

**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 8, 2019

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.)

**201 Santa Monica Boulevard, Suite 500
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))

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

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.

Item 2.02. Results of Operations and Financial Condition.

On August 8, 2019, Opiant Pharmaceuticals, Inc. (the “**Company**”), issued a press release announcing the Company’s financial results for the quarter and six months ended June 30, 2019 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 8, 2019.](#)

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: August 8, 2019 By: /s/ David D. O'Toole

Name: David D. O'Toole

Title: Chief Financial Officer

Opiant Pharmaceuticals Reports Second Quarter 2019 Financial Results and Provides Corporate Update

SANTA MONICA, Calif, August 8, 2019 – Opiant Pharmaceuticals, Inc. (“Opiant”) (NASDAQ: OPNT), a specialty pharmaceutical company developing medicines for addictions and drug overdose, today reported financial results for the second quarter and six months ended June 30, 2019 and provided a corporate update.

“During the first half of 2019, we continued to achieve important progress in advancing our pipeline and we look forward to reaching additional key milestones in the second half of the year,” said Roger Crystal, M.D., Chief Executive Officer of Opiant. “With a broad pipeline that is partially funded via multiple U.S. government sources, and multiple key upcoming catalysts, we are well-positioned for continued progress with our clinical programs throughout the remainder of the year and beyond.”

David O’Toole, Chief Financial Officer of Opiant added, “The significant increase in sales of NARCAN[®] Nasal Spray in 2019 continues to drive expanded royalty revenue for Opiant. In addition, we generated positive net income and earnings per share in the second quarter and expect to continue this throughout 2019. Moreover, we expect our balance sheet will be further strengthened in the next approximately six months, based on the timing of the one-time milestone payment of \$13.5 million due to Opiant from Emergent BioSolutions (EBS) when net sales of NARCAN[®] exceed \$200 million in the 2019 calendar year.”

Corporate Highlights and Near-Term Milestones

- Expanded relationship with Sanofi to include manufacturing of OPNT004 (drinabant) for the emergency treatment of Acute Cannabinoid Overdose (ACO). Opiant intends to initiate formulation development studies in the second half of 2019 with clinical trials to follow.
 - o It is estimated that ACO resulted in more than one million emergency department visits in the U.S. in 2016, and this rate is expected to rise with the increasing legalization of cannabis in North America.
 - o Opiant intends to reformulate drinabant for parenteral administration in an emergency department setting.
- Initiated human use characteristic studies with the Bespak Unidose[™] Xtra device that will be used in both the confirmatory pharmacokinetic (PK) study of nasal nalmefene, OPNT003, for the treatment of opioid overdose and the potential commercialization of the product.
- Planning for the confirmatory PK study of OPNT003; expect to report top-line data this year and file a New Drug Application for OPNT003 in 2020.
- Initiated OPNT002 formulation selection study in Alcohol Use Disorder and began preparations for a Phase 2 study; expect to begin enrolling patients in this study later this year.

Events and Presentations

- Developing Medical Countermeasures to Rescue Opioid-Induced Respiratory Depression Meeting
 - o August 6-7, Rockville, MD
 - o Dr. Phil Skolnick, Chief Scientific Officer, presented “Development of Intranasal Nalmefene: A High-Potency, Long-Duration Opioid Antagonist” moderated by Judith Laney, Branch Chief for Chemical Medical Countermeasures at Biomedical Advance Research and Authority (BARDA)
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- Wells Fargo Healthcare Conference
 - September 4-5, Boston, MA
- 21st Annual Rodman & Renshaw Global Healthcare Conference
 - September 8-10, New York, NY
- Cantor Fitzgerald Global Healthcare Conference
 - October 2-4, New York, NY
- Opiant R&D Investor Day
 - October 17, New York, NY
- 5th Annual Dawson James Small Cap Growth Conference
 - October 28-29, Jupiter, FL
- 10th Anniversary CNS Summit
 - October 31-November 3, Boca Raton, FL

Financial Results for the Second Quarter Ended June 30, 2019

For the three months ended June 30, 2019, Opiant recorded approximately \$6.8 million in revenue, compared to approximately \$3.2 million during the corresponding period of 2018. For the three months ended June 30, 2019, Opiant recognized approximately \$6.1 million of revenue from the license agreement (the Adapt License) between it and Adapt Pharma Operations Limited, a subsidiary of EBS, for the sale of NARCAN® Nasal Spray, compared to approximately \$3.1 million in the comparable period of 2018. The \$3.0 million increase in royalty revenue was attributable to a significant increase in sales of NARCAN® Nasal Spray to approximately \$73 million for the second quarter of 2019, as reported by EBS.

General and administrative expenses for the three months ended June 30, 2019, were approximately \$3.7 million, compared to approximately \$2.9 million in the comparable period of 2018. The increase was primarily due to a \$0.9 million increase in royalty expense, a \$0.2 million increase in legal, accounting and professional fees, partially offset by a \$0.3 million decrease in stock-based compensation expense.

Research and development expenses for the three months ended June 30, 2019, were approximately \$1.6 million, essentially flat as compared to the same period in 2018.

Net income for the three months ended June 30, 2019, was approximately \$1.6 million, or \$0.39 per basic and \$0.31 per diluted share, compared to a net loss of approximately (\$1.4) million, or a loss of (\$0.52) per basic and diluted share, for the comparable period of 2018.

Financial Results for the Six Months Ended June 30, 2019

For the six months ended June 30, 2019, Opiant recorded approximately \$12.2 million in revenue, compared to approximately \$4.9 million during the corresponding period of 2018. For the six months ended June 30, 2019, Opiant recognized approximately \$9.9 million of revenue from the license agreement between it and Adapt for the sale of NARCAN® Nasal Spray, compared to approximately \$4.7 million in the comparable period of 2018. The \$5.2 million increase in royalty revenue was attributable to a significant increase in sales of NARCAN® Nasal Spray to approximately \$138.5 million for the six months ended June 30, 2019, as reported by EBS.

General and administrative expenses for the six months ended June 30, 2019, were approximately \$7.4 million, compared to approximately \$5.8 million in the comparable period of 2018. The increase was primarily due to a \$1.3 million increase in royalty expense, a \$0.7 million increase in legal and professional fees, a \$0.4 million increase in personnel and related expense including recruiting, partially offset by a \$0.8 million decrease in stock-based compensation expense.

Research and development expenses for the six months ended June 30, 2019, were approximately \$5.2 million, compared to approximately \$4.0 million in the comparable period of 2018. The increase was primarily attributable to a \$1.2 million increase in third-party expenses associated with Opiant's research and development programs, \$0.4 million increase in employee related compensation expense, partially offset by a \$0.4 million decrease in stock-based compensation expense.

There were no license fees recorded for the six months ended June 30, 2019. Opiant recorded \$5.6 million of license fees incurred during the six months ended June 30, 2018. The license fees related to Opiant's obligations under the License Agreement with Adapt.

Net loss for the six months ended June 30, 2019, was approximately (\$0.2) million, or a loss of (\$0.04) per basic and diluted share, compared to a net loss of approximately (\$10.7) million, or a loss of (\$4.11) per basic and diluted share, for the comparable period of 2018.

As of June 30, 2019, Opiant had cash and cash equivalents of \$23.9 million, compared to approximately \$24.6 million at December 31, 2018. The cash balance at June 30, 2019, does not include the full impact of the National Institute on Drug Abuse (NIDA) grant of approximately \$7.4 million or the BARDA contract of approximately \$4.6 million. Opiant continues to project a cash balance in the range of \$17 million to \$20 million at the end of 2019. This anticipated range does not include the one-time milestone payment of \$13.5 million due to Opiant from EBS when net sales of NARCAN® by EBS exceed \$200 million in the 2019 calendar year. Based on the \$138.5 million in sales of NARCAN® Nasal Spray that was recently publicly reported by EBS for the six months ended June 30, 2019, and its full-year 2019 estimate of sales from \$240 million to \$260 million, it is possible that net sales of NARCAN® will exceed \$200 million in the third quarter of 2019. Under this scenario, Opiant would receive the one-time \$13.5 million milestone payment in the fourth quarter of 2019. Otherwise, net sales of NARCAN® will exceed \$200 million in the fourth quarter of 2019, and Opiant will receive the one-time \$13.5 million milestone payment in the first quarter of 2020. Pursuant to our license agreement with EBS, in the event that this milestone is achieved, EBS will reduce the amount payable to Opiant by the remaining \$2.7 million of the license fees payable.

National Emergency Department sample and United States Census Bureau figures, 2016

Conference Call Details

Thursday, August 8th @ 4:30pm Eastern Time/1:30pm Pacific Time

Toll Free: 877-407-0792

International: 201-689-8263

Conference ID: 13692263

Webcast: <http://public.viavid.com/index.php?id=135167>

About Opiant Pharmaceuticals, Inc.

Opiant Pharmaceuticals, Inc. is a specialty pharmaceutical company developing medicines for addictions and drug overdose. NIDA, a division of the National Institutes of Health, describes addictive disorders as chronic relapsing brain diseases which burden society at both the individual and community levels. Opiant's first drug overdose product, NARCAN® Nasal Spray, is approved

for marketing in the U.S. and Canada by its licensee, Adapt Pharmaceuticals, now owned by Emergent BioSolutions Inc. 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 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, 2018, filed with the Securities and Exchange Commission on March 21, 2019, 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 J une 30, 2019 (unaudited)	As of December 31, 2018
Assets		
Current Assets		
Cash & cash equivalents	\$ 23,917	\$ 24,614
Accounts receivable	4,345	4,489
Prepaid expenses and other current assets	493	267
Total Current Assets	28,755	29,370
Long-term Assets		
Property and equipment, net of depreciation	55	-
Patents and patent applications, net	15	16
Total Assets	\$ 28,825	\$ 29,386
Liabilities and stockholders' equity		
Current Liabilities		
Accounts payable and accrued expenses	\$ 1,074	\$ 1,133
License fees	4,500	5,400
Accrued salaries & wages	879	1,084
Royalty payable	935	998
Deferred revenue	1,374	1,212
Total Current Liabilities	8,762	9,827
Long-Term Liabilities		
License fees	-	2,700
Total Long-Term Liabilities	-	2,700
Total Liabilities	8,762	12,527
Stockholders' equity		
Common stock, \$0.001 par value, 200,000,000 shares authorized, 4,025,500 and 3,845,361 shares issued and outstanding at J une 30, 2019 and December 31, 2018, respectively	4	4
Additional paid-in-capital	94,638	91,276
Accumulated deficit	(74,579)	(74,421)
Total stockholders' equity	20,063	16,859
Total liabilities and stockholders' equity	\$ 28,825	\$ 29,386

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

	Three months ended		Six months ended	
	June 30,		June 30,	
	2019	2018	2019	2018
Revenues				
Royalty & licensing revenue	6,129	3,053	9,875	4,702
Treatment investment revenue	564	53	644	107
Grant revenue	82	44	1,691	44
Total Revenue	<u>6,775</u>	<u>3,150</u>	<u>12,210</u>	<u>4,853</u>
Operating Expenses				
General and administrative	3,731	2,857	7,427	5,822
Research and development	1,634	1,616	5,201	4,036
License fees	-	-	-	5,625
Total expenses	<u>5,365</u>	<u>4,473</u>	<u>12,628</u>	<u>15,483</u>
Income (loss) from operations	1,410	(1,323)	(418)	(10,630)
Other income (expense)				
Interest income	122	6	244	11
Loss on settlement of liability	-	(50)	-	(50)
Loss on foreign exchange	(11)	(30)	(41)	(38)
Total other income (expense)	<u>111</u>	<u>(74)</u>	<u>203</u>	<u>(77)</u>
Income (loss) before income taxes	1,521	(1,397)	(215)	(10,707)
Income tax (expense) benefit	57	-	57	(33)
Net income (loss)	<u>\$ 1,578</u>	<u>\$ (1,397)</u>	<u>\$ (158)</u>	<u>\$ (10,740)</u>
Net income (loss) per common share				
Basic	<u>\$ 0.39</u>	<u>\$ (0.52)</u>	<u>\$ (0.04)</u>	<u>\$ (4.11)</u>
Diluted	<u>\$ 0.31</u>	<u>\$ (0.52)</u>	<u>\$ (0.04)</u>	<u>\$ (4.11)</u>
Weighted-average common shares outstanding:				
Basic	<u>3,995,669</u>	<u>2,679,910</u>	<u>3,952,773</u>	<u>2,611,245</u>
Diluted	<u>5,128,575</u>	<u>2,679,910</u>	<u>3,952,773</u>	<u>2,611,245</u>