
**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, 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.)

**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.

Item 2.02. Results of Operations and Financial Condition.

On November 12, 2019, Opiant Pharmaceuticals, Inc. (the “**Company**”), issued a press release announcing the Company’s financial results for the quarter and nine months ended September 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 November 12, 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: November 12, 2019 By: /s/ David D. O'Toole

Name: David D. O'Toole
Title: Chief Financial Officer

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

SANTA MONICA, Calif., Nov. 12, 2019 -- Opiant Pharmaceuticals, Inc. (“Opiant”) (NASDAQ: OPNT), a specialty pharmaceutical company developing medicines to treat addictions and drug overdose, today reported financial results for the third quarter and nine months ended September 30, 2019, and provided a corporate update.

“We remain focused on advancing our robust pipeline, which is funded through multiple government sources and a growing revenue stream via royalties from net sales of NARCAN® Nasal Spray for the reversal of opioid overdose,” said Roger Crystal, M.D., Chief Executive Officer of Opiant. “We look forward to multiple clinical development catalysts over the next several quarters for each of our core development programs.”

David O’Toole, Chief Financial Officer of Opiant, added, “I am extremely pleased to report that, based on net sales of NARCAN® Nasal Spray exceeding \$200 million through the third quarter of 2019, we have earned a one-time \$13.5 million milestone. After certain required deductions, the net milestone payment of \$10.8 million will further fortify our already strong balance sheet, and we now expect a cash balance of \$28 million to \$30 million at the end of 2019, versus our prior projection of \$17 million to \$20 million.”

Corporate Highlights and Near-Term Milestones

- Earned a one-time \$13.5 million milestone payment based on net sales of NARCAN® exceeding \$200 million through the quarter ended September 30, 2019.
- Continued preparations to conduct confirmatory pharmacokinetic (PK) study of nasal nalmefene, OPNT003, for the treatment of opioid overdose.
 - Opiant now expects to report top-line data from the PK study in the first quarter of next year, but continues to anticipate filing a New Drug Application for OPNT003 in the fourth quarter of 2020.
- Dose selection study for OPNT002 for Alcohol Use Disorder is nearing completion. Opiant expects to complete the subsequent Phase 2 study during the second half of 2020.
- Strengthened the executive management team with the appointments of Aziz Mottiwala as Chief Commercial Officer, and Rahsaan Thompson, as General Counsel.
- Provided a detailed overview of Opiant’s development programs during an Investor Research & Development meeting in New York City.
- Expanded relationship with Sanofi to include manufacturing of OPNT004 for the emergency treatment of Acute Cannabinoid Overdose. Opiant intends to initiate formulation development studies in the second half of 2019, with clinical trials to follow.

Financial Results for the Third Quarter Ended September 30, 2019

For the three months ended September 30, 2019, Opiant recorded approximately \$20.6 million in revenue, compared to approximately \$4.4 million during the corresponding period of 2018. For the three months ended September 30, 2019, Opiant recognized approximately \$20.5 million of revenue from the license agreement (the Adapt License) between it and Adapt Pharma Operations Limited, now a subsidiary of Emergent BioSolutions Inc. (EBS), for the sale of NARCAN® Nasal Spray, compared to approximately \$4.2 million in the comparable period of 2018. The \$20.5 million of revenue from the license agreement between us and Adapt included a one-time milestone payment due to Opiant of \$13.5 million, as sales of Narcan exceeded \$200 million through the third quarter of 2019.

General and administrative expenses for the three months ended September 30, 2019, were approximately \$3.2 million, compared to approximately \$2.9 million in the comparable period of 2018. The increase was primarily due to a \$0.4 million increase in personnel and related expense, a \$0.3 million increase in royalty expense and a \$0.1 increase in consulting fees, partially offset by a \$0.5 million decrease in stock-based compensation expense.

Research and development expenses for the three months ended September 30, 2019, were approximately \$1.8 million, essentially flat as compared to the same period in 2018.

Sales and marketing expenses for the three months ended September 30, 2019, were approximately \$140,000, compared to none in the comparable period of 2018. The increase was primarily due to compensation-related expenses.

Royalty expense for the three months ended September 30, 2019, was approximately \$4.9 million, compared to approximately \$0.5 million in the comparable period of 2018. The increase was primarily due to a \$3.1 million increase in payments due to Net Profit Partners for the royalties and sales milestone received from the net sales of NARCAN® Nasal Spray and \$1.3 million for payments made to buyout the net profit interests in Nasal Nalmefene held by investors who had initially supported the development of NARCAN Nasal Spray.

Net income for the three months ended September 30, 2019, was approximately \$10.7 million, or \$2.64 per basic and \$1.97 per diluted share, compared to a net loss of approximately (\$0.9) million, or a loss of (\$0.32) per basic and diluted share, for the comparable period of 2018.

Financial Results for the Nine Months Ended September 30, 2019

For the nine months ended September 30, 2019, Opiant recorded approximately \$32.9 million in revenue, compared to approximately \$9.2 million during the corresponding period of 2018. For the nine months ended September 30, 2019, Opiant recognized approximately \$30.4 million of revenue from the license agreement between it and Adapt for the sale of NARCAN® Nasal Spray, compared to approximately \$8.9 million in the comparable period of 2018. The \$21.5 million increase in royalty revenue was attributable to a significant increase in sales of NARCAN® Nasal Spray to approximately \$213.5 million for the nine months ended September 30, 2019, as reported by EBS, as well as the one-time milestone payment of \$13.5 million earned due to net sales of NARCAN® Nasal Spray exceeding \$200 million through the third quarter of 2019.

General and administrative expenses for the nine months ended September 30, 2019, were approximately \$9.4 million, compared to approximately \$8.7 million in the comparable period of 2018. The increase was primarily due to an increase of \$0.7 million in royalty expense, a \$0.7 million increase in legal and professional fees, and a \$0.7 million increase in personnel and related expense, including recruiting, partially offset by a \$1.4 million decrease in stock-based compensation expense.

Research and development expenses for the nine months ended September 30, 2019, were approximately \$7.0 million, compared to approximately \$5.9 million in the comparable period of 2018. The increase was primarily attributable to an increase of \$1.5 million in third-party expenses associated with Opiant's research and development programs, a \$0.4 million increase in employee-related compensation expense, partially offset by a \$0.8 million decrease in stock-based compensation expense.

Sales and marketing expenses for the nine months ended September 30, 2019, were approximately \$140,000, compared to none in the comparable period of 2018. The increase was primarily due to compensation-related expenses.

Royalty expense for the nine months ended September 30, 2019, was approximately \$6.1 million, compared to approximately \$0.5 million in the comparable period in 2018. The increase was primarily due to a \$4.3 million increase in payments due to Net Profit Partners for the royalties and sales milestone received from the net sales of NARCAN® Nasal Spray and \$1.3 million for payments made to buyout the net profit interests in Nasal Nalmefene held by investors who had initially supported the development of NARCAN Nasal Spray.

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

Net income for the nine months ended September 30, 2019, was approximately \$10.5 million, or \$2.64 per basic and \$1.98 per diluted share, compared to a net loss of approximately (\$11.7) million, or a loss of (\$4.32) per basic and diluted share, for the comparable period of 2018.

As of September 30, 2019, Opiant had cash and cash equivalents of \$23.2 million, compared to approximately \$24.6 million at December 31, 2018. The cash balance at September 30, 2019, does not include the one-time milestone payment of \$13.5 million due to Opiant from EBS based on net sales of NARCAN® Nasal Spray exceeding \$200 million in the third quarter of 2019, as reported by EBS. Pursuant to Opiant's license agreement with EBS, EBS will reduce the amount payable to Opiant by the remaining \$2.7 million of the license fees payable. Opiant will receive the net sales milestone of \$10.8 million during the fourth quarter of 2019. The current cash balance also does not include the full impact of the National Institute on Drug Abuse grant of approximately \$7.4 million or the BARDA contract of approximately \$4.6 million. Opiant now projects a cash balance in the range of \$28 million to \$30 million at the end of 2019, versus its prior estimate of \$17 million to \$20 million.

Conference Call Details:

Thursday, November 12 at 4:30 p.m. Eastern Time/1:30 p.m. Pacific Time

Toll Free: 877-407-0792

International: 201-689-8263

Conference ID: 13695005

Webcast: <http://public.viavid.com/index.php?id=136281>

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 September 30, 2019 (unaudited)	As of December 31, 2018
Assets		
Current Assets		
Cash & cash equivalents	\$ 23,222	\$ 24,614
Accounts receivable	16,068	4,489
Prepaid expenses and other current assets	940	267
Total Current Assets	40,230	29,370
Long-term Assets		
Property and equipment, net of depreciation	274	-
Right of use assets - operating leases	849	-
Patents and patent applications, net	15	16
Total Assets	\$ 41,368	\$ 29,386
Liabilities and stockholders' equity		
Current Liabilities		
Accounts payable and accrued expenses	\$ 1,952	\$ 1,133
License fees	-	5,400
Accrued salaries & wages	1,129	1,084
Royalty payable	4,475	998
Deferred revenue	1,355	1,212
Operating leases - current	493	-
Total Current Liabilities	9,404	9,827
Long-Term Liabilities		
Operating leases - long term	358	-
License fees	-	2,700
Total Long-Term Liabilities	358	2,700
Total Liabilities	9,762	12,527
Stockholders' equity		
Common stock, \$0.001 par value, 200,000,000 shares authorized, 4,074,622 and 3,845,361 shares issued and outstanding at September 30, 2019 and December 31, 2018, respectively	4	4
Additional paid-in-capital	95,497	91,276
Accumulated deficit	(63,895)	(74,421)
Total stockholders' equity	31,606	16,859
Total liabilities and stockholders' equity	\$ 41,368	\$ 29,386

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,	
	2019	2018	2019	2018
Revenues				
Royalty & licensing revenue	20,494	4,185	30,369	8,887
Treatment investment revenue	-	63	644	170
Grant revenue	147	118	1,838	163
Total Revenue	<u>20,641</u>	<u>4,366</u>	<u>32,851</u>	<u>9,220</u>
Operating Expenses				
General and administrative	3,210	2,861	9,389	8,683
Research and development	1,843	1,908	7,044	5,945
Sales and marketing	141	-	141	-
Royalty expense	4,851	537	6,099	537
License fees	-	-	-	5,625
Total expenses	<u>10,045</u>	<u>5,306</u>	<u>22,673</u>	<u>20,790</u>
Income (loss) from operations	10,596	(940)	10,178	(11,570)
Other income (expense)				
Interest income	112	20	356	31
Loss on settlement of liability	-	-	-	(50)
Gain (loss) on foreign exchange	(24)	2	(65)	(36)
Total other income (expense)	<u>88</u>	<u>22</u>	<u>291</u>	<u>(55)</u>
Income (loss) before provision for income taxes	10,684	(918)	10,469	(11,625)
Income tax (expense) benefit	-	-	57	(33)
Net income (loss)	<u>\$ 10,684</u>	<u>\$ (918)</u>	<u>\$ 10,526</u>	<u>\$ (11,658)</u>
Net income (loss) per common share				
Basic	<u>\$ 2.64</u>	<u>\$ (0.32)</u>	<u>\$ 2.64</u>	<u>\$ (4.32)</u>
Diluted	<u>\$ 1.97</u>	<u>\$ (0.32)</u>	<u>\$ 1.98</u>	<u>\$ (4.32)</u>
Weighted-average common shares outstanding:				
Basic	<u>4,048,635</u>	<u>2,871,042</u>	<u>3,985,112</u>	<u>2,698,532</u>
Diluted	<u>5,422,345</u>	<u>2,871,042</u>	<u>5,310,157</u>	<u>2,698,532</u>