UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

(Mark One)

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended September 30, 2020
or

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _____to_____.

Commission File Number: **001-38193**

OPIANT PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**46-4744124**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
233 Wilshire Blvd. Suite 280, Santa Monica, CA	**90401**
(Address of principal executive offices)	(Zip Code)

(310)-598-5410
(Registrant's telephone number, including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See definitions of "large accelerated filer", "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large Accelerated Filer	☐	Accelerated Filer ☐
Non-Accelerated Filer	☒	Smaller Reporting Company ☒
		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. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

As of November 9, 2020, the registrant had 4,258,105 shares of common stock outstanding.

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

CAUTIONARY STATEMENT ON FORWARD-LOOKING INFORMATION

This Quarterly Report on Form 10-Q (this "Report") contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Forward-looking statements discuss matters that are not historical facts. Because they discuss future events or conditions, forward-looking statements may include words such as "anticipate," "believe," "estimate," "intend," "could," "should," "would," "may," "seek," "plan," "might," "will," "expect," "predict," "project," "forecast," "potential," "continue", negatives thereof or similar expressions. Forward-looking statements speak only as of the date they are made, are based on various underlying assumptions and current expectations about the future and are not guarantees. Such statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, level of activity, performance or achievement to be materially different from the results of operations or plans expressed or implied by such forward-looking statements.

We cannot predict all of the risks and uncertainties. Accordingly, such information should not be regarded as representations that the results or conditions described in such statements or that our objectives and plans will be achieved and we do not assume any responsibility for the accuracy or completeness of any of these forward-looking statements. These forward-looking statements are found at various places throughout this Report and include information concerning possible or assumed future results of our operations, including statements about potential acquisition or merger targets; business strategies; future cash flows; financing plans; plans and objectives of management, any other statements regarding future acquisitions, future cash needs, future operations, business plans and future financial results, and any other statements that are not historical facts.

From time to time, forward-looking statements also are included in our other periodic reports on Forms 10-K and 8-K, in our press releases, in our presentations, on our website and in other materials released to the public. Any or all of the forward-looking statements included in this Report and in any other reports or public statements made by us are not guarantees of future performance and may turn out to be inaccurate. These forward-looking statements represent our intentions, plans, expectations, assumptions and beliefs about future events and are subject to risks, uncertainties and other factors. Many of those factors are outside of our control and could cause actual results to differ materially from the results expressed or implied by those forward-looking statements. In light of these risks, uncertainties and assumptions, the events described in the forward-looking statements might not occur or might occur to a different extent or at a different time than we have described. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this Report. All subsequent written and oral forward-looking statements concerning other matters addressed in this Report and attributable to us or any person acting on our behalf are expressly qualified in their entirety by the cautionary statements contained or referred to in this Report.

Except to the extent required by law, we undertake no obligation to update or revise any forward-looking statements, whether as a result of new information, future events, a change in events, conditions, circumstances or assumptions underlying such statements, or otherwise.

CERTAIN TERMS USED IN THIS REPORT

When this Report uses the words "we," "us," "our," "Opiant," and the "Company," they refer to Opiant Pharmaceuticals, Inc. "SEC" refers to the Securities and Exchange Commission.

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PART 1 - FINANCIAL INFORMATION

Item 1. Financial Statements

Opiant Pharmaceuticals, Inc.
Condensed Consolidated Balance Sheets

	September 30, 2020	December 31, 2019
Assets	(unaudited)	
Current assets		
Cash and cash equivalents	$ 31,103,165	$ 30,980,473
Accounts receivable	8,613,358	7,218,367
Prepaid and other current assets	861,782	1,055,816
Total current assets	40,578,305	39,254,656
Other assets		
Property and equipment - net of accumulated depreciation	202,319	243,039
Right of use assets - operating leases	396,809	768,441
Patents and patent applications - net of accumulated amortization	13,344	14,373
Other non-current assets	1,051,234	—
Total assets	$ 42,242,011	$ 40,280,509
Liabilities and Stockholders' Equity		
Liabilities		
Current liabilities		
Accounts payable and accrued expenses	$ 2,553,416	$ 1,316,773
Accrued salaries and wages	1,435,189	1,237,661
Royalty payable	1,951,677	1,620,182
Deferred revenue	360,041	918,272
Operating leases - current	400,571	516,931
Total current liabilities	6,700,894	5,609,819
Long-term liabilities		
Operating leases - long term	—	254,664
Total long-term liabilities	—	254,664
Total liabilities	6,700,894	5,864,483
Stockholders' equity		
Common stock; par value $0.001; 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	4,259	4,187
Additional paid-in capital	99,654,992	97,239,455
Accumulated other comprehensive loss	(114,644)	—
Accumulated deficit	(64,003,490)	(62,827,616)
Total stockholders' equity	35,541,117	34,416,026
Total liabilities and stockholders' equity	$ 42,242,011	$ 40,280,509

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

Opiant Pharmaceuticals, Inc.
Condensed Consolidated Statements of Operations and Comprehensive Loss
(unaudited)

	Three months ended September 30,		Nine months ended September 30,	
	2020	2019	2020	2019
Revenues				
Royalty and licensing revenue	$ 8,600,811	$ 20,493,679	$ 19,056,999	$ 30,368,530
Treatment investment revenue	—	—	—	643,956
Grant and contract revenue	505,265	147,071	644,195	1,837,673
Total revenue	9,106,076	20,640,750	19,701,194	32,850,159
Operating expenses				
General and administrative	2,729,098	3,211,022	8,138,571	9,389,630
Research and development	2,783,452	1,843,207	4,762,749	7,043,857
Sales and marketing	914,349	140,690	3,737,793	140,690
Royalty expense	1,951,947	4,850,807	4,288,701	6,098,882
Total operating expenses	8,378,846	10,045,726	20,927,814	22,673,059
Income (loss) from operations	727,230	10,595,024	(1,226,620)	10,177,100
Other income (expense)				
Interest income	3,922	112,388	92,015	356,657
Loss on foreign exchange	(6,178)	(24,313)	(2,269)	(65,310)
Total other income (expense)	(2,256)	88,075	89,746	291,347
Income (loss) before income taxes	724,974	10,683,099	(1,136,874)	10,468,447
Income tax (expense) benefit	—	—	(39,000)	56,805
Net income (loss)	$ 724,974	$ 10,683,099	$ (1,175,874)	$ 10,525,252
Other comprehensive loss:				
Foreign currency translation adjustment	196,076	—	(114,644)	—
Total other comprehensive gain (loss)	196,076	—	(114,644)	—
Comprehensive income (loss)	$ 921,050	$ 10,683,099	$ (1,290,518)	$ 10,525,252
Net income (loss) per share of common stock:				
Basic	$ 0.17	$ 2.64	$ (0.28)	$ 2.64
Diluted	$ 0.15	$ 1.97	$ (0.28)	$ 1.98
Weighted average shares outstanding used to compute net income (loss) per share:				
Basic	4,258,105	4,048,635	4,247,045	3,985,112
Diluted	4,847,211	5,422,345	4,247,045	5,310,157

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

Opiant Pharmaceuticals, Inc.
Condensed Consolidated Statements of Stockholders Equity
(unaudited)

	Common Stock		Additional Paid In Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total
	Shares	Amount				
Balance at December 31, 2019	4,186,438	$ 4,187	$ 97,239,455	$ (62,827,616)	$ —	$ 34,416,026
Exercise of stock options	12,157	12	89,988	—	—	90,000
Exercise of warrants	59,510	60	595,041	—	—	595,101
Stock based compensation	—	—	686,599	—	—	686,599
Net loss	—	—	—	(1,684,643)	—	(1,684,643)
Other comprehensive loss - foreign currency translation adjustment	—	—	—	—	(293,491)	(293,491)
Balance at March 31, 2020	4,258,105	4,259	98,611,083	(64,512,259)	(293,491)	33,809,592
Stock based compensation	—	—	720,100	—	—	720,100
Net loss	—	—	—	(216,205)	—	(216,205)
Other comprehensive income - foreign currency translation adjustment	—	—	—	—	(17,229)	(17,229)
Balance at June 30, 2020	4,258,105	4,259	99,331,183	(64,728,464)	(310,720)	34,296,258
Stock based compensation	—	—	323,809	—	—	323,809
Net income	—	—	—	724,974	—	724,974
Other comprehensive gain - foreign currency translation adjustment	—	—	—	—	196,076	196,076
Balance at September 30, 2020	4,258,105	$ 4,259	$ 99,654,992	$ (64,003,490)	$ (114,644)	$ 35,541,117
Balance at December 31, 2018	3,845,361	$ 3,846	$ 91,276,086	$ (74,420,666)	$ —	$ 16,859,266
Exercise of stock options	80,000	80	601,170	—	—	601,250
Stock based compensation	—	—	1,065,852	—	—	1,065,852
Net loss	—	—	—	(1,736,020)	—	(1,736,020)
Balance at March 31, 2019	3,925,361	3,926	92,943,108	(76,156,686)	—	16,790,348
Exercise of stock options	100,139	100	833,790	—	—	833,890
Stock based compensation	—	—	860,654	—	—	860,654
Net income	—	—	—	1,578,173	—	1,578,173
Balance at June 30, 2019	4,025,500	4,026	94,637,552	(74,578,513)	—	20,063,065
Exercise of stock options	49,122	49	269,951	—	—	270,000
Stock based compensation	—	—	589,589	—	—	589,589
Net Income	—	—	—	10,683,099	—	10,683,099
Balance at September 30, 2019	4,074,622	$ 4,075	$ 95,497,092	$ (63,895,414)	$ —	$ 31,605,753

Opiant Pharmaceuticals, Inc.
Condensed Consolidated Statements of Cash Flows
(unaudited)

	For the Nine Months Ended	
	September 30, 2020	**September 30, 2019**
Cash flows from operating activities		
Net loss	$ (1,175,874)	$ 10,525,252
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	92,059	29,921
Non-cash lease expense	364,542	100,000
Stock based compensation	1,730,508	2,516,095
Change in assets and liabilities:		
Accounts receivable	(1,394,991)	(11,578,675)
Prepaid and other current assets	(857,828)	(672,194)
Accounts payable and accrued expenses	1,235,607	819,001
Accrued salaries and wages	200,991	45,759
Lease liabilities	(363,363)	(98,739)
Royalty payable	331,495	3,476,118
Deferred revenue	(558,231)	143,046
License fees	—	(8,100,000)
Net cash used in operating activities	(395,085)	(2,794,416)
Cash flows from investing activities		
Purchase of property and equipment	(50,887)	(302,475)
Net cash used in investing activities	(50,887)	(302,475)
Cash flows provided by financing activities		
Proceeds from stock option and warrant exercises	685,101	1,705,140
Net cash provided by financing activities	685,101	1,705,140
Effect of foreign currency translation on cash	(116,437)	—
Net increase (decrease) in cash and cash equivalents	122,692	(1,391,751)
Cash and cash equivalents, beginning of period	30,980,473	24,613,638
Cash and cash equivalents, end of period	$ 31,103,165	$ 23,221,887
Non-Cash Transactions		
Right of use assets obtained in exchange for new lease obligations	$ —	$ 948,575
Cashless exercise of options	$ 2	$ —
Supplemental Disclosures		
Income taxes paid	$ 39,000	$ —

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

Note 1. Description of Business

Company

Opiant is a specialty pharmaceutical company developing medicines for addiction and drug overdose. The Company developed NARCAN® (naloxone hydrochloride) Nasal Spray (“NARCAN®”), a treatment to reverse opioid overdose. This product was conceived and developed by the Company, licensed to Adapt Pharma Operations Limited (“Adapt”), an Ireland based pharmaceutical company in December 2014 and approved by the U.S. Food and Drug Administration (“FDA”) in November 2015. It is marketed by Adapt. In October 2018, Emergent BioSolutions, Inc. ("EBS") completed its acquisition of Adapt.

The Company's current pipeline includes medicines in development for Opioid Overdose Reversal (“OOR”), Alcohol Use Disorder (“AUD”), Opioid Use Disorder (“OUD”), and Acute Cannabinoid Overdose (“ACO”). The Company is also pursuing other treatment opportunities within the addiction and drug overdose field.

The Company has not had a bankruptcy, receivership or similar proceeding. The Company is required to comply with all regulations, rules and directives of governmental authorities and agencies applicable to the clinical testing and manufacturing and sale of pharmaceutical products.

Note 2. Basis of Presentation and Summary of Significant Accounting Policies

Basis of Presentation

The accompanying condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP") and the applicable rules and regulations of the SEC for interim financial information. Accordingly, they do not include all of the information and notes required by GAAP for complete financial statements. The condensed consolidated balance sheet at December 31, 2019 has been derived from the audited consolidated financial statements at that date, but does not include all disclosures, including notes, required by GAAP for complete financial statements.

The unaudited interim condensed consolidated financial statements have been prepared on the same basis as the audited consolidated financial statements and, in the opinion of management, reflect all adjustments of a normal recurring nature considered necessary to present fairly the Company's financial position as of September 30, 2020 and December 31, 2019, results of operations for the three and nine months ended September 30, 2020 and 2019, and cash flows for the nine months ended September 30, 2020 and 2019. The interim results are not necessarily indicative of the results for any future interim period or for the entire year. Certain prior period amounts have been reclassified to conform to current period presentation. These classifications have no effect on the previously reported net loss or loss per share.

The condensed consolidated financial statements include the accounts of the Company and its wholly-owned subsidiary, Opiant Pharmaceuticals UK Limited, a company incorporated on November 4, 2016 under the England and Wales Companies Act of 2006. Intercompany balances and transactions are eliminated upon consolidation.

The accompanying condensed consolidated financial statements and related financial information should be read in conjunction with the audited consolidated financial statements and the related notes thereto for the year ended December 31, 2019 included in the Company's Annual Report on Form 10-K filed with the SEC on March 4, 2020.

Use of Estimates

The preparation of condensed consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities, and reported amounts of expenses in the financial statements and accompanying notes. Actual results could differ from those estimates. Key estimates included in the financial statements include the valuation of: deferred income tax assets, equity instruments, stock-based compensation, acquired intangibles, and allowances for accounts receivable.

Cash and Cash Equivalents

The Company considers all highly liquid investments purchased with an original maturity of three months or less to be cash equivalents. Cash and cash equivalents were approximately $31.1 million and $31.0 million at September 30, 2020 and December 31, 2019, respectively. The Company maintains cash balances at financial institutions insured up to $250 thousand by the Federal Deposit Insurance Corporation. Balances in the UK are insured up to £85 thousand by the Financial Services Compensation Scheme (UK Equivalent). Although the Company's cash balances exceeded these insured amounts at various times during the nine months ended September 30, 2020, the Company has not experienced any losses on its deposits of cash and cash equivalents for the periods presented.

Earnings (Loss) Per Share

Basic earnings (loss) per share is computed by dividing the net income (loss) available to common stockholders by the weighted-average number of shares of Common Stock outstanding during the respective period presented in the Company's accompanying condensed consolidated financial statements. Fully-diluted earnings (loss) per share is computed similarly to basic income (loss) per share except that the denominator is increased to include the number of Common Stock equivalents (primarily outstanding options and warrants).

Common Stock equivalents represent the dilutive effect of the assumed exercise of outstanding stock options and warrants, using the treasury stock method, at either the beginning of the respective period presented or the date of issuance, whichever is later, and only if the Common Stock equivalents are considered dilutive based upon the Company's net income position at the calculation date.

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
Numerator:	**2020**	**2019**	**2020**	**2019**
Net income (loss)	$ 724,974	$ 10,683,099	$ (1,175,874)	$ 10,525,252
Denominator:				
Denominator for basic income (loss) per share - weighted-average shares	4,258,105	4,048,635	4,247,045	3,985,112
Effect of dilutive securities:				
Equity incentive plans	589,106	1,373,710	—	1,325,045
Denominator for diluted income (loss) per share	4,847,211	5,422,345	4,247,045	5,310,157
Income (loss) per share - Basic	$ 0.17	$ 2.64	$ (0.28)	$ 2.64
Income (loss) per share - Diluted	$ 0.15	$ 1.97	$ (0.28)	$ 1.98

The Company excluded the following securities from the calculation of diluted net income (loss) per share as the effect would have been antidilutive for the nine months ended September 30, 2020 due to the Company's net loss and the securities exercise prices were greater than the Company's average stock price for the three months ended September 30, 2020.

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2020	**2019**	**2020**	**2019**
Options to purchase common stock	729,692	409,025	3,077,692	476,438
Warrants to purchase common stock	240,000	—	278,800	—
Total	969,692	409,025	3,356,492	476,438

Foreign Currency Translation

The functional currency of our wholly-owned subsidiary, Opiant UK is the British Pounds, its local currency. Consequently, its assets and liabilities are translated at current rates of exchange at the balance sheet date. Income and expense items are translated at the average foreign currency exchange rates for the period. Adjustments resulting from the translation of

the financial statements of Opiant Pharmaceuticals UK Limited (“Opiant UK”), into U.S. dollars, the reporting currency, are excluded from the determination of net loss and are recorded in accumulated other comprehensive loss, a separate component of equity. Gains and losses arising on translation or settlement of foreign currency denominated transactions or balances are included in the determination of income.

Recently Adopted Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board, ("FASB"), or other standard setting bodies and adopted by us as of the specified effective date. Unless otherwise discussed, the impact of recently issued standards that are not yet effective will not have a material impact on the Company’s financial position or results of operations upon adoption.

The Company has considered all other recently issued accounting pronouncements and does not believe the adoption of such pronouncements will have a material impact on its consolidated financial statements.

Note 3. Prepaid Expenses and Other Current Assets

As of September 30, 2020, the Company had prepaid expenses and other current assets of approximately $0.9 million. The Company's prepaid expenses are primarily for advance research and development payments, insurance, software licenses, prepaid rent, and other amounts that relate to future periods of service. Other current assets primarily consist of such items as other receivables and security deposits.

Note 4. Accounts Receivable

As of September 30, 2020 and December 31, 2019, the Company had accounts receivable of $8.6 million and $7.2 million respectively, which primarily relates to royalty revenue from sales of NARCAN®.

Note 5. Leases

On January 1, 2019, the Company adopted a new accounting standard, Topic 842, that amends the guidance for the accounting and reporting of leases. Leases with terms of 12 months or less are expensed on a straight-line basis over the term and are not recorded in the Company's Condensed Consolidated Balance Sheets.

The Company entered into two operating leases during 2019 with terms greater than 12 months. In accordance with the guidance of Topic 842, the two leases which are classified as operating leases are included in the Company's Condensed Consolidated Balance Sheets. The Company's two operating leases do not include options to renew, do not contain residual value guarantees, do not have variable lease components, or impose significant restrictions or covenants.

Right of use assets, "ROU assets", represent the right to use an underlying asset for the lease term, and lease liabilities represent the obligation to make lease payments over the respective lease term, with the ROU asset adjusted for deferred rent liability. The ROU asset is recognized as lease expense on a straight line basis over the lease term. As the implicit rate on the leases is not determinable, the Company used an estimated incremental borrowing rate of 9% as the discount rate to determine the present value of lease payments. The weighted average discount rate used was 9% and the weighted average remaining lease term is 0.79 years. The ROU asset and corresponding operating lease liability recognized at lease inception in 2019 was $0.95 million.

The following table summarizes information related to the Company's two operating leases and are included in the Company's Balance Sheet as of September 30, 2020.

Balance Sheet descriptions		September 30, 2020
Assets:		**(in thousands)**
Right of use assets - operating leases	$	397
Liabilities:		
Operating leases - current	$	401
Total lease liabilities:	$	401

The following table summarizes the components of operating lease cost for the three and nine months ended September 30, 2020:

Lease costs, **(in thousands)**	Three months ended September 30, 2020	Nine months ended September 30, 2020
Operating expenses lease costs	$ 143	$ 365

As of September 30, 2020, future minimum operating leases payments related to the Company's operating lease liabilities were as follows for the subsequent years ended December 31:

(in thousands)	September 30, 2020
2020 (three months remaining)	134
2021	283
Total lease payments	417
Less imputed interest	(16)
Present value of operating lease liabilities	$ 401

Note 6. Other Non-Current Assets

As of September 30, 2020, the Company had non-current prepaid expenses of approximately $1.1 million. The Company's non-current prepaid expenses are for advance research and development payments which will be issued for projects that have estimated completion dates of more than one year.

Note 7. Revenue

The Company's primary source of revenue is from royalty and milestone payments received from NARCAN® net sales by EBS. During the three and nine months ended September 30, 2020 the Company recorded revenue of $8.6 million and $19.1 million, respectively, related to its agreement with EBS.

On September 19, 2018, the Company entered into a contract with the Biomedical Advanced Research and Development Authority ("BARDA"), which is part of the U.S. Health and Human Services Office of the Assistant Secretary for Preparedness and Response, to accelerate the Company's development of OPTN003, its lead product candidate. OPTN003, nasal nalmefene, is a potent, long-acting opioid antagonist currently in development for the treatment of opioid overdose. The contract will provide potential funding up to a maximum of approximately $4.6 million and cover activities related to a potential New Drug Application submission for OPTN003 with the Food and Drug Administration. BARDA has awarded approximately $3.0 million of the contract through December 20, 2021, with the balance expected to be funded, subject to satisfactory project progress, availability of funds and certain other conditions. During the nine months ended September 30, 2020 the Company recognized revenue of $86 thousand related to this contract.

Deferred revenue

On April 17, 2018, the Company was awarded a grant of approximately $7.4 million from the National Institutes of Health's National Institute on Drug Abuse, (NIDA). The grant provides the Company with additional resources for the ongoing development of OPNT003. The Company has been awarded approximately $5.6 million through the period ending March 31, 2021, with the remaining $1.8 million balance expected to be funded, subject to available funds and satisfactory progress on the development of OPNT003. Government grants are agreements that generally provide cost reimbursement for certain types of expenditures in return for research and development activities over a contractually defined period. The Company recognized revenues from grants in the period during which the related costs were incurred, provided that the conditions under which the grants were provided had been met and only perfunctory obligations were outstanding. During the nine months ended September 30, 2020, the Company recognized revenue of $558 thousand related to this grant.

As of September 30, 2020, the Company had recorded all of its deferred revenue as a current liability because the Company expects to recognize all such deferred revenue as revenue during the next 12 months.

The following is a summary of the Company's deferred revenue activity as of September 30, 2020:

(in thousands)	NIDA Grant	Total
Balance as of December 31, 2019	$ 918	$ 918
Additions to deferred revenue	—	—
Recognized as revenue	(558)	(558)
Balance as of September 30, 2020	$ 360	$ 360

Note 8. Royalty Payable

The Company entered into various agreements and subsequently received funding from investors for use by the Company for the research and development of its Opioid Overdose Reversal Treatment Product ("OORTP"). In exchange for this funding, the Company agreed to provide investors with interest in the OORTP Net Profit generated from NARCAN® sales by EBS into perpetuity. As of September 30, 2020 and December 31, 2019, the Company recorded a royalty payable of $2.0 million and $1.6 million, respectively.

Note 9. Stockholders' Equity

Common Stock

During the nine months ended September 30, 2020, the Company issued 71,667 shares of Common Stock as a result of stock option and warrant exercises, and received net cash proceeds of approximately $0.7 million.

Stock Options

On September 8, 2017, the Company held its Annual Meeting of Stockholders (the "Annual Meeting"), at which time the 2017 Long-Term Incentive Plan ("2017 Plan") was approved by stockholder vote. The 2017 Plan allows the Company to grant both incentive stock options ("ISOs") and non-qualified stock options ("NSOs") to purchase a maximum of 400,000 shares of the Company's Common Stock. Under the terms of the 2017 Plan, ISOs may only be granted to Company employees and directors, while NSOs may be granted to employees, directors, advisors, and consultants. The Board has the authority to determine to whom options will be granted, the number of options, the term, and the exercise price. Options are to be granted at an exercise price not less than fair value for an ISO or an NSO. The vesting period is normally over a period of four years from the vesting date. The contractual term of an option is no longer than 10 years. The 2017 Plan also allows the Company to issue restricted stock.

As provided in the 2017 Plan, on January 1, 2020 the number of shares available for issuance was increased by 4% of the outstanding stock as of December 31, 2019, which represents an increase of 167,457 shares. As of September 30, 2020, the Company had 160,910 shares available for future issuance under the 2017 Plan.

Prior to adopting the 2017 Plan, the Company did not have a formal long-term incentive stock plan. Prior to the implementation of the 2017 Plan, the Company had discretion to provide designated employees of the Company and its affiliates, certain consultants, and advisors who perform services for the Company and its affiliates, and non-employee members of the Board and its affiliates with the opportunity to receive grants of non-qualified stock options (the "Pre-2017 Non-Qualified Stock Options"). All of the Pre-2017 Non-Qualified Stock Option Grants were intended to qualify as non-qualified stock options. There were no Pre-2017 Non-Qualified Stock Option Grants that were intended to qualify as incentive stock options.

Pre-2017 Non-Qualified Stock Options

As of December 31, 2019, the Company had outstanding Pre-2017 Non-Qualified Stock Options to purchase, in the aggregate, 2,500,500 shares of the Company's Common Stock. During the nine months ended September 30, 2020, the Company did not grant any Pre-2017 Non-Qualified Stock Options.

Stock option activity for the Pre-2017 Non-Qualified Stock Options for the nine months ended September 30, 2020 is presented in the table below:

	Number of Shares	Weighted- average Exercise Price	Weighted- average Remaining Contractual Term (years)	Aggregate Intrinsic Value (In Thousands)
Outstanding at December 31, 2019	2,500,500	$ 7.03	5.05	$ 18,426
Exercised	(20,000)	9.50		
Forfeited	(15,000)	10.00		
Outstanding at September 30, 2020	2,465,500	$ 6.99	4.35	$ 1,683

A summary of the status of the Company's non-vested Pre-2017 Non-Qualified Stock Options as of September 30, 2020 is presented below:

	Number of Options	Weighted Average Grant Date Fair Value
Vested at September 30, 2020	2,430,502	$ 6.95
Non-vested at Non-vested at September 30, 2020	34,998	$ 10.00

During the nine months ended September 30, 2020 and 2019, the Company recognized approximately $1 thousand and $127 thousand, respectively, of non-cash expense related to Pre-2017 Non-Qualified Stock Options granted in prior periods. As of September 30, 2020, there was no further compensation expense to be recognized for the Pre-2017 Non-Qualified Stock Options.

The 2017 Plan

During the nine months ended September 30, 2020, the Company granted options to a number of employees and non-employees to purchase 191,500 shares of the Company's Common Stock at exercise prices from $8.79 to $13.60 per share, which represents the closing price of the Company's Common Stock on the date of the grants. These options were issued under the Company's 2017 Plan and have ten-year terms. Option grants to existing employees vest as follows: 1/48th of the option shares vest each month through the fourth anniversary of the grant date. Option grants to new employees vest as follows: 25% of the option shares vest on the one year anniversary of the grant date, and then 1/48th of the option shares vest on such date each month thereafter through the fourth anniversary of the grant date. Options issued to non-employees vest 100% upon the one year anniversary from the grant date. The Company valued these options using the Black-Scholes option pricing model and estimated the aggregate fair value of the option grants to be $1.8 million.

The assumptions used in the valuation of options granted under the 2017 Plan during the nine months ended September 30, 2020 were as follows:

	For the Nine Months Ended September 30, 2020
Market value of stock on measurement date	$8.79 to $13.60
Risk-free interest rate	0.33% to 1.68%
Dividend yield	—
Volatility factor	91.07% to 101.21%
Term	5.50 to 6.25 years

Stock option activity for options granted under the 2017 Plan during the nine months ended September 30, 2020 is presented in the table below:

	Number of Options Outstanding	Weighted-average Exercise Price	Weighted-average Remaining Contractual Term (years)	Aggregate Intrinsic Value (in thousands)
Balance at December 31, 2019	491,950	$ 24.08	8.43	$ 82
Granted	191,500	$ 12.12		
Exercised	—	—		
Forfeited	(71,258)	$ 15.05		
Balance at September 30, 2020	612,192	$ 21.39	8.1	$ —

A summary of the status of the Company's vested and non-vested options granted under the 2017 Plan as of September 30, 2020 is presented in the following table:

	Number of Shares	Weighted Average Grant Date Fair Value Per Share
Vested at September 30, 2020	291,803	25.63
Non-vested at September 30, 2020	320,389	$ 15.22

During the nine months ended September 30, 2020 and 2019, the Company recognized approximately $1.6 million and $2.4 million, respectively of non-cash expense related to options granted under the 2017 Plan. As of September 30, 2020, there was approximately $1.8 million of unrecognized compensation costs related to non-vested stock options that were granted under the 2017 Plan.

Restricted Stock Activity

The following summarizes the restricted stock activity under the Company's 2017 Plan during the nine months ended September 30, 2020:

	Number of Shares	Weighted Average Fair Value Per Share
Restricted stock outstanding and unvested at December 31, 2019	27,000	$ 14.51
Restricted stock granted	49,600	$ 12.00
Restricted stock forfeited	(27,000)	$ 14.51
Restricted stock outstanding and unvested at September 30, 2020	49,600	$ 12.00

Twenty-five percent (25%) of the restricted stock units will vest on the one year anniversary of the vesting commencement date, and twenty-five percent (25%) will vest annually thereafter on the same day as the vesting commencement date. During the nine months ended September 30, 2020, the Company recognized approximately $126 thousand of non-cash expense related to restricted stock units. As of September 30, 2020, there was $0.4 million of total unrecognized compensation cost related to restricted stock units.

Warrants

During the nine months ended September 30, 2020, the Company did not issue any warrants.

Warrant activity for the nine months ended September 30, 2020 is presented in the table below:

	Number of Shares	Weighted-average Exercise Price	Weighted-average Remaining Contractual Term (years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2019	342,610	$ 9.77	3.71	$ 1,585
Exercised	(59,510)	$ 10.00		
Forfeited	(4,300)	$ 10.00		
Outstanding at September 30, 2020	278,800	$ 9.72	3.76	$ —
Exercisable at September 30, 2020	278,800	$ 9.72	3.76	$ —

Note 10. Commitments and Contingencies

Commitments

The Company has entered into various agreements related to its business activities. The following is a summary of the Company's commitments:

Summit Agreement

On July 22, 2020, the Company the Company entered into a Project Scope Agreement ("PSA") pursuant to a Master Services Agreement ("MSA") with Summit Biosciences, Inc. ("Summit"), to support the development and manufacture of a nasal spray device for opioid overdose, with the ability to expand to additional programs in the future. In accordance with the PSA, Summit will develop and produce certain pre-filled nasal spray products using a device previously evaluated as part of other FDA-approved nasal spray products. The Company will pay Summit estimated costs and fees up to approximately $6.5 million of which a deposit of approximately $1.1 million was paid as of September 30, 2020 which is included in other non-current assets in the condensed consolidated balance sheet.

Torreya Agreement

The Company entered into a consulting agreement with Torreya Partners LLP ("Torreya"), a financial advisory firm, under which Torreya agreed to provide certain financial advisory services. The Company is required to pay fees equivalent to 3.375% of all amounts received by the Company from net sales of NARCAN® into perpetuity.

During the nine months ended September 30, 2020 and 2019, the Company recorded $643 thousand and $752 thousand, respectively of expense related to Torreya, and has recorded a liability of $290 thousand related to Torreya as of September 30, 2020.

Exclusive License and Collaboration Agreement

On November 19, 2015, the Company entered into an exclusive license agreement and collaboration agreement ("LOI") with a pharmaceutical company with certain desirable proprietary information. Pursuant to the agreement, the Company is obligated to issue shares of unregistered Common Stock upon the occurrence of various milestones. No shares were required to be issued under this agreement during the nine months ended September 30, 2020. During the nine months ended September 30, 2019 the Company recorded expenses of $177,394 for the final 11,787 shares of common stock it issued in November 2019, as the final milestone had been reached.

Supply Agreement

On June 22, 2017, the Company entered into a license agreement (the "License Agreement") and a related supply agreement (the "Supply Agreement") with Aegis Therapeutics LLC ("Aegis") pursuant to which the Company was granted an exclusive license (the "License") to Aegis' proprietary chemically synthesizable delivery enhancement and stabilization agents, including, but not limited to, Aegis' Intravail® absorption enhancement agents, ProTek® and HydroGel® (collectively, the "Technology") to exploit (a) the Compounds (as such are defined in the License Agreement) and (b) a product containing a Compound and formulated using the Technology ("Product"), in each case of (a) and (b) for any and all purposes. The License Agreement restricts the Company's ability to manufacture any Aegis excipients included in the Technology ("Excipients"), except for certain instances of supply failure, supply shortage or termination of the Supply Agreement, and the Company shall obtain all supply of such Excipients from Aegis under the Supply Agreement. The License Agreement also restricts Aegis's ability to compete with the Company worldwide with respect to the Exploitation (as defined in the License Agreement) of any therapeutic containing a Compound or derivative or active metabolite of a Compound without the Company's prior written consent. The effective date of the License Agreement and the Supply Agreement is January 1, 2017.

As consideration for the grant of the License, the Company paid Aegis two immaterial upfront payments, of which the Company paid 50% by issuing the Company's Common Stock to Aegis, with the number of shares issued equal to 75% of the average closing price of the Company's Common Stock over the 20 trading days preceding the date of payment. The License Agreement also provides for (A) additional developmental milestone payments for each Product containing a different Compound equal to up to an aggregate of $1.8 million, (B) additional commercialization milestone payments for each Product containing a different Compound equal to up to an aggregate of $5.0 million, and (C) single low digit royalties on the Annual Net Sales (as defined in the License Agreement) of all Products during the Royalty Term (as defined in the License Agreement) according to a tiered royalty rate based on Annual Net Sales of the Products by the Company, the Company's sublicensees and affiliates. The Company shall also pay to Aegis a sublicense fee based on a sublicense rate negotiated in good faith by the parties. The License Agreement contains customary representations and warranties, ownership, patent rights, confidentiality,

indemnification and insurance provisions. The License Agreement shall expire upon the expiration of the Company's obligation to pay royalties under such License Agreement; provided, however, that the Company shall have the right to terminate the License granted on a Product-by-Product or country-by-country basis upon 30 days' prior written notice to Aegis.

Under the terms of the Supply Agreement, Aegis shall deliver to the Company any preclinical, clinical and commercial supply of the Excipients, which Aegis sources from various contract manufacturers. The Supply Agreement has a term of 20 years but shall terminate automatically in the event of expiration or termination of the License Agreement or at any time upon the written agreement of both parties. The Supply Agreement contains customary provisions relating to pricing for such materials, forecasts, delivery, inspection, indemnification, insurance and representations, warranties and covenants. The Supply Agreement includes technology transfer provisions for the transfer of all materials and know-how specific to the manufacturing of the Excipients that is necessary or useful for the Company to manufacture such Excipients. The Company does not have the right to manufacture such Excipients except in the event that Aegis is unable to supply and sell any portion of the material to the Company (subject to a 60-day cure period).

Under the License Agreement, the Company will be required to pay Aegis $250 thousand upon the successful NDA filing.

For the nine months ended September 30, 2020, and 2019 the Company recorded zero and $225 thousand, respectively of expenses associated with the License Agreement.

Contingencies

The Company may be subject to various legal proceedings and claims that arise in the ordinary course of business. The Company records a liability when it is probable that a loss will be incurred and the amount is reasonably estimable. There is significant judgment required in both the probability determination and as to whether an exposure can be reasonably estimated. If any legal matter, were resolved against the Company in a reporting period for amounts in excess of management's expectations, the Company's would reflect any potential claim in the consolidated financial statements for that reporting period.

The Company and Emergent BioSolutions Inc., through its Adapt Pharma subsidiaries (collectively, "Plaintiffs"), filed complaints, in 2016 against Teva Pharmaceuticals Industries Ltd. ("Teva"), and in 2018 against Perrigo UK FINCO Limited Partnership ("Perrigo"), relating to Teva's and Perrigo's respective abbreviated new drug applications (each, an "ANDA") seeking to market generic versions of NARCAN® (naloxone hydrochloride) Nasal Spray 4mg/spray.

On February 12, 2020, Plaintiffs and Perrigo entered into a settlement agreement to resolve the ongoing litigation. Under the terms of the settlement, Perrigo has received a non-exclusive license under the Company's patents licensed to Adapt to make, have made and market its generic naloxone hydrochloride nasal spray under its own ANDA. Perrigo's license will be effective as of January 5, 2033 or earlier under certain circumstances including circumstances related to the outcome of the current litigation against Teva or litigation against future ANDA filers. The Perrigo settlement agreement is subject to review by the U.S. Department of Justice and the Federal Trade Commission, and entry of an order dismissing the litigation by the U.S. District Court for the District of New Jersey.

Closing arguments in the Teva trial were held on February 26, 2020. Plaintiffs also filed a complaint related to Teva's ANDA seeking to market a generic version of NARCAN® (naloxone hydrochloride) Nasal Spray 2mg/spray.

On June 5, 2020, the U.S. District Court for the District of New Jersey entered a decision in the patent litigation regarding NARCAN® (naloxone HCl) Nasal Spray 4mg/spray product. The Court ruled in favor of Teva. The Company's commercial partner Emergent BioSolutions, intends to appeal the decision to the Court of Appeals for the Federal Circuit.

Note 11. Subsequent Events

On October 26, 2020, the Company entered into a Master Services Agreement (“MSA”) with AptarGroup, Inc. (“Aptar”) to provide non-exclusive technology access and co-development services for the development and submission of an opioid antagonist for the treatment of opioid overdose using Aptar’s nasal Unidose device (the “UDS Device”). In addition to the cost of the UDS Devices, the Company expects to spend up to €3,750,000 over the course of the development program.

On September 7, 2018, the Company entered into a Development Agreement to develop a device capable of administrating nalmefene hrydrochloride and related Agreement for Reimbursement of Capital Expenditure and Service Fees (collectively, "Agreement") with Aesica Queenborough Limited ("Aesica"). On October 28, 2020, the Company notified Aesica that, effectively immediately, the Company was terminating the Agreement pursuant to Section 18.2(a) of the Agreement.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operation

The interim consolidated financial statements included in this Quarterly Report on Form 10-Q (this "Report") and this Management's Discussion and Analysis of Financial Condition and Results of Operations should be read in conjunction with the financial statements and notes thereto in this Report, and the related Management's Discussion and Analysis of Financial Condition and Results of Operations, contained in the Company's Form 10-K for the year ended December 31, 2019 (the "Form 10-K"). In addition to historical information, this discussion and analysis contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). These forward-looking statements are subject to risks and uncertainties, including those set forth in Part II - Other Information, Item 1A and in the Form 10-K. Risk Factors below and elsewhere in this Report could cause actual results to differ materially from historical results or anticipated results.

Overview

We are a specialty pharmaceutical company developing medicines for addiction and drug overdose. We developed NARCAN® (naloxone hydrochloride) Nasal Spray ("NARCAN®"), a treatment to reverse opioid overdose. This product was conceived and developed by us, licensed to Adapt Pharma Operations Limited ("Adapt"), an Ireland based pharmaceutical company in December 2014 and approved by the U.S. Food and Drug Administration ("FDA") in November 2015. It is marketed by Adapt. In October 2018, Emergent BioSolutions, Inc. ("EBS") completed its acquisition of Adapt.

We have not consistently attained profitable operations and have historically depended upon obtaining sufficient financing to fund our operations. We anticipate if revenues are not sufficient, then additional funding will be required in the form of debt financing and/or equity financing from the sale of our Common Stock, and/or financings from the sale of interests in our prospective products and/or royalty transactions. However, we may not be able to generate sufficient revenues or raise sufficient funding to fund our operations.

We have not had a bankruptcy, receivership or similar proceeding. We are required to comply with all regulations, rules and directives of governmental authorities and agencies applicable to the clinical testing and manufacturing and sale of pharmaceutical products.

Plan of Operation

During the fiscal year ending December 31, 2020, we plan to continue to focus on developing medicines in our product pipeline for Opioid Overdose Reversal ("OOR"), Alcohol Use Disorder ("AUD"), Opioid Use Disorder ("OUD"), and Acute Cannabinoid Overdose ("ACO"). Our lead development product is OPNT003 - Intranasal Nalmefene for OOR, which is further described below.

OPNT003 - Nasal Nalmefene for OOR

Development Program for OPNT003

In 2017, NIH leadership called for the development of stronger, longer-acting formulations of antagonists to counteract the very high potency synthetic opioids that are now claiming thousands of lives each year. We are pursuing a 505(b)(2) development path for OPNT003, with the potential to submit an NDA for the drug and intranasal delivery device combination in 2021. Nalmefene for injection was previously approved by the FDA for treating suspected or confirmed opioid overdose. The 505(b)(2) pathway allows companies to rely in part on the FDA's findings of safety and efficacy for a previously approved product and to supplement these findings with a more limited set of their own studies to satisfy FDA requirements, as opposed to conducting the full array of preclinical and clinical studies that would typically be required. We have reached agreement with the FDA to perform a pharmacodynamic ("PD") study in healthy volunteers to support the OPNT003 NDA application

On January 27, 2020, the Company received a letter from the FDA formalizing the "clinical hold" for the OPNT003 pharmacokinetic study which was discussed during a telephone conversation with the FDA on January 16, 2020. The FDA has requested additional information be provided to evaluate the sensitization and irritation endpoints of the final finished device.

On May 8, 2020, the Company received a letter from the FDA lifting the clinical hold, imposed by the FDA in January of 2020, on the pharmacokinetic study for OPNT003.

Market and Commercial potential for OPNT003

There is a large and growing addressable market for opioid overdose reversal agents driven by sales into community based and first responder institutions, as well as directly to patients via pharmacies. The current institutional market is substantial, to ensure an opioid overdose reversal agent is available for all first responders, including fire departments, emergency medical services, federal law enforcement, local law enforcement, and other community groups. The co-prescribing of opioid overdose reversal agents alongside prescription opioids has also driven growth. It is estimated that only five percent of patients at higher risk of an opioid overdose have a naloxone prescription. Currently there are only eleven states that have some form of mandatory co-prescription legislation in place, however several states are considering co-prescribing legislation in the near future.

We believe that U.S. sales of opioid reversal agents could exceed $1.0 billion by 2022.

We have full commercial rights to OPNT003, and we were awarded a grant of approximately $7.4 million from the National Institutes of Health ("NIH"). The grant provides us with additional resources for the ongoing development of OPNT003.We have been awarded approximately $5.6 million funded through the period ending March 31, 2021, with the balance of $1.8 million expected to be funded, subject to available funds and satisfactory progress on the development of OPNT003. We have also received a contract for approximately $4.6 million from the Biological Advance Research and Development Agency ("BARDA") to fund development of this project through NDA submission. BARDA has awarded approximately $3.0 million of the contract through December 20, 2021, with the balance expected to be funded, subject to satisfactory project progress, availability of funds and certain other conditions.

As we continue to advance OPNT003 towards market approval and should we self-commercialize the product, we anticipate that our sales and marketing expenses will increase in several areas to support the development of a commercial platform that would allow us to commercialize OPNT003, as well as future pipeline products. The development of this commercial infrastructure includes increasing commercial personnel, pre-launch sales and marketing planning activities, supply chain and distribution. As we build this infrastructure, we are continuing to evaluate the ideal go-to-market strategy that will allow us to maximize the full commercial potential of OPNT003 and shareholder value.

Impact of COVID-19 on our Business

The spread of the SARS-CoV-2 virus since the fourth quarter of 2019 has caused an economic downturn on a global scale, as well as significant volatility in the financial markets. In March 2020, the World Health Organization declared the spread of COVID-19 a pandemic.

Due to stay at home orders both in the United States and United Kingdom, we have instituted a work-from-home plan for our employees. We have ensured that all employees have essential resources to work from home.

We have not experienced a significant financial impact directly related to the COVID-19 pandemic. As of September 30, 2020, we have cash and cash equivalents of $31.1 million. We believe that we have sufficient capital resources to sustain operations through at least the next 12 months from the date of the filing of this Report. As a result of this financial position, we have not required any financial assistance under the Coronavirus Aid, Relief, and Economic Security ("CARES") Act or other similar COVID-19 related federal and state programs or United Kingdom financial assistant programs. We have no plans to furlough any employees at this time.

We have not experienced a significant operational impact on OPNT003 or OPNT004 programs as a result of the COVID-19 pandemic, although we cannot rule out future delays. For example, we recently executed the cooperative research and development agreement ("CRADA") with the National Institute of Health's National Center for Advancing Translational Sciences ("NCATS") and will collaborate to formulate OPNT004 for human studies.

However, we decided in April 2020 to pause the start of recruitment for our OPNT002 planned Phase 2 study. Our decision follows the COVID-19 related state of emergency declarations in the United Kingdom and across Europe where our study was to take place. We have adequate cash allocated to fund the cost of our Phase 2 study in OPNT002 and will continue to monitor the situation closely.

Results of Operations

The following table sets forth the results of operations for the periods shown:

(in thousands)	For the Three Months Ended September 30,			For the Nine Months Ended September 30,		
	2020	2019	Increase (Decrease)	2020	2019	Increase (Decrease)
Revenues						
Royalty and licensing revenue	$ 8,601	$ 20,494	$ (11,893)	$ 19,057	$ 30,369	$ (11,312)
Treatment investment revenue	—	—	—	—	644	(644)
Grant and contract revenue	505	147	358	644	1,838	(1,194)
Total revenue	9,106	20,641	(11,535)	19,701	32,851	(13,150)
Operating expenses						
General and administrative	2,729	3,210	(481)	8,138	9,389	(1,251)
Research and development	2,784	1,843	941	4,763	7,044	(2,281)
Sales and marketing	914	141	773	3,738	141	3,597
Royalty expense	1,952	4,851	(2,899)	4,289	6,099	(1,810)
Total operating expenses	8,379	10,045	(1,666)	20,928	22,673	(1,745)
Income (loss) from operations	727	10,596	(9,869)	(1,227)	10,178	(11,405)
Other income (expense)						
Interest income	4	112	(108)	92	356	(264)
Loss on foreign exchange	(6)	(24)	18	(2)	(65)	63
Total other income (expense)	(2)	88	(90)	90	291	(201)
Income (loss) before income taxes	725	10,684	(9,959)	(1,137)	10,469	(11,606)
Income tax (expense) benefit	—	—	—	(39)	57	(96)
Net income (loss)	$ 725	$ 10,684	$ (9,959)	$ (1,176)	$ 10,526	$ (11,702)

Comparison of Three Months ended September 30, 2020 to the Three Months ended September 30, 2019

Revenues

We recognized $9.1 million and $20.6 million of revenue during the three months ended September 30, 2020 and 2019, respectively. For the three months ended September 30, 2020 we recognized approximately $8.6 million of revenue from the license agreement between us and EBS, and $505 thousand from grant and contract revenue. For the three months ended September 30, 2019, we recognized $20.5 million of revenue from the license agreement between us and EBS which included a milestone payment of $13.5 million, as sales of NARCAN® exceeded $200 million for 2019.

General and Administrative Expenses

Our general and administrative expenses were $2.7 million and $3.2 million for the three months ended September 30, 2020 and 2019, respectively. Legal and professional fees decreased by 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

Our research and development expenses were $2.8 million and $1.8 million during the three months ended September 30, 2020 and 2019, respectively. 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

During the three months ended September 30, 2020, we recorded sales and marketing expenses of $0.9 million for pre-commercialization efforts related to our nasal nalmefene product, which is under clinical development. Sales and marketing expense during the three months ended September 30, 2019 was approximately $141 thousand.

Royalty Expenses

Our royalty expenses were $2.0 million and $4.9 million during the three months ended September 30, 2020 and 2019, respectively. The decrease of $2.9 million is primarily attributable to the reduction in license fee expense used to determine the net profit partner income for the three months ended September 30, 2020 compared to the three months ended September 30, 2019.

Other Income (expense)

During the three months ended September 30, 2020, other income was $2 thousand compared to other income of $88 thousand for the three months ended September 30, 2019, which primarily resulted from a decreased rate of return on our invested cash balances.

Comparison of Nine Months ended September 30, 2020 to the Nine Months ended September 30, 2019

Revenues

We recognized $19.7 million and $32.9 million of revenue during the nine months ended September 30, 2020 and 2019, respectively. For the nine months ended September 30, 2020 we recognized approximately $19.1 million of revenue from the license agreement between us and EBS, and approximately $0.6 million from grant and contract revenue. For the nine months ended September 30, 2019, we recognized $30.4 million of revenue from the license agreement between us and EBS, $1.8 million from grant and contract revenue, and $644 thousand from treatment investment revenue.

General and Administrative Expenses

Our general and administrative expenses were $8.1 million and $9.4 million for the nine months ended September 30, 2020 and 2019, respectively. 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

Our research and development expenses were $4.8 million and $7.0 million for the nine months ended September 30, 2020 and 2019, respectively. 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

During the nine months ended September 30, 2020, we recorded sales and marketing expenses of $3.7 million for pre-commercialization efforts related to our nasal nalmefene product, which is under clinical development. 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. Sales and marketing expense during the nine months ended September 30, 2019 was approximately $141 thousand.

Royalty Expenses

Our royalty expenses were $4.3 million and $6.1 million during the nine months ended September 30, 2020 and 2019, respectively. The decrease of $1.8 million is primarily attributable to the reduction in license fee expense used to determine net profit partner income for the nine months ended September 30, 2020 compared to the nine months ended September 30, 2019.

Other Income (expense)

During the nine months ended September 30, 2020, other income was $90 thousand compared to other income of $291 thousand for the nine months ended September 30, 2019. The decrease is primarily related to decreased rates of return on our invested cash balances.

Liquidity and Capital Resources

Cash Flows

The following table sets forth the primary sources and uses of cash for each of the periods presented below:

	Nine Months Ended September 30,	
(in thousands)	**2020**	**2019**
Net cash used in operating activities	$ (395)	$ (2,794)
Net cash used in investing activities	$ (51)	$ (302)
Net cash provided by financing activities	$ 685	$ 1,705

Net cash used in operating activities

During the nine months ended September 30, 2020, net cash used in operating activities was $0.4 million, which was primarily due to a net loss of $1.2 million and a $1.4 million change in other assets and liabilities, mostly offset by approximately $1.7 million of stock based compensation expense, approximately $0.4 million of operating lease amortization, and $0.1 million in depreciation and amortization.

During the nine months ended September 30, 2019, net cash used in operating activities was $2.8 million, which was primarily due to increase in accounts receivable of $11.6 million, a decrease in license fees of $8.1 million, and an increase in prepaid and other assets of $0.7 million totaling $20.4 million, which was mostly offset by net income of $10.5 million, stock based compensation expense of $2.5 million and changes in other assets and liabilities of $4.5 million, totaling $17.5 million.

Net cash used in investing activities

During the nine months ended September 30, 2020, we purchased approximately $51 thousand of office furniture and equipment and made certain leasehold improvements.

During the nine months ended September 30, 2019, we purchased approximately $302 thousand of office furniture and equipment and made certain leasehold improvements.

Net cash provided by financing activities

During the nine months ended September 30, 2020, net cash provided by financing activities was approximately $0.7 million, which was primarily attributable to proceeds received from stock option and warrant exercises.

During the nine months ended September 30, 2019, net cash provided by financing activities was approximately $1.7 million, which was primarily attributable to proceeds received from stock option exercises.

Critical Accounting Policies and Estimates

We believe that the following critical policies affect our significant judgments and estimates used in preparation of our financial statements.

We prepare our financial statements in conformity with accounting principles generally accepted in the United States of America ("GAAP"). These principals require management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Management believes that these estimates are reasonable and have been discussed with the Board; however, actual results could differ from those estimates.

We issue options and warrants to consultants, directors, and officers as compensation for services. These options and warrants are valued using the Black-Scholes option pricing model, which focuses on the current stock price and the volatility of

moves to predict the likelihood of future stock moves. This method of valuation is typically used to accurately price stock options and warrants based on the price of the underlying stock.

Fair value estimates used in preparation of the financial statements are based upon certain market assumptions and pertinent information available to management. The respective carrying value of certain on-balance-sheet financial instruments approximated their fair values. These financial instruments include cash, accounts receivable and accounts payable. Fair values were assumed to approximate carrying values for these financial instruments since they are short-term in nature and their carrying amounts approximate fair values or they are receivable or payable on demand.

Revenue Recognition

In May 2014, the FASB issued an accounting standard update ("ASU"), 2014-09, Revenue from Contracts with Customers (Topic 606). This ASU amends the existing accounting standards for revenue recognition and is based on the principle that revenue should be recognized to depict the transfer of goods or services to a customer at an amount that reflects the consideration a company expects to receive in exchange for those goods or services. On January 1, 2018, we adopted the new Accounting Standards Codification ("ASC") 606, Revenue from Contracts with Customers using the modified retrospective method, and we determined the new guidance does not change our policy of revenue recognition. Our primary source of revenue is through the recognition of royalty and milestone payments from EBS. Milestone revenue is recognized upon successful accomplishment of certain sales targets set forth in the license agreement between us and EBS. Royalty revenue is determined based on the agreed upon royalty rate applied to NARCAN® sales reported by EBS. There are no performance obligations by us and we recognize revenue according to the royalty report provided to us by EBS on a quarterly basis.

In regards to treatment revenue, we received certain investments from investors in return for an interest in its existing treatments. Investors carry an option to exchange investment into shares of our common stock. Revenue is deferred until such time that the option expires or milestones are achieved that eliminate the investor's right to exercise the option. Once the option has expired, we determine the performance obligations under the agreement which typically is to perform R&D services related to treatments, and recognize revenue over a period of time which is usually the expected research and development period. The treatment revenue is disaggregated by program treatments.

In June 2018, the FASB issued guidance clarifying the revenue recognition and measurement issues for grants, contracts, and similar arrangements, ASU Topic 958. Government grants and contracts are agreements that generally provide cost reimbursement for certain types of expenditures in return for research and development activities over a contractually defined period. We evaluated our grant with NIH and contract with BARDA and determined they are non-exchange transactions and fall within the scope of ASU 958, and revenue should be recognized in accordance with Topic 958 guidance. Accordingly, we recognize revenue from our grant and contract in the period during which the related costs are incurred, provided that the conditions under which the grant and contract were provided have been met and only perfunctory performance obligations are outstanding.

Licensing Agreement

Pursuant to the license agreement between us and EBS, we provided a global license to develop and commercialize our intranasal naloxone opioid overdose reversal treatment, now known as NARCAN®. We receive payments upon reaching various sales and regulatory milestones, as well as royalty payments for commercial sales of NARCAN® generated by EBS.

Effect of Inflation

Inflation did not have a significant impact on our net sales, revenues, or income from continuing operations for the three and nine months ended September 30, 2020 and 2019.

Off-Balance Sheet Arrangements

We have no off-balance sheet arrangements.

Recent Accounting Pronouncements

We reviewed accounting pronouncements and interpretations thereof that have effectiveness dates during the periods reported and in future periods. We have carefully considered the new pronouncements that alter previous generally accepted accounting principles and do not believe that any new or modified principles will have a material impact on our reported financial position or operations in the near term. The applicability of any standard is subject to the formal review of our financial management and certain standards are under consideration. Those standards have been addressed in the notes to the

condensed consolidated financial statements contained herein, and in the notes to the audited consolidated financial statements in the Annual Form 10-K and in the Form 10-K itself.

Net Profit Interests

NARCAN®

We have entered into agreements with certain investors whereby, in exchange for funding for the research, development, marketing and commercialization of a product relating to our treatment to reverse opioid overdoses (the “Opioid Overdose Reversal Treatment Product or OORTP), we provided such investors with an interest in any pre-tax profits received by us that were derived from the sale of the OORTP less any and all expenses incurred by and payments made by us in connection with the OORTP, including but not limited to an allocation of our overhead devoted by us to product-related activities, which allocation shall be determined in good faith by us (the “OORTP Net Profit”).

A summary of the investor agreements is below, and categorized by investor:

Potomac Construction Limited (“Potomac”)

In 2013, 2014 and 2015, we entered into a number of agreements with Potomac for funding from Potomac for the research, development, marketing and commercialization of the Opioid Overdose Reversal Treatment Product in the total amount of $2.25 million, in exchange for a 10.21% interest in the OORTP Net Profit in perpetuity (the "Potomac Agreement"). As of December 31, 2019, all buyback rights have expired, with the exception of the December 8, 2015 agreement, which expires in December of 2020.

Ernst Welmers (“Welmers”).

On May 15, 2014, we entered into an agreement with Welmers (the “Welmers Agreement”) and received funding from Welmers in the amount of $300 thousand for use by us for any purpose, in exchange for a 1.5% interest in the OORTP Net Profit in perpetuity.

Valour Fund, LLC (“Valour”)

On July 22, 2014, we received a $3.0 million commitment from a foundation (the “Foundation”) which later assigned its interest to Valour, from which we had the right to make capital calls from the Foundation for the research, development, marketing, commercialization and any other activities connected to the Opioid Overdose Reversal Treatment Product, certain operating expenses and any other purpose consistent with the goals of the Foundation. In exchange for funds invested by the Foundation, Valour currently owns a 6.0% interest in the OORTP Net Profit in perpetuity.

Binge Eating Disorder (BED)

From December 17, 2013 to July 20, 2015, we entered into three agreements with Potomac for total funding in the amount of $1.0 million for use by us for any purpose. In exchange for this funding, we agreed to provide Potomac with a 2% interest in the BED Treatment Product and pay Potomac 2% of the BED Net Profit in perpetuity. During June 2019, we determined not to continue development efforts on the BED Treatment Product.

Other Activities

On April 12, 2017, we entered into an amendment to the Potomac Agreements (the “Potomac Amendment”) and granted Potomac the right to receive 2.5525% of the Net Profit generated from OPNT003, nasal nalmefene. Pursuant the Potomac Amendment, for a period of four years, we could buy back the 2.5525% interest or any portion thereof at a price of $382,750 for the full 2.5525% interest; provided, that in the event we exercised this right within 2.5 years, we would pay Potomac two times the price of $382,750. In September 2019, we notified Potomac of our intent to exercise our right to buy back the entire 2.5525% interest at the buyback amount of $765,500. The payment was made in October 2019.

On March 13, 2017, we entered into a third amendment to the Senior Advisor Agreement with Brad Miles (the “Third Miles Amendment”) and granted Mr. Miles the right to receive 1.25% of the Net Profit generated from OPNT003, nasal nalmefene. Pursuant to the Third Miles Amendment, for a period of our years, we could buy back the 1.25% interest or any portion thereof at a price of $187.5 thousand for the full 1.25 interest; provided, that, in the event we exercised this right within 2.5 years, we would pay Mr. Miles two times the price of $187.5 thousand. In September 2019, we notified Mr. Miles of our intent to exercise our right to buy back the entire 1.25% interest at the buyback amount of $375 thousand. The payment was made in September 2019.

On June 1, 2017, we entered into an amendment to the Welmers Agreement with Welmers (the “Welmers Amendment”) and granted Welmers the right to receive 0.375% of the Net Profit generated from OPNT003, nasal nalmefene. Pursuant to the Welmers Amendment, until June 1, 2021 we could buy back all or any portion of the interest at the price of $56.25 thousand for the full 0.375% interest, provided, that in the event we exercise this right within 2.5 years, we would pay Welmers two times the price of $56.25 thousand. In September 2019, we notified Welmers of our intent to exercise our right to buy back the entire 0.375% interest at the buyback amount of $112.5 thousand. The payment was made in October 2019.

Royalty Payable

We entered into various agreements and subsequently received funding from certain investors for use by us for any purpose. In exchange for this funding, we agreed to provide certain investors with interest in the OORTP Net Profit generated from net NARCAN® sales by EBS.

License Fee Payable

On February 28, 2018, we were notified that Adapt, now a subsidiary of Emergent BioSolutions ("EBS"), had entered into a license agreement with a Third Party (as defined in the License Agreement) with regard to one or more patents pursuant to which Adapt invoked its right under Section 5.5 of that certain License Agreement, dated as of December 15, 2014 (the "Initial License Agreement"), by and between us and Adapt, as amended (the "License Agreement"), to offset 50% of the payments paid to such Third Party from the amounts payable by Adapt to us under the License Agreement, and SWK under the SWK Purchase Agreement. On March 1, 2018, we received net milestone payments of $6.1 million, which was net of a License Fee payment made by us under Section 5.5 of the License Agreement of $5.6 million. In accordance with the License Agreement, Adapt may enter into such a licensing arrangement and exercise its right to deduct any payments with respect thereto at any time without our consent.

As provided in Amendment No. 2 to the License Agreement, which the parties entered into on March 18, 2019, EBS made certain payments in October of 2018 to the Third Party Licensee (as defined in Amendment No. 2) and will be allowed to reduce the royalties and milestones that we would be due under the License Agreement by a maximum of $9.0 million. Under the SWK Purchase Agreement, we retain 90% of the royalties payable under the License Agreement, with SWK entitled to10%. The maximum amount payable by us is therefore $8.1 million (90% of $9 million), of which we recorded $4.5 million as a current liability at June 30, 2019.

As provided in Amendment No. 2, EBS was allowed to reduce the royalties and milestones due under the License Agreement during the year ended December 31, 2019 by a maximum of $2.0 million each quarter. As provided in the License Agreement, if net NARCAN® Sales (as defined in the License Agreement) were to exceed $200 million in any calendar year, we and SWK would be due a milestone payment of $15.0 million. During the year ended December 31, 2019, net NARCAN® Sales (as defined in the License Agreement) exceeded $200 million, and therefore we earned the $15.0 million milestone and it became payable to us and SWK, and EBS deducted $2.5 million from the $13.5 million (90% of $15.0 million) milestone payable to us.

As of December 31, 2019, the maximum amount payable by us of $8.1 million was paid, and accordingly there are no further License Fee payments.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

The Company is not required to provide the information required by this Item because it is a smaller reporting company.

Item 4. Controls and Procedures.

Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in reports filed under the Securities Exchange Act of 1934, as amended, or the Exchange Act, is recorded, processed, summarized and reported within the time periods specified in SEC rules and forms, and that such information is accumulated and communicated to our management to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives.

Our Principal Executive Officer and Principal Financial Officer, after evaluating the effectiveness of our disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) as of the end of the period covered by this Quarterly Report on Form 10-Q, have concluded that, based on such evaluation, our disclosure controls and procedures were effective to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported, with the time periods specified in the SEC's rules and forms, and is accumulated and communicated to our management, including our Principal Executive Officer and Principal Financial Officer as appropriate to allow timely decisions regarding required disclosure.

Changes in Internal Controls over Financial Reporting

There were no significant changes to our internal controls over financial reporting that occurred during the three months ended September 30, 2020 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II— OTHER INFORMATION

Item 1. Legal Proceedings.

On February 27, 2018,the Company and Adapt received notice from Teva, pursuant to 21 U.S.C. § 355(j)(2)(B)(ii) (the "February 2018 Notice Letter"), that Teva had filed an ANDA with the FDA seeking regulatory approval to market a generic version of NARCAN® 2 mg/spray Nasal Spray before the expiration of the '644 patent and the '226 patent. The '644 and '226 patents are listed with respect to Adapt's New Drug Application No. 208411 for NARCAN 2 mg/spray Nasal Spray in the FDA's Orange Book and each patent expires on March 16, 2035. The Company is the record owner of the '644 patent and the Company and Adapt are joint record owners of the '226 patent. Teva's Notice Letter asserts that the commercial manufacture, use or sale of its generic drug product described in its ANDA will not infringe the '644 patent or the '226 patent, or that the '644 patent and '226 patent are invalid or unenforceable.

On September 14, 2018, the Company and Adapt Pharma, Inc. ("Adapt") received notice from Perrigo UK FINCO Limited Partnership ("Perrigo"), pursuant to 21 U.S.C. ß 355(j)(2)(B)(ii) (the "Notice Letter"), that Perrigo had filed an ANDA with the FDA seeking regulatory approval to market a generic version of NARCAN® (naloxone hydrochloride) Nasal Spray before the expiration of U.S. Patent Nos. 9,211,253 (the "'253 Patent"), 9,468,747 (the "'747 Patent"), 9,561,177 (the "'177 Patent"), 9,629,965 (the "'965 Patent") and 9,775,838 (the "'838 Patent"). The '253, '747, '177, '965 and '838 patents are listed with respect to NARCAN® in the FDA's Orange Book and expires on March 16, 2035. Perrigo's Notice Letter asserts that its generic product will not infringe the '253, '747, '177, '965 and '838 patents or that the '253, '747, '177, '965 and '838 patents are invalid or unenforceable. Pursuant to an Exclusive License Agreement, entered into on December 14, 2014, as amended, the Company has exclusively licensed the '253, '747, '177, '965 and '838 patents to Adapt.

On October 25, 2018, Emergent BioSolutions' Adapt subsidiaries and Opiant (collectively, the "Plaintiffs") filed a complaint for patent infringement against Perrigo in the United States District Court for the District of New Jersey arising from Perrigo's ANDA filing with the FDA. As a result of timely filing the lawsuit in accordance with the Hatch-Waxman Act, a 30-month stay of approval will be imposed by the FDA on Perrigo's ANDA, which is expected to remain in effect until March 2021 absent an earlier judgment, unfavorable to the Plaintiffs, by the U.S. District Court for the District of New Jersey. The Plaintiffs seek, among other relief, an order that the effective date of FDA approval of the ANDA be a date no earlier than the expiration of each of the Patents-In-Suit, as well as equitable relief enjoining Perrigo from infringing these patents, and monetary relief as a result of any such infringement. Emergent BioSolutions Inc. continues to vigorously enforce the intellectual property portfolio related to NARCAN® Nasal Spray.

In each of the complaints described above, the Plaintiffs seek, among other relief, an order that the effective date of FDA approval of the Teva or Perrigo ANDA be a date not earlier than the expiration of the applicable patent, as well as equitable relief enjoining Teva and Perrigo from making, using, offering to sell, selling, or importing the product that is the subject of the Teva or Perrigo ANDA until after the expiration of the applicable patent, and monetary relief as a result of any such infringement.

On or about February 19, 2019, Emergent BioSolutions' Adapt subsidiaries and Opiant received notice from a company called Nalox-1 Pharmaceuticals LLC that it had filed fifteen petitions for inter partes review of U.S. Patent Nos. 9,211,253, 9,468,747, 9,561,177, 9,629,965, and 9,775,838 (IPR Nos. 2019-00685, 2019-00686, 2019-00687, 2019-00688, 2019-00689, 2019-00690, 2019-00691, 2019-00692, 2019-00693, 2019-00694, 2019-00695, 2019-00696, 2019-00697, 2019-00698, 2019-00699) with the Patent Trial and Appeal Board of the United States Patent and Trademark Office. Nalox-1's Petitions assert that each of the foregoing patents are invalid as obvious in view of prior art.

The Patent Trial and Appeal Board of the United States Patent and Trademark Office denied twelve of the petitions, but instituted review of three of the petitions. On August 21, 2020, the Patent Trial and Appeal Board of the United States Patent and Trademark Office issued final rulings in each of the three petitions, all in the Company's favor.

On February 12, 2020, Plaintiffs and Perrigo entered into a settlement agreement to resolve the ongoing litigation. Under the terms of the settlement, Perrigo has received a non-exclusive license under the Company's patents licensed to Adapt to make, have made and market its generic naloxone hydrochloride nasal spray under its own ANDA. Perrigo's license will be effective as of January 5, 2033 or earlier under certain circumstances including circumstances related to the outcome of the current litigation against Teva or litigation against future ANDA filers. The Perrigo settlement agreement is subject to review by the U.S. Department of Justice and the Federal Trade Commission, and entry of an order dismissing the litigation by the U.S. District Court for the District of New Jersey.

Closing arguments in the Teva trial were held on February 26, 2020. Plaintiffs also filed a complaint related to Teva's ANDA seeking to market a generic version of NARCAN® (naloxone hydrochloride) Nasal Spray 2mg/spray.

On June 5, 2020, the District Court for the District of New Jersey entered a decision in the patent litigation regarding NARCAN® (naloxone HCl) Nasal Spray 4mg/spray product, and ruled in favor of Teva. The Company and the Company's commercial partner, Emergent BioSolutions, intends to appeal the decision to the Court of Appeals for the Federal Circuit.

Except as described above, there is no action, suit, proceeding, inquiry or investigation before or by any court, public board, government agency, self-regulatory organization or other body pending or, to the knowledge of the executive officers of the Company or any of the Company's subsidiaries, threatened against or affecting the Company, the Company's Common Stock, any of the Company's subsidiaries or the Company's or the Company's subsidiaries' officers or directors in their capacities as such, in which an adverse decision could have a material adverse effect.

Item 1A. Risk Factors.

We have included in Part I, Item 1A of our Form 10-K, a description of certain risks and uncertainties that could affect our business, future performance or financial condition (the "Risk Factors"). With the exception of the risk factors listed below, there are no material changes from the disclosure provided in the Form 10-K with respect to the Risk Factors. Investors should consider the Risk Factors prior to making an investment decision with respect to our stock.

The approval and launch of a generic version of NARCAN® or other naloxone hydrochloride nasal spray products that compete with NARCAN® would adversely affect sales of NARCAN®.

Although NARCAN® (naloxone hydrochloride) Nasal Spray ("NARCAN®") is protected by patents covering its manufacture, formulation, distribution system and method of use, multiple third parties have filed ANDAs seeking FDA approval of generic versions of NARCAN®. Notwithstanding our patents, it is possible that once its application is approved, an ANDA filer could introduce a competing naloxone hydrochloride product before our patents expire if it is determined that it does not infringe our patents, or that our patents are invalid or unenforceable, or if such company or companies decide, before applicable ongoing patent litigation is concluded, to launch a naloxone hydrochloride product at risk of being held liable for damages for patent infringement. As discussed below, the FDA has approved the first ANDA for NARCAN®.

Two separate companies, (i) Teva Pharmaceuticals Industries Ltd. and its wholly owned subsidiary Teva Pharamceuticals USA, Inc. (collectively "Teva"), and (ii) Perrigo UK FINCO Limited Partnership, sent us and our partner Emergent BioSolutions, Inc and its wholly owned subsidiary Adapt Pharma Operations Limited (collectively "EBS") notices that they had filed ANDAs with the FDA seeking approval to market a generic version of NARCAN®, and we, along with EBS, filed patent lawsuits against each of these companies in the District Court for New Jersey.

On April 19, 2019, the FDA announced approval of Teva's ANDA for a generic version of NARCAN®.

On June 5, 2020, the District Court for the District of New Jersey entered a decision in the patent litigation regarding NARCAN® (naloxone HCl) Nasal Spray 4mg/spray product. The Court ruled in favor of Teva. Opiant's commercial partner EBS, intends to appeal the decision to the Court of Appeals for the Federal Circuit.

The timing of any potential commercial launch of a generic version of NARCAN® by Teva is still uncertain. However, after any introduction of a generic competitor, a significant percentage of the prescriptions written for NARCAN® may be filled with the generic version, which may result in a loss in sales of NARCAN®. Generic competition often also results in decreases in the prices at which branded products can be sold, particularly when there is more than one generic available in the marketplace. In addition, certain U.S. state laws allow for, and in some instances in the absence of specific instructions from the prescribing physician mandate, the dispensing of generic products rather than branded products where a generic version is available.

We expect that the launch of a generic version of NARCAN®, or the approval and launch of other products that compete with NARCAN®, will have a material adverse effect on our licensing partner's sales of NARCAN® and as a result will have a material adverse effect on the royalties that we would receive from such sales of NARCAN®, on our business, financial condition, results of operations and growth prospects.

Public health epidemics, pandemics or outbreaks, including the recent novel coronavirus pandemic (COVID-19), could adversely affect our business.

In December 2019, a novel coronavirus ("COVID-19") was identified in Wuhan, China. The virus continues to spread globally, has been declared a pandemic by the World Health Organization and has spread to over 100 countries, including the United States The COVID-19 outbreak is significantly affecting our employees, patients, communities and business operations, as well as the U.S. economy and financial markets. The full extent to which the COVID-19 outbreak will impact our business, results of operations, financial condition and cash flows will depend on future developments that are highly uncertain and cannot be accurately predicted, including new information that may emerge concerning COVID-19 and the actions to contain it or treat its impact and the economic impact on local, regional, national and international markets. As the COVID-19 pandemic continues, our results of operations, financial condition and cash flows are likely to be materially adversely affected, particularly if the pandemic persists for a significant amount of time.

COVID-19 or other public health epidemics, pandemics or outbreaks, and the resulting business or economic disruptions resulting therefrom, may adversely impact our business as well as our ability to raise capital. The impact of this pandemic has been and will likely continue to be extensive in many aspects of society, which has resulted in and will likely continue to result in significant disruptions to the global economy, as well as businesses and capital markets around the world.

While we cannot presently predict the scope and severity of any potential business shutdowns or disruptions, if we or any of our business partners, clinical trial sites, distributors and other third parties with whom we conduct business, were to experience shutdowns or other business disruptions, our ability to conduct our business in the manner and on the timelines presently planned could be materially and negatively impacted. For example, if our primary development program for OPNT003, nasal nalmefene, for the treatment of Opioid Overdose, or OPNT004, for treatment of Acute Cannabinoid Overdoes, were to be delayed, it may have a material adverse effect on our business, results of operations, and financial condition.

The COVID 19 pandemic's impact on the medical community and the global economy could have an adverse impact on our distributor's sales upon which we derive royalties and milestones, which could lead to a decrease in our revenues, net income and assets.

Several measures are currently being implemented by the United States and other governments to address the current COVID-19 pandemic and its economic impacts, including the State of California and local government entities. At this time, it is impossible to predict the success of these measures and whether or not they will have unforeseen negative consequences for our business. In addition, our results of operations, financial position and cash flows may be adversely affected by federal or state laws, regulations, orders, or other governmental or regulatory actions addressing the current COVID-19 pandemic or the U.S. healthcare system, which, if adopted, could result in direct or indirect restrictions to our business, results of operations, financial condition and cash flow.

The foregoing and other continued disruptions to our business as a result of COVID-19 could result in a material adverse effect on our business, results of operations, financial condition and cash flows. Furthermore, the COVID-19 pandemic could heighten the risks in certain of the other risk factors described herein.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.

None.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

None.

Item 6. Exhibits.

See the Exhibit Index on the page immediately following for a list of exhibits filed as part of this Report, which Exhibit Index is incorporated herein by reference.

EXHIBIT INDEX

Exhibit Number	Description of Document	Incorporation by Reference			
		Form	File No.	Exhibit	Filing Date
10.1	Master Services Agreement dated July 1, 2020 and Project Scope Agreement dated July 22, 2020 between the Company and Summit Biosciences, Inc.	8-K	001-38193	10.1	July 28, 2020
31.1*	Certification of the Principal Executive Officer pursuant to Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				
31.2*	Certification of the Principal Financial Officer pursuant to Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				
32.1**	Certification of the Principal Executive Officer pursuant to 18 U.S.C Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				
32.2**	Certification of the Principal Financial Officer pursuant to 18 U.S.C Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				
101.INS*	XBRL Instance Document.				
101.SCH*	XBRL Taxonomy Extension Schema Document.				
101.CAL*	XBRL Taxonomy Extension Calculation Linkbase Document.				
101.DEF*	XBRL Taxonomy Extension Definition Linkbase Document.				
101.LAB*	XBRL Taxonomy Extension Label Linkbase Document.				
101.PRE*	XBRL Taxonomy Extension Presentation Linkbase Document.				

* Filed herewith

** The certifications attached as Exhibit 32.1 and 32.2 that accompany this Quarterly Report on Form 10-Q are not deemed filed with the Securities and Exchange Commission and are not to be incorporated by reference into any filing of Opiant Pharmaceuticals, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Quarterly Report on Form 10-Q, irrespective of any general incorporation language contained in such filing.

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 thereunto duly authorized.

OPIANT PHARMACEUTICALS, INC.

November 12, 2020 By: /s/ *Dr. Roger Crystal*

Name: Dr. Roger Crystal
Title: Chief Executive Officer and Director
(Principal Executive Officer)

November 12, 2020 By: /s/ *David D. O'Toole*

Name: David D. O'Toole
Title: Chief Financial Officer
(Principal Financial and Accounting Officer)

EXHIBIT 31.1

**CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER,
PURSUANT TO 18 U.S.C. SECTION 1350
AS ADOPTED PURSUANT TO SECTION 302
OF THE SARBANES–OXLEY ACT OF 2002**

I, Dr. Roger Crystal, Chief Executive Officer of Opiant Pharmaceuticals, Inc., certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Opiant Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 12, 2020

By: */s/ Dr. Roger Crystal*
Dr. Roger Crystal
Chief Executive Officer
(Principal Executive Officer)

EXHIBIT 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER,
PURSUANT TO 18 U.S.C. SECTION 1350
AS ADOPTED PURSUANT TO SECTION 302
OF THE SARBANES–OXLEY ACT OF 2002

I, David O'Toole, Chief Financial Officer of Opiant Pharmaceuticals, Inc., certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Opiant Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 12, 2020

By: */s/ David O'Toole*
David O'Toole
Chief Financial Officer
(Principal Financial and Accounting Officer)

EXHIBIT 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of Opiant Pharmaceuticals, Inc. (the "Company") for the period ended September 30, 2020, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), Dr. Roger Crystal, as Chief Executive Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 12, 2020

By: */s/ Dr. Roger Crystal*
Dr. Roger Crystal
Chief Executive Officer
(Principal Executive Officer)

EXHIBIT 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of Opiant Pharmaceuticals, Inc. (the "Company") for the period ended September 30, 2020, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), David O'Toole, as Chief Financial Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 12, 2020

By: */s/ David O'Toole*
David O'Toole
Chief Financial Officer
(Principal Financial and Accounting Officer)