

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, 2021

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**

(State or other jurisdiction of incorporation or organization)

**46-4744124**

(I.R.S. Employer Identification No.)

**233 Wilshire Blvd. Suite 280, Santa Monica, CA**

(Address of principal executive offices)

**90401**

(Zip Code)

**(310)-598-5410**

(Registrant's telephone number, including area code)

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

Non-Accelerated Filer

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, 2021, the registrant had 4,720,285 shares of common stock outstanding.

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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

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## 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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**OPIANT PHARMACEUTICALS, INC.**  
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PART 1 - FINANCIAL INFORMATION

Item 1. Financial Statements

Opiant Pharmaceuticals, Inc.  
Condensed Consolidated Balance Sheets

Assets	September 30, 2021 (unaudited)	December 31, 2020
<b>Current assets</b>		
Cash and cash equivalents	\$ 35,284,595	\$ 48,251,336
Marketable securities	15,044,750	—
Accounts receivable	15,425,938	8,910,975
Prepaid and other current assets	2,121,145	1,936,842
<b>Total current assets</b>	<b>67,876,428</b>	<b>59,099,153</b>
<b>Other assets</b>		
Property and equipment - net	93,519	171,190
Right of use assets - operating leases	997,777	278,455
Patents and patent applications - net	11,971	13,000
Other non-current assets	—	1,051,234
<b>Total assets</b>	<b>\$ 68,979,695</b>	<b>\$ 60,613,032</b>
<b>Liabilities and Stockholders' Equity</b>		
<b>Liabilities</b>		
<b>Current liabilities</b>		
Accounts payable and accrued expenses	\$ 2,580,904	\$ 2,966,479
Accrued salaries and wages	1,347,552	908,516
Royalty payable	3,136,677	1,908,072
Deferred revenue	—	354,756
Operating leases	287,139	282,421
<b>Total current liabilities</b>	<b>7,352,272</b>	<b>6,420,244</b>
<b>Long-term liabilities</b>		
Operating leases - long term	716,343	—
Convertible debt, net of unamortized discount	18,905,723	18,700,546
<b>Total long-term liabilities</b>	<b>19,622,066</b>	<b>18,700,546</b>
<b>Total liabilities</b>	<b>26,974,338</b>	<b>25,120,790</b>
<b>Stockholders' equity</b>		
Common stock; par value \$0.001; 200,000,000 shares authorized; 4,618,221 and 4,258,105 shares issued and outstanding at September 30, 2021 and December 31, 2020, respectively	4,618	4,259
Additional paid-in capital	104,460,194	100,203,979
Accumulated other comprehensive loss	(26,850)	(26,931)
Accumulated deficit	(62,432,605)	(64,689,065)
<b>Total stockholders' equity</b>	<b>42,005,357</b>	<b>35,492,242</b>
<b>Total liabilities and stockholders' equity</b>	<b>\$ 68,979,695</b>	<b>\$ 60,613,032</b>

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

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

	Three months ended September 30,		Nine months ended September 30,	
	2021	2020	2021	2020
<b>Revenues</b>				
Royalty revenue	\$ 14,041,006	\$ 8,600,811	\$ 27,688,713	\$ 19,010,000
Grant and contract revenue	2,298,055	505,265	6,296,542	6,296,542
Total revenue	16,339,061	9,106,076	33,985,255	19,702,542
<b>Operating expenses</b>				
General and administrative	3,378,707	2,729,098	8,758,601	8,110,000
Research and development	4,881,398	2,783,452	12,119,088	4,700,000
Sales and marketing	1,059,649	914,349	3,080,211	3,700,000
Royalty expense	3,058,865	1,951,947	6,145,057	4,200,000
Total operating expenses	12,378,619	8,378,846	30,102,957	20,900,000
Income (loss) from operations	3,960,442	727,230	3,882,298	(1,200,000)
<b>Other income (expense)</b>				
Interest income	3,498	3,922	10,334	10,334
Interest expense	(547,296)	—	(1,626,273)	—
Gain (loss) on foreign exchange	455	(6,178)	(9,899)	—
Total other income (expense)	(543,343)	(2,256)	(1,625,838)	10,334
Income (loss) before income taxes	3,417,099	724,974	2,256,460	(1,190,000)
Income tax (expense)	—	—	—	(300,000)
Net income (loss)	\$ 3,417,099	\$ 724,974	\$ 2,256,460	\$ (1,190,000)
<b>Other comprehensive income (loss):</b>				
Foreign currency translation adjustment	(7,974)	196,076	81	(110,000)
Comprehensive income (loss)	\$ 3,409,125	\$ 921,050	\$ 2,256,541	\$ (1,290,000)
<b>Net income (loss) per share of common stock:</b>				
Basic	\$ 0.77	\$ 0.17	\$ 0.52	\$ —
Diluted	\$ 0.56	\$ 0.15	\$ 0.41	\$ —
<b>Weighted average shares outstanding used to compute net income (loss) per share:</b>				
Basic	4,462,236	4,258,105	4,359,759	4,258,105
Diluted	6,065,044	4,847,211	5,565,065	4,258,105

*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, 2020	4,258,105	\$ 4,259	\$ 100,203,979	\$ (64,689,065)	\$ (26,931)	\$ 35,492,242
Exercise of stock options	65,962	66	579,553	—	—	579,619
Restricted stock issued	6,527	6	(6)	—	—	—
Stock based compensation	—	—	745,620	—	—	745,620
Net loss	—	—	—	(2,844,230)	—	(2,844,230)
Foreign currency translation adjustment	—	—	—	—	12,501	12,501
Balance at March 31, 2021	<u>4,330,594</u>	<u>\$ 4,331</u>	<u>\$ 101,529,146</u>	<u>\$ (67,533,295)</u>	<u>\$ (14,430)</u>	<u>\$ 33,985,752</u>
Exercise of stock options	5,630	6	36,599	—	—	36,605
Restricted stock issued	13,375	13	(13)	—	—	—
Stock based compensation	—	—	654,562	—	—	654,562
Net income	—	—	—	1,683,591	—	1,683,591
Foreign currency translation adjustment	—	—	—	—	(4,446)	(4,446)
Balance at June 30, 2021	<u>4,349,599</u>	<u>4,350</u>	<u>102,220,294</u>	<u>(65,849,704)</u>	<u>(18,876)</u>	<u>36,356,064</u>
Exercise of stock options	268,622	268	1,545,566	—	—	1,545,834
Stock based compensation	—	—	694,334	—	—	694,334
Net income	—	—	—	3,417,099	—	3,417,099
Foreign currency translation adjustment	—	—	—	—	(7,974)	(7,974)
Balance at September 30, 2021	<u>4,618,221</u>	<u>\$ 4,618</u>	<u>\$ 104,460,194</u>	<u>\$ (62,432,605)</u>	<u>\$ (26,850)</u>	<u>\$ 42,005,357</u>
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)
Foreign currency translation adjustment	—	—	—	—	(293,491)	(293,491)
Balance at March 31, 2020	<u>4,258,105</u>	<u>\$ 4,259</u>	<u>\$ 98,611,083</u>	<u>\$ (64,512,259)</u>	<u>(293,491)</u>	<u>\$ 33,809,592</u>
Stock based compensation	—	—	720,100	—	—	720,100
Net loss	—	—	—	(216,205)	—	(216,205)
Foreign currency translation adjustment	—	—	—	—	(17,229)	(17,229)
Balance at June 30, 2020	<u>4,258,105</u>	<u>4,259</u>	<u>99,331,183</u>	<u>(64,728,464)</u>	<u>(310,720)</u>	<u>34,296,258</u>
Stock based compensation	—	—	323,809	—	—	323,809
Net Income	—	—	—	724,974	—	724,974
Foreign currency translation adjustment	—	—	—	—	196,076	196,076
Balance at September 30, 2020	<u>4,258,105</u>	<u>\$ 4,259</u>	<u>\$ 99,654,992</u>	<u>\$ (64,003,490)</u>	<u>\$ (114,644)</u>	<u>\$ 35,541,117</u>

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

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

	<b>For the Nine Months Ended</b>	
	<b>September 30, 2021</b>	<b>September 30, 2020</b>
<b>Cash flows from operating activities</b>		
Net income (loss)	\$ 2,256,460	\$ (1,175,874)
Adjustments to reconcile net income (loss) to net cash used in operating activities:		
Depreciation and amortization	78,701	92,059
Amortization of debt discount	205,177	—
Non-cash lease expense	388,598	364,542
Stock based compensation	2,094,516	1,730,508
Change in assets and liabilities:		
Accounts receivable	(6,514,964)	(1,394,991)
Prepaid and other current assets	860,631	(857,828)
Accounts payable and accrued expenses	(481,464)	1,235,607
Accrued salaries and wages	553,996	200,991
Lease liabilities	(392,564)	(363,363)
Royalty payable	1,228,605	331,495
Deferred revenue	(354,756)	(558,231)
Net cash used in operating activities	(77,064)	(395,085)
<b>Cash flows from investing activities</b>		
Purchase of marketable securities	(15,044,750)	—
Purchase of property and equipment	—	(50,887)
Net cash used in investing activities	(15,044,750)	(50,887)
<b>Cash flows provided by financing activities</b>		
Proceeds from stock option and warrant exercises	2,162,058	685,101
Net cash provided by financing activities	2,162,058	685,101
Effect of foreign currency translation on cash	(6,985)	(116,437)
<b>Net increase (decrease) in cash and cash equivalents</b>	<b>(12,966,741)</b>	<b>122,692</b>
<b>Cash and cash equivalents, beginning of period</b>	<b>48,251,336</b>	<b>30,980,473</b>
<b>Cash and cash equivalents, end of period</b>	<b>\$ 35,284,595</b>	<b>\$ 31,103,165</b>
<b>Supplemental disclosure</b>		
Interest paid during the period	\$ 1,051,508	\$ —
Income taxes paid during the period	\$ —	\$ 39,000
<b>Supplemental disclosure of non-cash finance transactions</b>		
Right of use assets obtained in exchange for new lease obligations	\$ 1,094,259	\$ —
Issuance of restricted stock	\$ 19	\$ —
Cashless exercise of options	\$ —	\$ 2

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

**Opiant Pharmaceuticals, Inc.**  
**Notes to 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. 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, 2020 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, 2021 and December 31, 2020, results of operations for the three and nine months ended September 30, 2021 and 2020, and cash flows for the three and nine months ended September 30, 2021 and 2020. The interim results are not necessarily indicative of the results for any future interim period or for the entire year.

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, 2020 included in the Company’s Annual Report on Form 10-K filed with the SEC on March 4, 2021.

**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 \$35.3 million and \$48.3 million at September 30, 2021 and December 31, 2020, 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, 2021, the Company has not experienced any losses on its deposits of cash and cash equivalents for the periods presented.

### Earnings (Loss) Per Share

Basic and diluted earnings (loss) per share is computed by dividing loss attributable to common stockholders by the weighted average number of shares of Common Stock outstanding during the period.

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).

(in thousands, except per share data)	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2021	2020	2021	2020
<b>Numerator:</b>				
Net Income (loss)	\$ 3,417	\$ 725	\$ 2,256	\$ (1,176)
<b>Denominator:</b>				
Denominator for basic income (loss) per share - weighted average shares	4,462,236	4,258,105	4,359,759	4,247,045
Effect of dilutive securities:				
Equity incentive plans	1,602,808	589,106	1,205,306	—
Denominator for diluted income (loss) per share	6,065,044	4,847,211	5,565,065	4,247,045
Income (loss) per share - Basic	\$ 0.77	\$ 0.17	\$ 0.52	\$ (0.28)
Income (loss) per share - Diluted	\$ 0.56	\$ 0.15	\$ 0.41	\$ (0.28)

The Company excluded the following securities from the calculation of basic and diluted net loss per share as the effect would have been antidilutive.

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2021	2020	2021	2020
Options to purchase common stock	295,550	729,692	407,975	3,077,692
Warrants to purchase common stock	—	240,000	—	278,800
Unvested restricted stock	—	—	21,425	—
Convertible Debt	509,165	—	509,165	—
Total	804,715	969,692	938,565	3,356,492

### Foreign Currency Translation

The functional currency of the Company's wholly-owned subsidiary, Opiant UK is the British Pound, 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. Marketable Securities

The Company invests in debt securities and has the intent and ability to hold until maturity. Therefore, the Company's Securities are classified as held-to-maturity. The Company's debt securities are all U.S. Treasury securities. The investments in debt securities are carried at either amortized cost or fair value. As of September 30, 2021, the Company had a total of \$15.0 million of total marketable securities, all invested in U.S. Treasury securities all of which is classified as a short term asset as the maturity is greater than three months, but less than one year. Any debt securities with original maturities of three months or less are classified as cash equivalents.

### Note 4. Accounts Receivable

As of September 30, 2021 and December 31, 2020, the Company had accounts receivable of \$15.4 million and \$8.9 million respectively, which primarily relates to royalty revenue from sales of NARCAN®.

### Note 5. Prepaid Expenses and Other Current Assets

As of September 30, 2021, the Company had prepaid expenses and other current assets of approximately \$2.1 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 6. 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 has entered into operating leases with terms greater than 12 months during the nine months ended September 30, 2021. In accordance with the guidance of Topic 842, the leases which are classified as operating leases are included in the Company's Condensed Consolidated Balance Sheets. The Company's 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 uses judgement to estimate the incremental borrowing rate which is used as the discount rate to determine the present value of lease payments. The weighted average discount rate used was 8.8% and the weighted average remaining lease term is 4.45 years.

The ROU asset and corresponding operating lease liability recognized at lease inception during the nine months ended September 30, 2021 was \$1.09 million.

The following table summarizes information related to the Company's operating leases and are included in the Company's Balance Sheet as of September 30, 2021.

Balance Sheet descriptions	September 30, 2021	
<b>Assets:</b>	<b>(in thousands)</b>	
Right of use assets - operating leases	\$	998
<b>Liabilities:</b>		
Operating leases - current		287
Operating leases - long term		716
<b>Total lease liabilities:</b>	<b>\$</b>	<b>1,003</b>

The following table summarizes the components of operating lease cost for the three and nine months ended September 30, 2021:

Lease costs, (in thousands)	Three months ended September 30, 2021	Nine months ended September 30, 2021
Operating expenses lease costs	\$ 112	\$ 412

As of September 30, 2021, future minimum operating leases payments related to the Company's operating lease liabilities were as follows:

(in thousands)	September 30, 2021	
2021 (three months remaining)	\$	118
2022		257
2023		236
2024		247
2025		276
2026		115
Total lease payments		1,249
Less imputed interest		(246)
Present value of operating lease liabilities	<b>\$</b>	<b>1,003</b>

#### Note 7. Other Non-Current Assets

As of September 30, 2021 and December 31, 2020, the Company had non-current prepaid expenses of zero and approximately \$1.1 million, respectively. 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. As of September 30, 2021 all prepaid research and development expenses is classified as current as the services are expected to be provided prior to September 30, 2022.

#### Note 8. 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, 2021 the Company recorded revenue of \$14.0 million and \$27.7 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 nalmeferene, 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 \$8.1 million and cover activities related to a planned new drug application ("NDA") submission for OPTN003 with the FDA. BARDA has awarded approximately \$6.5 million of the contract through September 30, 2022, with the balance expected to be funded, subject to satisfactory project progress, availability of funds and certain other conditions. During the three and nine months ended September 30, 2021 the Company recognized revenue of \$0.9 million and \$3.3 million, respectively 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 the entire \$7.4 million through the period ending March 31, 2022. 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 three and nine months ended September 30, 2021, the Company recognized revenue of \$1.4 million and \$3.0 million, respectively related to this grant.

The following is a summary of the Company's deferred revenue activity as of September 30, 2021:

<b>(in thousands)</b>	<b>NIDA Grant</b>	<b>Total</b>
Balance as of December 31, 2020	\$ 355	\$ 355
Additions to deferred revenue	2,187	2,187
Recognized as revenue	(2,542)	(2,542)
Balance as of September 30, 2021	<u>\$ —</u>	<u>\$ —</u>

## **Note 9. 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 NARCAN®. In exchange for this funding, the Company agreed to provide investors with interest in the net profit generated from NARCAN® sales by EBS into perpetuity. As of September 30, 2021 and December 31, 2020, the Company recorded a royalty payable of \$3.1 million and \$1.9 million, respectively.

## **Note 10. Long Term Debt**

As of September 30, 2021 and December 31, 2020 the Company had long term debt of \$18.9 million and \$18.7 million, respectively. There have been no changes to the maturity or other conditions of the debt for the nine months ended September 30, 2021.

## **Note 11. Stockholders' Equity**

### Common Stock

During the nine months ended September 30, 2021, the Company issued 340,214 shares of Common Stock as a result of stock option exercises, and received net cash proceeds of approximately \$2.2 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 Company's Board of Directors (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, but can also be one year, from the grant date. The contractual term of an option is no longer than 10 years. The 2017 Plan also allows the Company to issue restricted stock units.

As provided in the 2017 Plan, on January 1, 2021 the number of shares available for issuance was increased by 4% of the outstanding stock as of December 31, 2020, which represents an increase of 170,324 shares. As of September 30, 2021, the Company had 101,857 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, 2020, the Company had outstanding Pre-2017 Non-Qualified Stock Options to purchase, in the aggregate, 2,465,500 shares of the Company's Common Stock. During the nine months ended September 30, 2021, 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, 2021 is presented in the table below:

	Number of Shares	Weighted- average Exercise Price	Weighted- average Remaining Contractual Term (years)	Aggregate Intr Value
Outstanding at December 31, 2020	2,465,500	\$ 6.99	4.09	\$ 2,77
Exercised	(337,693)	5.85		
Forfeited	(23,332)	10.00		
Outstanding at September 30, 2021	<u>2,104,475</u>	\$ 7.08	3.59	\$ 39,26

A summary of the status of the Company's non-vested Pre-2017 Non-Qualified Stock Options as of September 30, 2021 is presented below:

	Number of Options	Weighted Average Grant Date Fair Value
Vested at September 30, 2021	2,092,809	\$ 7.06
Non-vested at September 30, 2021	<u>11,666</u>	\$ 10.00

During the nine months ended September 30, 2021 and 2020, the Company recognized zero and \$1 thousand, respectively, of non-cash expense related to Pre-2017 Non-Qualified Stock Options granted in prior periods. As of September 30, 2021, 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, 2021, the Company granted options to a number of employees to purchase 159,585 shares of the Company's Common Stock at exercise prices from \$8.20 to \$16.41 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. The Company valued these options using the Black-Scholes option pricing model and estimated the aggregate fair value of the option grants to be \$1.4 million.

The assumptions used in the valuation of options granted under the 2017 Plan during the nine months ended September 30, 2021 were as follows:

	<b>For the Nine Months Ended September 30, 2021</b>
Market value of stock on measurement date	\$8.2 to \$16.41
Risk-free interest rate	0.5% to 1.11%
Dividend yield	—
Volatility factor	75.92% to 88.79%
Term	5.50 to 6.25 years

Stock option activity for options granted under the 2017 Plan during the nine months ended September 30, 2021 is presented in the table below:

	<b>Number of Options Outstanding</b>	<b>Weighted-average Exercise Price</b>	<b>Weighted-average Remaining Contractual Term (years)</b>	<b>Aggregate Intrinsic Value</b>
Balance at December 31, 2020	61,760	21.39	\$ .85	—
Granted	15,585	12.11		
Exercised	(2,521)	9.03		
Forfeited	(6,044)	11.38		
Balance at September 30, 2021	<u>68,780</u>	<u>19.53</u>	<u>\$ .57</u>	<u>6,307,064</u>

A summary of the status of the Company's vested and non-vested options granted under the 2017 Plan as of September 30, 2021 is presented in the following table:

	<b>Number of Shares</b>	<b>Weighted Average Grant Date Fair Value Per Share</b>
Vested at September 30, 2021	481,750	22.31
Non-vested at September 30, 2021	281,030	\$ 10.29

During the nine months ended September 30, 2021 and 2020, the Company recognized approximately \$1.4 million and \$1.6 million, respectively of non-cash expense related to options granted under the 2017 Plan. As of September 30, 2021, there was approximately \$1.3 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, 2021:

	<b>Number of Shares</b>	<b>Weighted Average Fair Value Per Share</b>
Restricted stock outstanding and unvested at December 31, 2020	49,600	\$ 12.00
Restricted stock granted	76,268	\$ 12.47
Restricted stock vested	(19,902)	\$ 10.79
Restricted stock outstanding and unvested at September 30, 2021	<u>105,966</u>	<u>\$ 12.57</u>

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, 2021, the Company recognized approximately \$563 thousand of non-cash expense related to restricted stock units. As of September 30, 2021, there was \$0.7 million of total unrecognized compensation cost related to restricted stock units.

#### Inducement Equity Incentive Plan

On July 8, 2021, the Board of Directors of the Company adopted the 2021 Inducement Equity Incentive Plan (the “Inducement Plan”) and, subject to the adjustment provisions of the Inducement Plan, reserved 100,000 shares of the Company’s common stock for issuance pursuant to equity awards granted under the Inducement Plan.

During July 2021 the Company issued options to purchase 56,500 shares of common stock, and restricted stock units for 18,200 shares of common stock under the Inducement Plan.

The assumptions used in the valuation of options granted under the Inducement Plan during the nine months ended September 30, 2021 were as follows:

	<b>For the Nine Months Ended September 30, 2021</b>
Market value of stock on measurement date	\$ 16.41
Risk-free interest rate	0.84 %
Dividend yield	—
Volatility factor	76.26 %
Term	6.25 years

Stock option activity for options granted under the Inducement Plan during the nine months ended September 30, 2021 is presented in the table below:

	<b>Number of Options Outstanding</b>	<b>Weighted-average Exercise Price</b>	<b>Weighted-average Remaining Contractual Term (years)</b>	<b>Aggregate Intrinsic Value</b>
Balance at December 31, 2020	—			
Granted	56,500	16.41		
Exercised	—			
Forfeited	—			
Balance at September 30, 2021	<u>56,500</u>	16.41	\$9.8	527,145

During the three months ended September 30, 2021, the Company recognized approximately \$91 thousand of non-cash expense related to options granted under the Inducement Plan. As of September 30, 2021, there was approximately \$0.5 million of total unrecognized compensation cost related to the non-vested stock options that were granted under the 2021 Inducement Equity Incentive Plan.

The following summarizes the restricted stock activity under the Inducement Plan during the nine months ended September 30, 2021:

	Number of Shares	Weighted Average Fair Value Per Share
Restricted stock outstanding and unvested at December 31, 2020	—	
Restricted stock granted	18,200	\$ 16.41
Restricted stock vested	—	
Restricted stock outstanding and unvested at September 30, 2021	<u>18,200</u>	<u>\$ 16.41</u>

During the three months ended September 30, 2021, the Company recognized approximately \$39 thousand of non-cash expense related to restricted stock units. As of September 30, 2021, there was approximately \$260 thousand of total unrecognized compensation cost related to restricted stock units.

#### Warrants

During the nine months ended September 30, 2021, the Company did not issue any warrants.

Warrant activity for the nine months ended September 30, 2021 is presented in the table below:

	Number of Shares	Weighted- average Exercise Price	Weighted- average Remaining Contractual Term (years)	Aggregate Intrinsic Value
Outstanding at December 31, 2020	278,800	\$ 9.72	3.51	\$ 1,164,000
Exercised	—	\$ —		
Forfeited	—	\$ —		
Outstanding at September 30, 2021	<u>278,800</u>	<u>\$ 9.72</u>	<u>2.76</u>	<u>\$ 4,465,912</u>
Exercisable at September 30, 2021	<u>278,800</u>	<u>\$ 9.72</u>	<u>2.76</u>	<u>\$ 4,465,912</u>

## **Note 12. 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:

#### ***Aptar Agreement***

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 approximately \$5.2 million over the course of the development program.

#### ***Summit Agreement***

On July 22, 2020, 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 \$7.5 million of which a deposit of approximately \$1.1 million was paid as of September 30, 2021, which is included in current assets in the condensed consolidated balance sheet.

#### ***Torreyia Agreement***

The Company entered into a consulting agreement with Torreyia Partners LLP ("Torreyia"), a financial advisory firm, under which Torreyia 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, 2021 and 2020, the Company recorded \$935 thousand and \$643 thousand, respectively of expense related to the agreement with Torreyia.

#### ***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, 2021 and 2020.

#### ***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, acquired by Neurelis, Inc. in 2018, (the combined entity hereafter, "Neurelis", pursuant to which the Company was granted an exclusive license (the "License") to Neurelis' proprietary chemically synthesizable delivery enhancement and stabilization agents, including, but not limited to, Neurelis' 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 Neurelis under the Supply Agreement. The License Agreement also restricts Neurelis'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 Neurelis two immaterial upfront payments, of which the Company paid 50% by issuing the Company's Common Stock to Neurelis 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 Neurelis 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 Neurelis.

Under the terms of the Supply Agreement, Neurelis 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 Neurelis 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 Neurelis \$250 thousand upon the successful NDA filing.

For the nine months ended September 30, 2021, and 2020 the Company did not have any 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, Inc., has appealed the decision to the Court of Appeals for the Federal Circuit. On August 2, 2021, a panel consisting of three appeals-court judges held a hearing on EBS's appeal of the New Jersey District Court's decision. A decision by the Court of Appeals is expected in the fourth quarter of 2021 or early 2022.

**Note 13. Subsequent Events**

During October 2021, 17,064 shares of common stock subject to outstanding options were exercised, and the Company received net cash proceeds of approximately \$95,000.

During October 2021, the Company issued options to purchase 3,700 shares of common stock under the 2017 Plan.

During October 2021, Pontifax Medisen Finance ("Pontifax") voluntarily converted approximately \$1.7 million of the outstanding \$10.0 million convertible debt held by Pontifax into a total of 85,000 shares of common stock at a conversion rate of \$19.64 per share.

## 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, 2020 (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. 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, 2021, 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 - Nasal Nalmefene for OOR, which is further described below.

#### OPNT003 - Nasal Nalmefene for OOR

##### *Development Program for OPNT003*

In 2017, National Institute of Health 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 a NDA with the FDA for the drug and intranasal delivery device combination in the first quarter of 2022. 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 our OPNT003 NDA application.

In February 2021, the first patients were dosed in a confirmatory pharmacokinetic ("PK") study for OPNT003, nasal nalmefene, for the treatment of opioid overdose. In July 2021, we announced positive top-line results from the study. The study was conducted in 68 healthy subjects and compared OPNT003, nasal nalmefene, with an intramuscular nalmefene hydrochloride injection, 1 mg, which was the comparator previously agreed upon with the FDA. According to an initial analysis, the top-line data demonstrated that nasal nalmefene achieved significantly higher plasma concentrations compared to an intramuscular injection ( $p < 0.0001$ ). The time for nasal nalmefene to achieve maximum plasma concentrations ( $T_{max}$ ) was consistent with data from the previously completed pilot study (approximately 15 minutes). The maximum plasma

concentration ( $C_{max}$ ) was higher than observed in the pilot study, and the plasma half-life of nasal nalmefene (approximately 11 hours) was consistent with reported values following other routes (oral and parenteral) of administration.

In April 2021, first subjects were dosed in a head-to-head clinical PD study comparing the effectiveness of OPNT003, nasal nalmefene, with nasal naloxone.

In November 2021, we received Fast Track Designation from the FDA for OPNT003, nasal nalmefene. Fast Track is an FDA process designed to facilitate the development and expedite review of potential therapies that seek to treat serious conditions and fill an unmet medical need. This designation enables early and frequent communication with the FDA, in addition to the potential for a rolling submission of an NDA application.

#### *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 addressable 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 thirteen 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 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 the entire \$7.4 million. 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. In December of 2020, BARDA provided an additional commitment of up to \$3.5 million. The contract modification increases the total potential value of the BARDA contract to \$8.1 million. BARDA has awarded approximately \$6.5 million of the contract through September 30, 2022, 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, establishing the 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. In July 2021, we hired a new Chief Commercial Officer to build and lead the commercial organization.

#### **Debt Financing**

On December 10, 2020 (the "Closing Date"), we entered into a Note Purchase and Security Agreement (the "Loan Agreement") with a syndicate of Pontifax Medison Finance, a healthcare-dedicated venture and debt fund, and Kreos Capital VI (Expert Fund) LP (each a "Lender").

The Loan Agreement provides for term loans in an aggregate principal amount of up to \$50.0 million in three tranches as follows: (a) on the Closing Date, a loan in the aggregate principal amount of \$20.0 million, (b) upon the submission of a new drug application ("NDA") with the FDA, a loan in the aggregate principal amount of \$10.0 million, and (c) upon FDA approval of an opioid overdose product, a loan in the aggregate principal amount of \$20.0 million (each a "Loan, and collectively, the "Loans").

The outstanding principal of each term Loan bears an average interest rate of 8.75% per annum based on the date of issuance and a year consisting of 365 days. There is an interest-only period of 30 months, with interest on outstanding Loans payable on a quarterly basis based on the principal amount outstanding during the preceding quarter. After the interest-only period, principal of the outstanding Loans is payable in ten equal quarterly installments. All Loans have a maturity date of October 1, 2025.

Each Lender may, at its option, elect to convert up to half of the then-outstanding Loans and all accrued and unpaid interest thereon into shares our Common Stock. The Conversion Price shall be \$19.64 per share subject to certain customary adjustments as specified in the Loan Agreement.

Our obligations are secured by a security interest, senior to any current and future debts and to any security interest, in all of Company's right, title, and interest in, to and under all of our property and other assets, other than its NARCAN® Nasal Spray licensed intellectual property and other limited exceptions specified in the Loan Agreement.

The Loan Agreement contains customary representations, warranties and covenants, including covenants by us limiting additional indebtedness, liens, including on intellectual property, guaranties, mergers and consolidations, substantial asset sales, investments and loans, certain corporate changes, transactions with affiliates and fundamental changes. The Loan Agreement provides for events of default customary for term loans of this type, including but not limited to non-payment, breaches or defaults in the performance of covenants, insolvency, bankruptcy and the occurrence of a material adverse effect on the Company.

On December 10, 2020, we received the first tranche of \$20 million.

### **Impact of COVID-19 on our Business**

The spread of the SARS-CoV-2 virus ("COVID-19") since the fourth quarter of 2019 has caused an economic downturn on a global scale, as well as significant volatility in the financial markets.

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, 2021, we have cash, cash equivalents, and marketable securities of \$50.4 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. We 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,		
	2021	2020	Increase (Decrease)	2021	2020	Increase (Decrease)
<b>Revenues</b>						
Royalty revenue	\$ 14,041	\$ 8,601	\$ 5,440	\$ 27,689	\$ 19,057	\$ 8,632
Grant and contract revenue	2,298	505	1,793	6,296	644	5,652
Total revenue	16,339	9,106	7,233	33,985	19,701	14,284
<b>Operating expenses</b>						
General and administrative	3,379	2,729	650	8,759	8,138	621
Research and development	4,881	2,784	2,097	12,119	4,763	7,356
Sales and marketing	1,060	914	146	3,080	3,738	(658)
Royalty expense	3,059	1,952	1,107	6,145	4,289	1,856
Total operating expenses	12,379	8,379	4,000	30,103	20,928	9,175
Income (loss) from operations	3,960	727	3,233	3,882	(1,227)	5,109
<b>Other income (expense)</b>						
Interest income	3	4	(1)	10	92	(82)
Interest expense	(546)	—	(546)	(1,626)	—	(1,626)
Gain (loss) on foreign exchange	—	(6)	6	(10)	(2)	(8)
Total other income (expense)	(543)	(2)	(541)	(1,626)	90	(1,716)
Income (loss) before income taxes	3,417	725	2,692	2,256	(1,137)	3,393
Income tax (expense)	—	—	—	—	(39)	39
Net income (loss)	\$ 3,417	\$ 725	\$ 2,692	\$ 2,256	\$ (1,176)	\$ 3,432

## Comparison of Three Months ended September 30, 2021 to the Three Months ended September 30, 2020

### Revenues

We recognized \$16.3 million of revenue during the three months ended September 30, 2021, compared to \$9.1 million for the three months ended September 30, 2020. For the three months ended September 30, 2021, we recognized approximately \$14.0 million of revenue from our license agreement with EBS, and \$2.3 million from grant and contract revenue. For the three months ended September 30, 2020, we recognized \$8.6 million of revenue from our license agreement with EBS and \$0.5 million from grant and contract revenue. The \$5.4 million increase in revenue from our license agreement with EBS was primarily due to a \$44.5 million increase in net NARCAN® sales in the three months ended September 30, 2021 compared to the three months ended September 30, 2020. The \$1.8 million increase in grant and contract revenue was primarily due to the funding received from NIH and BARDA for the development of OPNT003.

### General and Administrative Expenses

Our general and administrative expenses increased by \$0.6 million to \$3.4 million from \$2.8 million for the three months ended September 30, 2021 compared to the three months ended September 30, 2020, primarily due to an increase in legal, professional and other fees of \$0.6 million.

#### *Research and Development Expenses*

Our research and development expenses for the three months ended September 30, 2021 increased by \$2.1 million to \$4.9 million, from \$2.8 million for the three months ended September 30, 2020, primarily due to increased activity on our lead product candidate, OPNT003 - Nasal Nalmefene for OOR.

#### *Sales and Marketing Expenses*

During the three months ended September 30, 2021, we recorded sales and marketing expenses of \$1.1 million for pre-commercialization efforts related to our nasal nalmefene product, which is under clinical development. Sales and marketing expenses during the three months ended September 30, 2020 were approximately \$0.9 million.

#### *Royalty Expenses*

Our royalty expenses were \$3.1 million and \$2.0 million for the three months ended September 30, 2021 and 2020, respectively. The increase of \$1.1 million is attributable to the increase in net revenue recorded from sales of NARCAN® by EBS.

#### *Other Income (expense)*

During the three months ended September 30, 2021, interest expense was approximately \$0.5 million. We had no interest expense for the three months ended September 30, 2020. Interest expense is all related to our convertible debt.

### **Comparison of Nine Months ended September 30, 2021 to the Nine Months ended September 30, 2020**

#### *Revenues*

We recognized \$34.0 million of revenue during the nine months ended September 30, 2021, compared to \$19.7 million for the nine months ended September 30, 2020. For the nine months ended September 30, 2021 we recognized approximately \$27.7 million of revenue from our license agreement with EBS and \$6.3 million from grant and contract revenue. For the nine months ended September 30, 2020, we recognized \$19.1 million of revenue from our license agreement with EBS and \$0.6 million from grant and contract revenue. The \$8.6 million increase in revenue from our license agreement with EBS was primarily due to a \$80.0 million increase in net NARCAN® sales in the nine months ended September 30, 2021 compared to the nine months ended September 30, 2020. The \$5.7 million increase in grant and contract revenue was all attributable to the funding received from NIH and BARDA for the development of OPNT003.

#### *General and Administrative Expenses*

Our general and administrative expenses increased by \$0.6 million to \$8.7 million from \$8.1 million for the nine months ended September 30, 2021 compared to the nine months ended September 30, 2020, primarily due to an increase in legal and professional fees of \$0.3 million and personnel and related expense of \$0.3 million.

#### *Research and Development Expenses*

Our research and development expenses increased by \$7.3 million during the nine months ended September 30, 2021 to \$12.1 million, compared to \$4.8 million for the nine months ended September 30, 2020, primarily due to an increase in external development expense related to increased activity on our lead product candidate, OPNT003.

#### *Sales and Marketing Expenses*

During the nine months ended September 30, 2021, we recorded sales and marketing expenses of \$3.1 million for pre-commercialization efforts related to our nasal nalmefene product, which is under clinical development. Sales and marketing expense during the nine months ended September 30, 2020 was approximately \$3.7 million.

#### *Royalty Expenses*

Our royalty expenses were \$6.1 million and \$4.3 million during the nine months ended September 30, 2021 and 2020, respectively. The increase of \$1.8 million is attributable to the increase in net revenue recorded from sales of NARCAN® by EBS.

#### *Other Income (expense)*

During the nine months ended September 30, 2021, interest income was \$10 thousand compared to interest income of \$92 thousand for the nine months ended September 30, 2020, which primarily resulted from a decreased rate of return on our invested cash balances.

During the nine months ended September 30, 2021, interest expense was approximately \$1.6 million. We had no interest expense for the nine months ended September 30, 2020. Interest expense is all related to our convertible debt.

### **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:

<b>(in thousands)</b>	<b>Nine Months Ended September 30,</b>	
	<b>2021</b>	<b>2020</b>
Net cash used in operating activities	\$ (77)	\$ (395)
Net cash used in investing activities	\$ (15,045)	\$ (51)
Net cash provided by financing activities	\$ 2,162	\$ 685

#### **Net cash used in operating activities**

During the nine months ended September 30, 2021, net cash used in operating activities was \$77 thousand, which was primarily due to changes in operating assets and liabilities of \$5.1 million, mostly offset by stock based compensation expense of \$2.1 million, other non-cash expenses totaling \$0.7 million, and net income of \$2.3 million.

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.

#### **Net cash used in investing activities**

During the nine months ended September 30, 2021, we purchased net marketable securities of approximately \$15.0 million.

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

#### **Net cash provided by financing activities**

During the nine months ended September 30, 2021, net cash provided by financing activities was approximately \$2.2 million, which was attributable to proceeds received from stock option exercises.

During the nine months ended September 30, 2020, net cash provided by financing activities was approximately \$0.7 million which was attributable to proceeds received from stock option and warrant 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 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 revenues, or income from continuing operations for the three months and nine months ended September 30, 2021 and 2020.

## **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, 2020, all buyback rights have expired.

#### 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.

#### *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.

**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, 2021 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 12, 2020, Emergent BioSolutions, Inc. ("EBS") and the Company entered into a settlement agreement with Perrigo UK FINCO Limited Partnership ("Perrigo") to resolve the ongoing litigation. Under the terms of the settlement, Perrigo received a non-exclusive license under the Company's patents licensed to EBS 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.

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 EBS have appealed the decision to the Court of Appeals for the Federal Circuit. On August 2, 2021, a panel consisting of three appeals-court judges held a hearing on EBS's appeal of the New Jersey District Court's decision. A decision by the Court of Appeals is expected in the fourth quarter of 2021 or early 2022.

On June 11, 2020, the Company and EBS received from Teva Canada Limited a Notice of Allegation and Detailed Statement, stating that Teva had filed an Abbreviated New Drug Submission with the Canadian Minister of Health for the issuance of a Notice of Compliance for naloxone hydrochloride in the strength of 4 mg/0.1 ml for nasal administration. Teva's Notice of Allegation and Detailed Statement asserted that its proposed generic product will not infringe Canadian Patent No. 2,942,611 and/or that Canadian Patent No. 2,942,611 is invalid or void. Canadian Patent No. 2,942,611 expires on March 16, 2035. On July 23, 2020, the Company and EBS filed a Statement of Claim in Case Number T-798-20 in Toronto, Ontario, which alleges that Teva's product would infringe Canadian Patent No. 2,942,611.

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 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"). 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.

**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
<a href="#">31.1*</a>	<a href="#">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.</a>				
<a href="#">31.2*</a>	<a href="#">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.</a>				
<a href="#">32.1**</a>	<a href="#">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.</a>				
<a href="#">32.2**</a>	<a href="#">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.</a>				
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, 2021

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

November 12, 2021

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







