Toole

Name: David D. O'Toole

Title: Chief Financial Officer

## Opiant Pharmaceuticals Announces Second Quarter 2021 Financial Results and Provides Corporate Update

**SANTA MONICA, Calif., August 5, 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 six months ended June 30, 2021, and provided a corporate update. Recent highlights include:

### Pipeline and Corporate Update:

#### **OPNT003, nasal nalmefene, for opioid overdose:**

- Completed confirmatory pharmacokinetic ("PK") study; data demonstrate rapid absorption and higher plasma concentrations versus a nalmefene intramuscular injection ( $p < 0.0001$ )
- Data from Pharmacodynamic ("PD") anticipated later in the fourth quarter
- Increasing need for OPNT003, with the Center for Disease Control released provisional overdose death data for the full year 2020:
  - 66,813 overdoses were caused by opioids, up 30% vs 2019, the highest annual increase in three decades
  - 53,877 opioid overdose deaths, or 80%, were due to illicit synthetic opioids, including fentanyl

**OPNT004, drinabant, for Acute Cannabinoid Overdose:** Preclinical activities and formulation development on track to support a Phase 1 study with parenteral drinabant in 2022

**OPNT002, nasal naltrexone, for Alcohol Use Disorder:** Start of Phase 2 study remains on pause; Company continues to assess optimal time to proceed

**Appointed Matthew Ruth as Chief Commercial Officer on July 12;** Mr. Ruth led the launch and commercialization of the first FDA-approved nasal naloxone spray to treat opioid overdose

**Appointed Brian Gorman to Executive Vice President, Corporate Development and General Counsel;** Mr. Gorman was promoted from General Counsel

### Financial Highlights

**Q2 revenues of \$11.3 million**, a 79% increase over the same period in 2020, driven by NARCAN® Nasal Spray ("NARCAN®") royalties

**\$48.5 million** in cash, cash equivalents and marketable securities (as of June 30, 2021)

**Raises full-year 2021 royalty revenue guidance** from the sale of NARCAN® Nasal Spray to approximately \$28.9 million and **raises full year 2021 cash, cash equivalents and marketable securities guidance** in the range of approximately \$42 million to \$44 million excluding any additional tranches from the convertible debt deal

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

“We continue to achieve significant pipeline progress, having recently announced positive confirmatory PK data for OPNT003, nasal nalmeferene, which we believe provides strong support for its continued development as a potential new standard of care in the treatment of opioid overdose. We are now focused on the PD study and our preparations for NDA submission, expected to occur at year end or in the first quarter of 2022. This program has never been more relevant as opioid overdose deaths increase. The U.S. experienced its deadliest year in 2020 driven by potent synthetic opioids such as fentanyl. Our goal is to provide the first responders, healthcare providers and communities responding to these highly potent, yet treatable, overdoses with a much needed new rescue agent option as quickly as possible.”

“With the addition of Matt and our promotion of Brian, we are fortunate to have such experienced leaders to support us in delivering on the promise of our pipeline and advancing our mission to create best-in-class medicines for the treatment of addictions and drug overdose.”

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

“Increased demand for NARCAN® in the current quarter meant we recognized significantly higher than expected royalties this quarter. Looking forward through the end of the year, we remain confident in our ability to achieve or even exceed our updated royalty revenue guidance and ending cash target in 2021, while we continue to focus on delivering a potentially breakthrough new treatment to confront the escalating opioid overdose crisis.”

### **Financial Results for the Three Months Ended June 30, 2021**

For the three months ended June 30, 2021, Opiant recorded approximately \$11.3 million in revenue, compared to approximately \$6.3 million during the corresponding period of 2020. For the three months ended June 30, 2021, the Company recorded approximately \$9.3 million of revenue from its license agreement with Emergent BioSolutions, Inc. (“EBS”) for the sale of NARCAN®, compared to approximately \$6.3 million in the same period of 2020. Second quarter 2021 sales of NARCAN® were approximately \$106.2 million, as reported by EBS. For the three months ended June 30, 2021, the Company recorded approximately \$1.9 million in grant and contract revenue compared to approximately \$0.1 million in the same period in 2020. The \$3.0 million increase in revenue from our license agreement with EBS was primarily due to a \$33.4 million increase in net NARCAN® sales in the three months ended June 30, 2021, compared to the three months ended June 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 June 30, 2021, general and administrative (“G&A”) expenses were approximately \$2.7 million, as compared to approximately \$2.8 million in the comparable period in 2020.

Research and development (“R&D”) expenses for the three months ended June 30, 2021, were approximately \$3.2 million, as compared to approximately \$0.6 million in the comparable period in 2020. External development expense increased by \$2.6 million due to increased activity on the Company’s lead product candidate, OPNT003, nasal nalmefene.

Sales and marketing (“S&M”) expenses for the three months ended June 30, 2021, were approximately \$1.0 million for pre-commercialization efforts related to OPNT003, nasal nalmefene. Sales and marketing expense during the three months ended June 30, 2020, were approximately \$1.7 million.

Royalty expense for the three months ended June 30, 2021, was approximately \$2.1 million and \$1.4 million for the comparable period of 2020. The \$0.7 million increase was due to increased royalty revenue from net sales of NARCAN®.

Net income for the three months ended June 30, 2021, was approximately \$1.7 million, or income of \$0.39 per basic share and \$0.31 diluted share, compared to net loss of approximately \$0.2 million, or a loss of \$0.05 per basic and diluted share, for the comparable period of 2020.

### **Financial Results for the Six Months Ended June 30, 2021**

For the six months ended June 30, 2021, Opiant recorded approximately \$17.6 million in revenue, compared to approximately \$10.6 million during the corresponding period of 2020. For the six months ended June 30, 2021, the Company recorded approximately \$13.6 million of revenue from the sale of NARCAN®, compared to approximately \$10.5 million in the same period of 2020. First half 2021 sales of NARCAN® were approximately \$180.4 million, as reported by EBS. For the six months ended June 30, 2021, the Company recorded approximately \$4.0 million in grant and contract revenue compared to approximately \$0.1 million in the same period in 2020. The \$3.1 million increase in revenue from our license agreement with EBS was primarily due to a \$35.5 million increase in net NARCAN® sales in the six months ended June 30, 2021, compared to the six months ended June 30, 2020. The \$3.9 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 six months ended June 30, 2021 and June 30, 2020, G&A expenses were approximately \$5.4 million.

R&D expenses for the six months ended June 30, 2021, were approximately \$7.2 million, as compared to approximately \$2.0 million in the comparable period in 2020. External development expense increased by \$5.2 million due to increased activity on the Company’s lead product candidate, OPNT003, nasal nalmefene.

S&M expenses for the six months ended June 30, 2021, were approximately \$2.0 million compared to approximately \$2.8 million in the comparable period in 2020.

Royalty expense for the six months ended June 30, 2021, was approximately \$3.1 million, compared to approximately \$2.3 million for the comparable period of 2020. The \$0.7 million increase was due to increased royalty revenue from the net sale of NARCAN®.

Net loss for the six months ended June 30, 2021, was approximately \$1.2 million, or a loss of \$0.27 per basic and diluted share, compared to net loss of approximately \$1.9 million, or a loss of \$0.45 per basic and diluted share, for the comparable period of 2020.

As of June 30, 2021, Opiant had \$48.5 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 \$325 million, Opiant expects full-year 2021 royalty revenue from the sale of NARCAN® Nasal Spray of approximately \$28.9 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 \$42 million to \$44 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:**

**Tuesday, May 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: 13718590

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, 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](mailto:Batkins@opiant.com)

(310) 598-5410

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

	Three months ended June 30 2021 (Unaudited)	Three months ended June 30 2020 (Unaudited)	Six months ended June 30 2021 (Unaudited)	Six months ended June 30 2020 (Unaudited)
Revenues				
Royalty revenue	\$ 9,314	\$ 6,258	\$ 13,648	\$ 10,456
Grant and contract revenue	1,945	55	3,998	139
Total Revenue	<u>11,259</u>	<u>6,313</u>	<u>17,646</u>	<u>10,595</u>
Operating expenses				
General and administrative	2,733	2,836	5,380	5,410
Research and development	3,150	558	7,238	1,979
Sales & marketing	1,023	1,747	2,020	2,823
Royalty expense	2,107	1,403	3,086	2,337
Total expenses	<u>9,013</u>	<u>6,544</u>	<u>17,724</u>	<u>12,549</u>
Income (loss) from operations	2,246	(231)	(78)	(1,954)
Other income (expense)				
Interest income	4	11	7	88
Interest expense	(542)	-	(1,079)	-
Loss on foreign exchange	(24)	4	(10)	4
Total other income (expense)	<u>(562)</u>	<u>15</u>	<u>(1,082)</u>	<u>92</u>
Income (loss) before provision for income taxes	1,684	(216)	(1,160)	(1,862)
Income tax expense	-	-	-	39
Net income (loss)	<u>\$ 1,684</u>	<u>\$ (216)</u>	<u>\$ (1,160)</u>	<u>\$ (1,901)</u>
Other comprehensive income (loss):				
Foreign currency translation adjustment	(5)	(17)	8	(311)
Comprehensive income (loss)	<u>\$ 1,679</u>	<u>\$ (233)</u>	<u>\$ (1,152)</u>	<u>\$ (2,212)</u>
Net income (loss) per common share				
Basic	<u>\$ 0.39</u>	<u>\$ (0.05)</u>	<u>\$ (0.27)</u>	<u>\$ (0.45)</u>
Diluted	<u>\$ 0.31</u>	<u>\$ (0.05)</u>	<u>\$ (0.27)</u>	<u>\$ (0.45)</u>
Weighted-average common shares outstanding:				
Basic	<u>4,332,601</u>	<u>4,258,105</u>	<u>4,308,027</u>	<u>4,241,423</u>
Diluted	<u>5,427,831</u>	<u>4,258,105</u>	<u>4,308,027</u>	<u>4,241,423</u>

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

	As of June 30, 2021 (unaudited)	As of December 31, 2020
<b>Assets</b>		
Current assets		
Cash & cash equivalents	\$ 33,443	\$ 48,251
Marketable securities	15,072	-
Accounts receivable	9,726	8,911
Prepaid expenses and other current assets	2,277	1,937
Total current assets	<u>60,518</u>	<u>59,099</u>
Other assets		
Property and equipment, net	109	171
Right of use assets - operating leases	1,119	279
Patents and patent applications, net	12	13
Other non-current assets	-	1,051
Total assets	<u>\$ 61,758</u>	<u>\$ 60,613</u>
<b>Liabilities and stockholders' equity</b>		
Current liabilities		
Accounts payable and accrued liabilities	\$ 2,447	\$ 2,966
Accrued salaries and wages	891	909
Royalty payable	2,107	1,908
Deferred revenue	-	355
Operating leases	339	282
Total current liabilities	<u>5,784</u>	<u>6,420</u>
Long-term liabilities		
Operating leases	781	-
Convertible debt, net of unamortized discount	18,837	18,701
Total long-term liabilities	<u>19,618</u>	<u>18,701</u>
Total liabilities	25,402	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	4	4
Additional paid-in-capital	102,220	100,204
Accumulated other comprehensive loss	(19)	(27)
Accumulated deficit	(65,849)	(64,689)
Total stockholders' equity	<u>36,356</u>	<u>35,492</u>
Total liabilities and stockholders' equity	<u>\$ 61,758</u>	<u>\$ 60,613</u>