

**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 11, 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 400, 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 August 11, 2022, Opiant Pharmaceuticals, Inc. (the “**Company**”), issued a press release announcing the Company’s financial results for the second quarter ended June 30, 2022 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 11, 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: August 11, 2022 **OPIANT PHARMACEUTICALS, INC.**

By: /s/ David D. O'Toole

Name: David D. O'Toole

Title: Chief Financial Officer

Opiant Pharmaceuticals Announces Second Quarter and First Half 2022 Financial Results and Provides Corporate Update

SANTA MONICA, Calif., Aug 11, 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 months and six months ended June 30, 2022, and provided a corporate update. Recent highlights include:

Pipeline Update

Rolling New Drug Application (NDA) submission for OPNT003, nasal nalmefene for opioid overdose remains on track, with completion expected in the second half of 2022

Announced that the United States (U.S.) Patent and Trademark Office has issued a Notice of Allowance for U.S. patent with claims covering OPNT003 for opioid overdose

Enrollment and dosing on track in 300-patient Phase 2 study for OPNT002, nasal naltrexone, for Alcohol Use Disorder (AUD); data expected in H1 2023

Finance Update

Q2 revenues of \$3.9 million; \$2.3 million of revenue was attributable to the sales of NARCAN® Nasal Spray from Opiant's License Agreement with Emergent BioSolutions, Inc. (EBS)

- o *EBS communicated that royalties from U.S. NARCAN® sales were calculated using a 2% rate, despite Q2 2022 U.S. net sales having been greater than 70% of Q3 2021 thus requiring higher rates*
- o *Opiant delivered to EBS a default notice of material breach of its License Agreement for failure to pay the royalty rate set out in the License Agreement*

Announced \$2.1 million funding awarded under its contract with the Biomedical Advanced Research and Development Authority (BARDA) for OPNT003 nasal nalmefene

Approximately \$40.2 million in cash and cash equivalents, as of June 30, 2022

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

"At Opiant, we feel a strong sense of urgency to meet the need for new treatment options for opioid overdose, driven largely by fentanyl and other very potent illicit synthetic opioids, which are doing so much harm in our communities. We are on track to complete our NDA this year, and believe that OPNT003, nasal nalmefene, is particularly well suited to help confront this national overdose crisis. The value of OPNT003 was further validated by the allowance of our patent application by the USPTO. By year-end, we also anticipate completing enrollment in the Phase 2 study evaluating OPNT002 for the treatment of Alcohol Use Disorder, with data expected during the first half of next year. I am excited by the progress we have made and look forward to advancing our mission to deliver medicines to better treat addiction and drug overdose."

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

"Looking ahead, we are prudently managing expenses while maintaining our good financial position with multiple value creating catalysts expected over the next 12 months. With that said, we intend to pursue all avenues to ensure the terms of the NARCAN® licensing agreement are appropriately enforced."

Financial Results for the Three Months Ended June 30, 2022

For the three months ended June 30, 2022, Opiant recorded approximately \$3.9 million in revenue, compared to approximately \$11.3 million during the corresponding period of 2021. For the three months ended June 30, 2022, the Company recorded approximately \$2.3 million of revenue from its license agreement with Emergent BioSolutions, Inc. (EBS) for the sale of NARCAN®, and \$1.6 million from grant and contract revenue, compared to approximately \$9.3 million and \$1.9 million respectively in the same period of 2021. Second quarter 2022 sales of NARCAN® were approximately \$101.5 million, as reported by EBS.

For the three months ended June 30, 2022, general and administrative (G&A) expenses were approximately \$4.0 million, as compared to approximately \$2.7 million in the comparable period in 2021. Personnel and non-cash stock-based compensation expense increased by \$1.3 million.

Research and development (R&D) expenses for the three months ended June 30, 2022, increased by \$4.8 million to \$7.9 million, from \$3.1 million for the three months ended June 30, 2021. External development expense increased by \$3.9 million primarily due to increased activity on our lead product candidate, OPNT003, nasal nalmeferene, for opioid overdose, and personnel and non-cash stock-based compensation expense increased by \$0.9 million.

Sales and marketing (S&M) expenses for the three months ended June 30, 2022, were approximately \$2.8 million, as compared to approximately \$1.0 million in the comparable period in 2021. Personnel and non-cash stock-based compensation expense increased by \$1.1 million and external third party spend related to pre-commercial activities increased by \$0.7 million.

Royalty expense for the three months ended June 30, 2022, was approximately \$0.5 million, compared to \$2.1 million in the comparable period in 2021.

During the three months ended June 30, 2022, interest expense was \$0.4 million compared to \$0.5 million during the three months ended June 30, 2021. Interest expense is all related to the Company's convertible debt.

Net loss for the three months ended June 30, 2022, was approximately \$11.8 million, or a loss of \$2.31 per basic share and diluted share, compared to net income of approximately \$1.7 million, or \$0.39 per basic and \$0.31 per diluted share, for the comparable period of 2021.

On August 10, 2022, Opiant delivered a Default Notice to EBS under section 10.3 of its License Agreement. The Default Notice put EBS on notice it had materially breached one or more of its obligations under the License Agreement. Opiant stated cause for breach based upon the royalty report EBS provided Opiant for the quarter ended June 30, 2022. The EBS royalty report confirmed U.S. net NARCAN® sales during the second quarter were greater than 70% of the U.S. net NARCAN® sales in the third quarter 2021. As provided under the License Agreement, the Generic Reduction Clause would not apply and Opiant should have been entitled to the higher tiered royalty rate structure. However, EBS arbitrarily applied a 2% rate, disregarding the terms of the License Agreement, and resulting in a royalty payment of approximately \$2.3 million. Opiant believes that it is due approximately \$9.1 million, a significantly higher royalty payment. The Default Notice allows EBS sixty days to meet its obligations under the License Agreement and pay the correct amount owed. If EBS fails to do so, Opiant intends to vigorously pursue all remedies aimed at ensuring EBS complies with the existing License Agreement. The License Agreement was originally between LightLake Therapeutics Inc. and Adapt Pharma Limited, which Opiant and EBS are successors to, respectively.

Financial Results for the Six Months Ended June 30, 2022

For the six months ended June 30, 2022, Opiant recorded approximately \$8.4 million of revenue, compared to \$17.6 million during the corresponding period of 2021. For the six months ended June 30, 2022, Opiant recognized \$4.5 million of revenue from its license agreement with EBS and \$3.8 million from grant and contract revenue. This compares to \$13.6 million and \$4.0 million, respectively, for the same period in 2021. First half 2022 sales of NARCAN® were approximately \$194.6 million, as reported by EBS.

For the six months ended June 30, 2022, G&A expenses were approximately \$8.3 million, compared to \$5.4 million in 2021. Personnel and non-cash stock-based compensation increased by \$2.4 million along with a net increase of approximately \$0.5 million associated with legal and other fees for the six months ended June 30, 2022, compared to the six months ended June 30, 2021.

R&D expenses during the six months ended June 30, 2022, increased by \$9.5 million to \$16.7 million, compared to \$7.2 million for the six months ended June 30, 2021. The increase was primarily due to increased activity by \$7.8 million on our lead product candidate, OPNT003, nasal nalmeferene, and to personnel and non-cash stock-based compensation expense of \$1.7 million.

S&M expenses for the six months ended June 30, 2022, increased by \$3.5 million to \$5.5 million from \$2.0 million for the six months ended June 30, 2021. Personnel and non-cash stock-based compensation expense increased by \$2.0 million, and external third party spend related to pre-commercial activities increased by \$1.5 million.

Royalty expense for the six months ended June 30, 2022, was approximately \$0.9 million, compared to approximately \$3.1 million for the comparable period of 2021. The decrease of \$2.2 million is attributable to the decrease in net revenue recorded from sales of NARCAN® by EBS.

Net loss for the six months ended June 30, 2022, was approximately \$24.0 million, or a loss of \$4.74 per basic and diluted share, compared to net loss of approximately \$1.2 million, or a loss of \$0.27 per basic and diluted share, for the comparable period of 2021.

As of June 30, 2022, Opiant had \$40.2 million in cash and cash equivalents.

In August, Opiant announced that the Biomedical Advanced Research and Development Authority (BARDA) has awarded an additional approximately \$2.1 million to support OPNT003, nasal nalmeferene. The funding is primarily directed toward the preparation and filing of a New Drug Application for OPNT003 to the Food and Drug Administration.

Awards from BARDA for up to \$10.8 million, combined with a \$7.4 million grant Opiant received from the National Institute on Drug Abuse, support the clinical development and U.S. regulatory submission of OPNT003. The contract with BARDA will also potentially allow for the development of OPNT003 as a medical countermeasure in a chemical attack using weaponized synthetic opioids as well as reverse opioid overdoses in the community.

BARDA is part of the Office of the Assistant Secretary for Preparedness and Response within the U.S. Department of Health and Human Services. This project has been funded in whole or 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, August 11th 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: 13730815
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 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, submit a New Drug Application in the second half of 2022. 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 comparable 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 Form 10-K for the year ended December 31, 2021, and our Form 10-Q for the quarter ended June 30, 2022, filed with the Securities and Exchange Commission on March 4, 2022, and August 11, 2022, respectively, 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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VP of Corporate Communications and Investor Relations

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(310) 598-5410

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

	As of June 30 2022	As of December 31, 2021
Assets	(unaudited)	
Current Assets		
Cash & cash equivalents	\$ 40,173	\$ 37,854
Marketable securities	-	\$ 15,015
Accounts receivable	2,336	13,327
Unbilled receivable	1,637	-
Prepaid and other current assets	3,612	2,963
Total Current Assets	47,758	69,159
Other Assets		
Property and equipment, net	71	78
Right of use assets - operating leases	733	1,000
Patents and patent applications, net	11	12
Other non-current assets	251	179
Total Assets	\$ 48,824	\$ 70,428
Liabilities and stockholders' equity		
Current Liabilities		
Accounts payable and accrued expenses	\$ 3,102	\$ 3,370
Accrued salaries & wages	1,226	202
Royalty payable	440	2,920
Deferred revenue	-	17
Operating leases	227	338
Total Current Liabilities	4,995	6,847
Long-Term Liabilities		
Operating leases - long term	523	673
Convertible debt - net of unamortized discount	13,710	16,069
Total Long-Term Liabilities	14,233	16,742
Total Liabilities	19,228	23,589
Stockholders' equity		
Common stock, \$0.001 par value, 200,000,000 shares authorized, 5,122,575 and 4,909,846 shares issued and outstanding at June 30, 2022 and December 31, 2021, respectively	5	4
Additional paid-in-capital	115,439	108,570
Accumulated other comprehensive loss	(243)	(55)
Accumulated deficit	(85,605)	(61,680)
Total stockholders' equity	29,596	46,839
Total liabilities and stockholders' equity	\$ 48,824	\$ 70,428

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

	Three months ended	Three months ended	Six months ended	Six months ended
	June 30	June 30	June 30	June 30
	2022	2021	2022	2021
	(Unaudited)	(Unaudited)	(Unaudited)	(Unaudited)
Revenues				
Royalty revenue	\$ 2,326	\$ 9,314	\$ 4,520	\$ 13,648
Grant and contract revenue	1,568	1,945	3,845	3,998
Total Revenue	<u>3,894</u>	<u>11,259</u>	<u>8,365</u>	<u>17,646</u>
Operating expenses				
General and administrative	4,011	2,733	8,343	5,380
Research and development	7,916	3,150	16,739	7,238
Sales & marketing	2,016	1,023	5,493	2,020
Royalty expense	517	2,107	943	3,086
Total expenses	<u>15,260</u>	<u>9,013</u>	<u>31,518</u>	<u>17,724</u>
Income (loss) from operations	(11,366)	2,246	(23,153)	(78)
Other income (expense)				
Interest income	63	4	68	7
Interest expense	(401)	(542)	(822)	(1,079)
Loss on foreign exchange	-	(24)	16	(10)
Total other income (expense)	<u>(338)</u>	<u>(562)</u>	<u>(738)</u>	<u>(1,082)</u>
Income (loss) before provision for income taxes	(11,704)	1,684	(23,891)	(1,160)
Income tax expense	(33)	-	(33)	-
Net income (loss)	<u>\$ (11,737)</u>	<u>\$ 1,684</u>	<u>\$ (23,924)</u>	<u>\$ (1,160)</u>
Other comprehensive income (loss):				
Foreign currency translation adjustment	(161)	(5)	(188)	8
Comprehensive income (loss)	<u>\$ (11,898)</u>	<u>\$ 1,679</u>	<u>\$ (24,112)</u>	<u>\$ (1,152)</u>
Net income (loss) per common share				
Basic	<u>\$ (2.31)</u>	<u>\$ 0.39</u>	<u>\$ (4.74)</u>	<u>\$ (0.27)</u>
Diluted	<u>\$ (2.31)</u>	<u>\$ 0.31</u>	<u>\$ (4.74)</u>	<u>\$ (0.27)</u>
Weighted-average common shares outstanding:				
Basic	<u>5,087,647</u>	<u>4,332,601</u>	<u>5,051,814</u>	<u>4,308,027</u>
Diluted	<u>5,087,647</u>	<u>5,427,831</u>	<u>5,051,814</u>	<u>4,308,027</u>