

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, 2018  
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.)

**201 Santa Monica Blvd., Suite 500, 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

Accelerated Filer

Non-Accelerated Filer

Smaller Reporting Company

(Do not check if a 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 5, 2018, the registrant had 3,834,542 shares of common stock outstanding.

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**OPIANT PHARMACEUTICALS, INC.**  
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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.

PART 1 - FINANCIAL INFORMATION

Item 1. Financial Statements

Opiant Pharmaceuticals, Inc.  
**Condensed Consolidated Balance Sheets**  
*(In thousands, except share and per share data)*

	<u>September 30, 2018</u>	<u>December 31, 2017</u>
<b>Assets</b>	(unaudited)	
<b>Current assets</b>		
Cash and cash equivalents	\$ 24,825	\$ 8,116
Accounts receivable	4,112	11,697
Deferred financing costs	—	209
Prepaid and other current assets	346	733
Total current assets	<u>29,283</u>	<u>20,755</u>
<b>Other assets</b>		
Computer equipment - net of accumulated depreciation	—	1
Patents and patent applications - net of accumulated amortization	16	17
Total assets	<u>\$ 29,299</u>	<u>\$ 20,773</u>
<b>Liabilities and Stockholders' Equity</b>		
<b>Liabilities</b>		
<b>Current liabilities</b>		
Accounts payable and accrued expenses	\$ 1,318	\$ 3,157
Accrued salaries and wages	948	713
Royalty payable	800	1,408
Deferred revenue	660	379
Total current liabilities	<u>3,726</u>	<u>5,657</u>
<b>Long-term liabilities</b>		
Deferred revenue	402	2,116
Total long-term liabilities	<u>402</u>	<u>2,116</u>
Total liabilities	<u>\$ 4,128</u>	<u>\$ 7,773</u>
<b>Stockholders' equity</b>		
Common stock; par value \$0.001; 200,000,000 shares authorized; 3,795,429 shares issued and outstanding at September 30, 2018 and 2,535,766 shares issued and outstanding at December 31, 2017	4	2
Additional paid-in capital	90,050	66,223
Accumulated deficit	(64,883)	(53,225)
Total stockholders' equity	<u>25,171</u>	<u>13,000</u>
Total liabilities and stockholders' equity	<u>\$ 29,299</u>	<u>\$ 20,773</u>

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

**Opiant Pharmaceuticals, Inc.**  
**Condensed Consolidated Statements of Operations**  
**(unaudited)**  
*(In thousands, except share and per share data)*

	Three months ended September 30,		Nine months ended September 30,	
	2018	2017	2018	2017
<b>Revenues</b>				
Royalty and licensing revenue	\$ 4,185	\$ —	\$ 8,887	\$ 3,750
Treatment investment revenue	63	22	170	54
Grant revenue	118	—	163	—
Total revenue	<u>4,366</u>	<u>22</u>	<u>9,220</u>	<u>3,804</u>
<b>Operating expenses</b>				
General and administrative	3,398	2,175	9,220	6,295
Research and development	1,908	691	5,945	2,963
License fees	—	—	5,625	—
Total operating expenses	<u>5,306</u>	<u>2,866</u>	<u>20,790</u>	<u>9,258</u>
Loss from operations	(940)	(2,844)	(11,570)	(5,454)
<b>Other income (expense)</b>				
Interest income, net	20	7	31	29
Loss on settlement of liability	—	(33)	(50)	(33)
Gain (Loss) on foreign exchange	2	11	(36)	41
Total other income (expense)	<u>22</u>	<u>(15)</u>	<u>(55)</u>	<u>37</u>
Loss before provision for income taxes	(918)	(2,859)	(11,625)	(5,417)
Provision for income taxes	—	550	33	550
Net loss	<u>\$ (918)</u>	<u>\$ (3,409)</u>	<u>\$ (11,658)</u>	<u>\$ (5,967)</u>
<b>Net loss per share of common stock:</b>				
Basic and Diluted	<u>\$ (0.32)</u>	<u>\$ (1.68)</u>	<u>\$ (4.32)</u>	<u>\$ (2.96)</u>
<b>Weighted average shares outstanding used to compute net loss per share:</b>				
Basic and Diluted	<u>2,871,042</u>	<u>2,026,477</u>	<u>2,698,532</u>	<u>2,018,986</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)**  
*(In thousands)*

	<b>For the Nine Months Ended</b>	
	<b>September 30, 2018</b>	<b>September 30, 2017</b>
<b>Cash flows from operating activities</b>		
Net loss	\$ (11,658)	\$ (5,967)
Adjustments to reconcile net loss to net cash from operating activities:		
Depreciation and amortization	2	5
Stock based compensation from issuance of options	4,642	1,189
Stock based compensation from issuance of warrants	—	229
Issuance of common stock for services	782	98
Loss on settlement of liability	50	33
Change in assets and liabilities:		
Accounts receivable	7,585	—
Prepaid and other current assets	387	(425)
Accounts payable and accrued liabilities	(2,497)	1,198
Accrued salaries and wages	235	(2,752)
Deferred revenue	167	(54)
Net cash used in operating activities	(305)	(6,446)
<b>Cash flows provided by financing activities</b>		
Proceeds from issuance of warrants	34	—
Proceeds from issuance of common shares	17,153	—
Finance costs	(173)	—
Net cash provided by financing activities	17,014	—
<b>Net increase (decrease) in cash and cash equivalents</b>	<b>16,709</b>	<b>(6,446)</b>
<b>Cash and cash equivalents, beginning of period</b>	<b>8,116</b>	<b>13,200</b>
<b>Cash and cash equivalents, end of period</b>	<b>\$ 24,825</b>	<b>\$ 6,754</b>
<b>Non-Cash Transactions</b>		
Issuance of Common Shares to Net Profit Partner	\$ 1,600	\$ —
Offset of deferred financing costs against APIC	\$ 209	\$ —
Issuance of common stock as settlement of accrued liability	\$ —	\$ 100
Forgiveness of related party debt	\$ —	\$ 762

*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**

**Change in Fiscal Year**

On December 8, 2017, the Board of Directors of Opiant Pharmaceuticals, Inc. ("Opiant" or the "Company"), acting pursuant to Section 5.1 of the Company's Bylaws, approved a resolution changing the Company's fiscal year-end from July 31 to December 31. As such, the end of the quarters in the new fiscal year do not coincide with the end of the quarters in the Company's previous fiscal years. The Company made this change to align its fiscal year end with other companies within its industry.

**Company**

Opiant is a specialty pharmaceutical company developing pharmacological treatments for addiction and drug overdose. The Company was incorporated in the State of Nevada in June 2005 as Madrona Ventures, Inc. and, in September 2009, changed its name to Lightlake Therapeutics Inc. In January 2016, the Company again changed its name to Opiant Pharmaceuticals, Inc. On November 4, 2016 the Company formed a wholly-owned subsidiary, Opiant Pharmaceuticals, UK Limited.

On October 2, 2017, the Company changed its state of incorporation from the State of Nevada to the State of Delaware pursuant to an Agreement and Plan of Merger, dated October 2, 2017 whereby the Company merged with and into its recently formed, wholly-owned Delaware subsidiary, Opiant Pharmaceuticals, Inc. Pursuant to the Agreement and Plan of Merger, (i) the Company merged with and into its Delaware subsidiary, (ii) the Company's separate corporate existence in Nevada ceased to exist, (iii) the Company's Delaware subsidiary became the surviving corporation, (iv) each share of the Company's common stock, \$0.001 par value per share (the "Common Stock"), outstanding immediately prior to the effective time was converted into one fully-paid and non-assessable share of common stock of Opiant Pharmaceuticals, Inc., a Delaware corporation, \$0.001 par value per share, and (v) the certificate of incorporation and bylaws of the Company's Delaware subsidiary were adopted as its certificate of incorporation and bylaws at the effective time of the merger. The merger and the Agreement and Plan of Merger were approved by the Company's Board of Directors and stockholders representing a majority of the outstanding shares of Common Stock.

The Company conceived, developed and licensed NARCAN® (naloxone hydrochloride) Nasal Spray, a treatment to reverse opioid overdose. This product was approved by the U.S. Food and Drug Administration ("FDA") in November 2015. It is marketed by Adapt Pharma Operations Limited ("Adapt"), an Ireland-based pharmaceutical company. In October 2018, Emergent BioSolutions, Inc. completed its acquisition of Adapt. The Company plans to replicate this relatively low cost business strategy primarily through developing nasal opioid antagonists in the fields of addiction and drug overdose. The Company primarily aims to identify and progress those drug development opportunities that have the potential to file additional New Drug Applications ("NDA") with the FDA within three to five years, with larger market opportunities and with the potential to self-commercialize in the fields of addiction and drug overdose.

The Company's current pipeline of product candidates includes pharmacological treatments for Bulimia Nervosa ("BN"), Alcohol Use Disorder ("AUD"), Opioid Use Disorder ("OUD") and a long acting Opioid Overdose Reversal ("OOR") product. We are also pursuing other treatment opportunities within the addiction space.

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, 2017 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, 2018 and December 31, 2017, results of its operations for the three and nine months ended September 30, 2018 and 2017 and cash flows for the nine months ended September 30, 2018 and 2017. 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 five-month period ended December 31, 2017 included in the Company's Transition Report on Form 10-KT filed with the SEC on March 7, 2018.

#### **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 \$24.8 million and \$8.1 million at September 30, 2018 and December 31, 2017, 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, 2018, 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 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. Diluted weighted average shares outstanding for the three and nine months ended September 30, 2018 and 2017 excludes 3.7 million and 4.1 million shares, underlying stock options and warrants, respectively, because the effects would be anti-dilutive. Accordingly, basic and diluted loss per share is the same.

#### **Recently Issued Accounting Pronouncements**

In May 2014, the FASB issued ASU 2014-09, "*Revenue from Contracts with Customers (Topic 606)*" ("ASU 2014-09"). ASU 2014-09 supersedes the revenue recognition requirements in ASC Topic 605, "Revenue Recognition" and some cost guidance included in ASC Subtopic 605-35, "Revenue Recognition - Construction-Type and Production-Type Contracts." The core principle of ASU 2014-09 is that revenue is recognized when the transfer of goods or services to customers occurs in an amount that reflects the consideration to which the Company expects to be entitled in exchange for those goods or services. ASU 2014-09 requires the disclosure of sufficient information to enable readers of the Company's financial statements to understand the nature, amount, timing and uncertainty of revenue and cash flows arising from customer contracts. ASU 2014-09 also requires disclosure of information regarding significant judgments and changes in judgments, and assets recognized from costs incurred to obtain or fulfill a contract. ASU 2014-09 provides two methods of retrospective application. The first method would require the Company to apply ASU 2014-09 to each prior reporting period presented. The second method would require the Company to retrospectively apply ASU 2014-09 with the cumulative effect recognized at the date of initial application.

There have been four new ASUs issued amending certain aspects of ASU 2014-09, ASU 2016-08, "*Principal versus Agent Considerations (Reporting Revenue Gross Versus Net)*," was issued in March 2016 to clarify certain aspects of the principal versus agent guidance in ASU 2014-09. In addition, ASU 2016-10, "*Identifying Performance Obligations and Licensing*," issued in April 2016, amends other sections of ASU 2014-09 including clarifying guidance related to identifying performance obligations

and licensing implementation. ASU 2016-12, "Revenue from Contracts with Customers - Narrow Scope Improvements and Practical Expedients" provides amendments and practical expedients to the guidance in ASU 2014-09 in the areas of assessing collectability, presentation of sales taxes received from customers, noncash consideration, contract modification and clarification of using the full retrospective approach to adopt ASU 2014-09. Finally, ASU 2016-20, "Technical Corrections and Improvements to Topic 606, Revenue from Contracts with Customers," was issued in December 2016, and provides elections regarding the disclosures required for remaining performance obligations in certain cases and also makes other technical corrections and improvements to the standard. With its evaluation of ASU 2014-09, the Company does not expect a material impact on its consolidated financial statements.

The Company adopted Topic 606 using the modified retrospective method applied to those contracts which were not completed as of January 1, 2018. Results for reporting periods beginning after January 1, 2018 are presented under Topic 606, while prior period amounts are not adjusted and continue to be reported in accordance with our historic accounting under Topic 605. The Company did not have a cumulative impact as of January 1, 2018 due to the adoption of Topic 606 and there was not an impact to its consolidated statements of operations for the three and nine months ended September 30, 2018 as a result of applying Topic 606.

The Company has implemented all new accounting pronouncements that are in effect and that may impact its financial statements and does not believe that there are any other new pronouncements that have been issued that might have a material impact on its financial position or results of operations.

### **Note 3. Prepaid Expenses and Other Current Assets**

As of September 30, 2018, the Company had approximately \$346 thousand recorded as prepaid expenses and other current assets. Of this amount, approximately \$22 thousand is the amount of remaining prepaid expense related to Renaissance Lakewood, LLC ("Renaissance") (see Note 9 - Commitments). Per the terms of its agreement with Renaissance, the Company was obligated to make a \$245 thousand deposit during 2017 to fund the initial costs of the product development work to be performed by Renaissance on behalf of the Company.

As of September 30, 2018, the Company has prepaid insurance in the amount of \$104 thousand.

During the year ended December 31, 2017, the Company purchased approximately \$100 thousand of research and development supplies related to the above referenced product development work being performed by Renaissance. As provided under the agreement with Renaissance, the Company is obligated to pay for all supplies and materials that are needed to complete this product development work. As of September 30, 2018 and December 31, 2017, the amount of remaining prepaid expense was \$76 thousand and \$100 thousand, respectively because it is estimated that these supplies will be used within 12 months of the reporting date.

The remaining balance consists primarily of prepaid expenses such as rent, other insurance, and software licenses.

### **Note 4. Related Party Transactions**

The Company uses office space provided by Dr. Phil Skolnick, the Company's Chief Scientific Officer, free of charge.

### **Note 5. Accounts Receivable**

On December 13, 2016, the Company entered into a Purchase and Sale Agreement (the "SWK Purchase Agreement") with SWK Funding LLC ("SWK"), pursuant to which the Company sold, and SWK purchased, the Company's right to receive, commencing on October 1, 2016, all Royalties (as defined in the SWK Purchase Agreement) arising from the sale by Adapt of NARCAN or any other Product, in an amount up to (i) \$20,625,000 and then the Residual Royalty thereafter or (ii) \$26,250,000 (the "Capped Royalty Amount"), if Adapt has received in excess of \$25,000,000 of cumulative Net Sales for any two consecutive fiscal quarters during the period from October 1, 2016 through September 30, 2017 from the sale of NARCAN (the "Earn Out Milestone"), and then the Residual Royalty thereafter. The Residual Royalty is defined in the SWK Purchase Agreement as follows: (i) if the Earn Out Milestone is paid, then SWK shall receive 10% of all Royalties; provided, however, that if no generic version of NARCAN is commercialized prior to the sixth anniversary of the SWK Closing Date, then SWK shall receive 5% of all Royalties after such date, and (ii) if the Earn Out Milestone is not paid, then SWK shall receive 7.86% of all Royalties; provided, however, that if no generic version of NARCAN is commercialized prior to the sixth anniversary of the SWK Closing Date, then SWK shall receive 3.93% of all Royalties after such date. Under the SWK Purchase Agreement, the Company received an upfront purchase price of \$13,750,000 less \$40,000 of legal fees on the SWK Closing Date, and

received an additional \$3,750,000 from SWK on August 10, 2017 after the Earn Out Milestone was achieved during the first two calendar quarters in 2017.

As of December 31, 2017, the Company determined that the Capped Royalty Amount provided in the SWK Agreement had been met. As a result, 90% of any succeeding milestone payments and royalties due from Adapt will revert to the Company while the remaining 10% will be paid to SWK. As of December 31, 2017, the Company recognized accounts receivable of \$11.7 million, which is equivalent to 90% of the milestone payments and royalties earned during the five months ended December 31, 2017.

On February 28, 2018, the Company was notified that Adapt 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 had 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 the Company and Adapt, as amended (the "License Agreement"), to offset 50%, or \$6,250,000, of the payment paid to such Third Party from the amounts payable by Adapt to the Company (under the License Agreement) and to SWK (under the SWK Purchase Agreement). To the extent that the license agreement which Adapt has entered into with the Third Party requires additional payments that fall under the scope of Section 5.5 of the License Agreement, Adapt may seek from the Company future payment offsets of up to 50% of such amounts that Adapt pays to such Third Party. 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 the consent of the Company. Under the License Agreement, royalty or milestone payments for a calendar quarter are payable from Adapt to the Company, and Adapt may not deduct more than 50% of the amount payable for that calendar quarter. The Company has not been given access to the license agreement between Adapt and the Third Party and Adapt may not give the Company notice of any future offset payments until they are incurred. The Company is not aware of any potential offset payments related to the three months ended September 30, 2018.

On March 1, 2018, the Company received net milestone payments of \$6.1 million. The remaining accounts receivable balance of \$5.6 million, which is associated with the royalty and milestones earned during the twelve months ended December 31, 2017, was applied as an offset to the license fee owed to Adapt, as provided under Section 5.5 of the License Agreement. The \$5.6 million of fees paid to Adapt is reported as license fees in the condensed consolidated statements of operations.

At September 30, 2018, the Company recorded \$4.1 million as a receivable relating to royalty revenue recognized during the three months ended September 30, 2018.

#### **Note 6. Deferred Revenue**

On December 17, 2013, the Company entered into an agreement with an investor, Potomac, and subsequently received additional funding totaling \$250 thousand for use by the Company for any purpose. In exchange for this funding, the Company agreed to provide the investor with a 0.5% interest in the Company's BED treatment product (the "BED Treatment Product") and pay the investor 0.5% of the BED Net Profit in perpetuity (the "2013 0.5% Investor Interest"). "BED Net Profit" is defined as the pre-tax profit generated from the BED Treatment Product after the deduction of all expenses incurred by and payments made by the Company in connection with the BED Treatment Product, including but not limited to an allocation of Company overhead. In the event that the BED Treatment Product was not approved by the FDA by December 17, 2016, the investor would have a 60-day option to exchange its entire 0.5% Investor Interest for 31,250 shares of Common Stock of the Company. On February 17, 2017, the investor's option to receive the shares of Common Stock terminated by its terms, which resulted in the Company beginning to recognize revenue in relation to this agreement in February 2017. The Company estimates that sufficient research and development will be completed by December 31, 2020 to allow the Company to advance the program into final registration studies. Therefore, the Company recognized revenue on a straight-line basis over the expected completion date. The Company recognized approximately \$14.4 thousand and \$21.7 thousand of revenue relating to the agreement for the three month period ended September 30, 2018 and 2017, respectively. During the nine months ended September 30, 2018 and 2017 the Company recognized approximately \$43.4 thousand and \$54.3 thousand of revenue related to the agreement, respectively.

On September 17, 2014, the Company entered into an agreement with an investor, Potomac, and subsequently received funding totaling \$500 thousand for use by the Company for any purpose. In exchange for this funding, the Company agreed to provide the investor with a 1.0% interest in the Company's BED Treatment Product and pay the investor 1.0% of the BED Net Profit generated from the BED Treatment Product in perpetuity (the "1.0% Investor Interest"). "BED Net Profit" is defined as the pre-tax profit generated from the BED Treatment Product after the deduction of all expenses incurred by and payments made by the Company in connection with the BED Treatment Product, including but not limited to an allocation of Company overhead. In the event that the BED Treatment Product was not approved by the FDA by September 17, 2017, the investor would have a 60-day option to exchange its entire 1.0% Investor Interest for 62,500 shares of Common Stock of the Company. On November 15, 2017, the investor's option to receive the shares of Common Stock terminated by its terms, which resulted in the Company beginning to recognize revenue in relation to this agreement in November 2017. The Company estimates that sufficient research and development will be completed by December 31, 2020 to allow the Company to advance the program into final registration studies. Therefore, the Company recognized revenue on a straight-line basis over the expected completion date. During the three and nine months ended September 30, 2018, the Company recognized revenue of approximately \$39.2 thousand and \$117.6 thousand, respectively related to this agreement. The Company recognized no revenue for the three and nine months ended September 30, 2017.

On July 20, 2015, the Company entered into an agreement with an investor, Potomac, and subsequently received funding from an individual investor in the amount of \$250 thousand for use by the Company for any purpose. In exchange for this funding, the Company agreed to provide the investor with a 0.5% interest in the BED Net Profit (the "2015 0.5% Investor Interest") generated from the BED Treatment Product in perpetuity. The investor also has rights with respect to the 2015 0.5% Investor Interest if the BED Treatment Product is sold or the Company is sold. If the product is not introduced to the market and not approved by the FDA or an equivalent body in Europe and not marketed by July 20, 2018, the investor will have a 60-day option to exchange the 2015 0.5% Investor Interest for 25,000 shares of Common Stock of the Company. As of September 30, 2018, the Company recognized \$8.9 thousand of revenue related to this agreement.

On September 22, 2015, the Company received a \$1.6 million commitment from the Foundation which later assigned its interest to Valour in October 2016, from which the Company had the right to make capital calls from the Foundation for the research, development, and any other activities connected to the Company's opioid antagonist treatments for addictions and related disorders that materially rely on certain studies funded by the Foundation's investment, excluding the Opioid Overdose Reversal Treatment Product (the "Certain Studies Products"), 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 2.1333% interest in the Certain Studies Products Net Profit (the "2.1333% Interest"). The "Certain Studies Net Profit" is defined as any pre-tax revenue received by the Company that was derived from the sale of the Certain Studies Products less any and all expenses incurred by and payments made by the Company in connection with the Certain Studies Products, including but not limited to an allocation of Company overhead based on the proportionate time, expenses and resources devoted by the Company to Certain Studies Product-related activities, which allocation shall be determined in good faith by the Company. Valour also has rights with respect to its up to a 2.1333% Interest if the Certain Studies Product is sold or the Company is sold. Additionally, the Company may buy back, in whole or in part, the 2.1333% Interest from Valour within 2.5 years or after 2.5 years of the initial investment at a price of two times or 3.5 times, respectively, the relevant investment amount represented by the interests to be bought back. If an aforementioned treatment is not introduced to the market by September 22, 2018, Valour will have a 60-day option to exchange its 2.1333% Interest for shares of the Common Stock of the Company at an exchange rate of one-tenth of a share for every dollar of its investment. On October 2, 2015, December 23, 2015, and May 28, 2016, the Company made capital calls of approximately \$618 thousand, \$715.5 thousand, and \$266.5 thousand, respectively, from the Foundation in exchange for 0.824%, 0.954% and 0.355333% interests in the aforementioned treatments, respectively. The Company will defer recording revenue until such time as Valour's option expires or Valour's right to exercise the option is eliminated by the achievement of certain milestones. Upon expiration of the exercise option, the deliverables of the arrangement will be reviewed and evaluated under Accounting Standards Codification (ASC) 605. In the event Valour chooses to exchange its 2.1333% Interest, in whole or in part, for shares of Common Stock of the Company, that transaction will be accounted for in a manner similar to a sale of shares of Common Stock for cash. As of September 30, 2018, no revenue had been recognized in relation to this agreement. During September 2018 Valour elected to exchange its interest for shares of Common Stock and accordingly the Company issued 160,000 shares of its Common Stock to Valour.

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 (intranasal nalmefene), a long-lasting opioid antagonist for the treatment of opioid overdose. The grant includes approximately \$2.6 million to be funded for the period ending March 31, 2019, with the balance to be funded over the subsequent two years, 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, 2018 the Company received the first tranche cash draw of \$500 thousand and recognized revenue of \$163 thousand related to this grant.

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. The Contract will provide approximately \$611,000 for the project through September 30, 2019, with the balance to be funded over the following two years, subject to satisfactory project progress, availability of funds and certain other conditions. No revenue was recorded for the period ended September 30, 2018.

The following is a summary of the Company’s deferred revenue activity as of September 30, 2018:

(in thousands)	<b>BED</b>	<b>Other Opioid Treatments</b>	<b>Grants</b>	<b>Total</b>
Balance as of December 31, 2017	\$ 895	\$ 1,600	\$ —	\$ 2,495
Converted to Equity	—	(1,600)	—	(1,600)
Increase to deferred revenue	—	—	500	500
Recognized as revenue	(170)	—	(163)	(333)
Balance as of September 30, 2018	\$ 725	\$ —	\$ 337	\$ 1,062

As of September 30, 2018, the Company had recorded approximately \$660 thousand of its deferred revenue as a current liability because the Company expects to recognize that amount as revenue during the next 12 months. The remaining \$402 thousand was recorded as a long-term liability as of September 30, 2018, as detailed in the following table:

(in thousands)	<b>BED</b>	<b>Other Opioid Treatments</b>	<b>Grants</b>	<b>Total</b>
Current portion	\$ 323	\$ —	\$ 337	\$ 660
Long-term portion	402	—	—	402
Total	\$ 725	\$ —	\$ 337	\$ 1,062

#### Note 7. 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 OORT Product. In exchange for this funding, the Company agreed to provide investors with interest in the OORT Net Profit generated from its OORT Product in perpetuity. As of December 31, 2017, the Company determined an OORT Net Profit as a result of NARCAN sales by Adapt and recorded a royalty payable of \$1.4 million. As of September 30, 2018, the Company has a royalty payable of \$800 thousand to all of the Net Profit Partners.

#### Note 8. Stockholders' Equity

##### Common Stock

During the nine months ended September 30, 2018, the Company issued 1,259,663 shares of Common Stock.

In October 2017, the Company entered into a Controlled Equity Offering<sup>SM</sup> sales agreement (the "Sales Agreement") with Cantor Fitzgerald & Co., as agent ("Cantor Fitzgerald"), pursuant to which the Company may offer and sell, from time to time through Cantor Fitzgerald, shares of Common Stock having an aggregate offering price as set forth in the Sales Agreement and a related prospectus supplement filed with the SEC on March 19, 2018. The Company agreed to pay Cantor Fitzgerald a cash commission of 3.0% of the aggregate gross proceeds from each sale of shares under the Sales Agreement. The Company sold

239,270 shares of Common Stock for gross proceeds of \$4.31 million and received net proceeds of \$4.18 million, after sales commissions, under the Sales Agreement during the nine months ended September 30, 2018. As of September 30, 2018, the Company does not have the ability to use the Controlled Equity Offering.

On September 27, 2018, the Company completed a registered public offering with Cantor Fitzgerald as underwriter and sold 811,764 shares of its Common Stock (including 105,882 shares purchased by Cantor Fitzgerald upon the exercise in full of its right to purchase up to an additional 105,882 shares to cover over-allotments) at a price of \$17.00 per share. The Company received approximately \$13.0 million of net proceeds from the offering after deducting sales commissions.

During the nine months ended September 30, 2018, the Company offset net financing proceeds received with \$0.4 million of current and deferred financing costs. All deferred financing costs were offset against additional paid-in capital as of September 30, 2018. There were no additional deferred financing costs at September 30, 2018.

During the nine months ended September 30, 2018, the Company issued 3,400 shares of its Common Stock as a result of the exercise of stock purchase warrants with an exercise price of \$10.00 per share for total proceeds of \$34,000. During the nine months ended September 30, 2018 the Company issued 38,166 shares of its Common Stock with an aggregate value of \$782 thousand for services and 7,063 shares of its Common Stock for a cashless exercise of stock options. On September 5, 2018, the Company also issued 160,000 shares of Common Stock to Valour Fund, LLC, as a result of Valour's exercise of its option to exchange its interest in certain product revenues for Common Stock of the Company

#### 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 ten years.

As provided in the 2017 Plan, on January 1, 2018 the number of options available for issuance was increased by 4% of the outstanding stock as of December 31, 2017, which represents an increase of 101,431 options.

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, 2017, the Company had granted Pre-2017 Non-Qualified Stock Options to purchase, in the aggregate, 2,980,500 shares of the Company's Common Stock. During the nine months ended September 30, 2018, 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, 2018 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, 2017	2,980,500	\$ 7.33	7.06	\$ 46,606
Exercised	(15,000)	10.00		
Forfeited	—	—		
Outstanding at September 30, 2018	<u>2,965,500</u>	\$ 7.32	6.33	\$ 31,258
Exercisable at September 30, 2018	<u>2,803,399</u>	\$ 7.20	6.19	\$ 29,889

A summary of the status of the Company's non-vested Pre-2017 Non-Qualified Stock Options as of September 30, 2018 and changes during the nine months ended September 30, 2018 is presented below:

	Number of Options	Weighted Average Grant Date Fair Value
Non-vested at December 31, 2017	288,902	\$ 7.87
Vested	(126,801)	\$ 7.93
Non-vested at September 30, 2018	<u>162,101</u>	\$ 7.82

During the nine months ended September 30, 2018 and 2017, the Company recognized approximately \$751 thousand and \$826 thousand, respectively, of non-cash expense related to Pre-2017 Non-Qualified Stock Options granted in prior periods. As of September 30, 2018, there was approximately \$342.3 thousand of unrecognized compensation costs related to non-vested Pre-2017 Non-Qualified Stock Options.

#### The 2017 Plan

On January 4, 2018, the Company granted options to a number of employees to purchase 57,050 shares of the Company's Common Stock at an exercise price of \$24.84 per share, which represents the closing price of the Company's Common Stock on the date of grant. These options were issued under the Company's 2017 Plan and have ten-year terms. The options vest as follows: 25% on the one year anniversary of the grant date and then 1/48<sup>th</sup> of the options shares vest on such date every 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 fair value on the date of grant to be \$1.4 million.

On February 13, 2018, the Company granted an option to an employee to purchase 100,000 shares of the Company's Common Stock at an exercise price of \$24.79 per share, which represents the closing price of the Company's Common Stock on the date of grant. This option was issued under the Company's 2017 Plan and has a ten-year term. The option vests as follows: 25% on the one year anniversary of the grant date and then 1/48<sup>th</sup> of the option shares vest on such date every month thereafter through the fourth anniversary of the grant date. The Company valued this option using the Black-Scholes option pricing model and estimated the fair value on the date of grant to be \$2.5 million.

During the nine month period ended September 30, 2018, the Company granted 31,500 options to employees and certain Directors of the Board at exercise prices from \$14.31 to \$19.83, which represents the closing price of the Company's common stock on the date of the grant. These options were issued under the Company's 2017 Plan and have ten-year terms. The options vest over a period of one to four years. The Company valued these options using the Black-Scholes option pricing model and estimated the fair value of these options granted during the nine months ended September 30, 2018 to be \$476,025.

The assumptions used in the valuation of options granted under the 2017 Plan during the nine months ended September 30, 2018 are as follows:

	<b>For the Nine Months Ended September 30, 2018</b>
Market value of stock on measurement date	\$14.31 to \$24.84
Risk-free interest rate	2.47% to 2.89%
Dividend yield	—
Volatility factor	121% to 324%
Term	5.5 - 10 Years

Stock option activity for options granted under the 2017 Plan during the nine months ended September 30, 2018 is presented in the table below:

	Number of Shares Available	Number of Options Outstanding	Weighted- average Exercise Price	Weighted- average Remaining Contractual Term (years)	Aggregate Intrinsic Value (in Thousands)
Outstanding at July 31, 2017	—	—	—		
Total shares authorized	400,000	—	—		
Granted	(214,000)	214,000	\$ 37.62	9.71	
Exercised	—	—	—		
Forfeited	40,000	(40,000)	\$ 49.93		
Balance at December 31, 2017	226,000	174,000	\$ 34.78	9.71	
Annual additional options authorized	101,431	—	—		
Granted	(188,550)	188,550	\$ 23.49		
Exercised	—	—	—		
Forfeited	27,000	(27,000)	\$ 24.84		
Balance at September 30, 2018	165,881	335,550	\$ 29.24	9.18	\$ 50

A summary of the status of the Company's non-vested options granted under the 2017 Plan as of September 30, 2018 and changes during the nine months ended September 30, 2018 are presented in the following table:

	Number of Shares	Weighted Average Grant Date Fair Value Per Share
Non-vested at December 31, 2017	174,000	\$ 34.78
Granted	188,550	\$ 23.19
Forfeited	(27,000)	\$ 24.84
Balance at September 30, 2018	335,550	\$ 29.07
Vested	(42,500)	35.01
Non-vested at September 30, 2018	293,050	\$ 28.21

During the nine months ended September 30, 2018 and 2017, the Company recognized approximately \$3.9 million and \$362,986 of non-cash expense related to options granted under the 2017 Plan. As of September 30, 2018, there was approximately \$4.5 million of unrecognized compensation costs related to non-vested stock options that were granted under the 2017 Plan.

#### Warrants

During the nine months ended September 30, 2018, the Company did not issue any warrants.

Warrant activity for the nine months ended September 30, 2018 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, 2017	357,010	\$ 9.78	5.57	\$ 4,708
Exercised	(3,400)	\$ 10.00		
Outstanding at September 30, 2018	<u>353,610</u>	\$ 9.78	4.85	\$ 2,857
Exercisable at September 30, 2018	<u>353,610</u>	\$ 9.78	4.85	\$ 2,857

#### **Note 9. Commitments**

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

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

On December 18, 2014, the Company entered into a consulting agreement with Torreyia (the "2014 Agreement"), a financial advisory firm, under which Torreyia agreed to provide financial advisory services with regard to the License Agreement. The 2014 Agreement also requires the Company to pay an additional fee equivalent to 3.75% of all amounts received by the Company in excess of \$3.0 million, in perpetuity.

On April 25, 2016, the Company entered into a consulting agreement with Torreyia, under which Torreyia agreed to provide financial advisory services for financing activities. In exchange for these services, the Company is required to pay a fee on all funding received by the Company as a result of assistance provided by Torreyia. Torreyia's fee would be equal to 5% of gross funding received by the Company up to \$20 million plus 3.5% of any proceeds received in excess of \$20 million.

On September 8, 2017, the Company and Torreyia entered into the Supplemental Engagement Letter to provide financial advisory services with respect to the licensing of the intellectual property rights to develop and commercialize certain products with Adapt. The revised engagement amends total consideration as follows: (i) an aggregate of \$300 thousand in cash payments to be paid by the Company to Torreyia in three equal installments over a 16-month period; (ii) shares of Common Stock, equal to an aggregate value of \$300 thousand, to be issued by the Company to Torreyia in three equal installments over a 16-month period; (iii) if the Earn Out Milestone Payment is paid under the SWK Agreement, approximately \$140.6 thousand, or 3.75% of the Earn Out Milestone Payment (as defined in the SWK Agreement), shall be paid by the Company to Torreyia within 15 days of the date that the Earn Out Milestone (as defined in the SWK Agreement) has been paid to the Company; (iv) once SWK has received the Capped Royalty Amount, if the Earn Out Milestone Payment (as defined in the SWK Agreement) is paid, Torreyia shall receive 3.375% of the Total Consideration (as defined in the 2014 Agreement) received thereafter or 3.5625% of the Total Consideration received thereafter if no generic version of NARCAN is commercialized prior to the sixth anniversary of the Closing Date (as defined in the SWK Agreement) as per the terms of the SWK Agreement; and (v) once SWK has received the Capped Royalty Amount, if the Earn Out Milestone Payment has not been paid, Torreyia shall receive 3.45525% of the Total Consideration received thereafter or 3.602625% of the Total Consideration received thereafter if no generic version of NARCAN is commercialized prior to the sixth anniversary of the Closing Date as per the terms of the SWK Agreement. Payments made by the Company in the form of shares of Common Stock will be a defined number of shares calculated based upon the average closing price of the Common Stock for the ten trading days prior to the relevant date for the payment. On September 23, 2017, the Company issued 3,283 shares of its Common Stock to Torreyia as payment for \$100 thousand of fees owed by the Company to Torreyia. The Company valued these shares at \$40.58 per share, or approximately \$133 thousand in the aggregate, which represents the closing price of the Company's Common Stock on September 22, 2017.

The Company had \$639 thousand recorded as a liability as of December 31, 2017. For the nine months ended September 30, 2018 the Company made payments to Torreyia totaling \$344 thousand representing 3.375% of the milestone payments the Company received from Adapt during for the same period. As of September 30, 2018, the Company had a liability of \$338 thousand owed to Torreyia as a current liability, because it was due and payable to Torreyia within 12 months of September 30, 2018.

During the three months ended September 30, 2018, the Company recorded \$66 thousand of expense related to Torreyia. The Company recorded \$0 thousand and \$412 thousand of fees for the three and nine months ended September 30, 2017.

##### ***Exclusive License and Collaboration Agreement***

On November 19, 2015, the Company issued 14,327 shares of unregistered Common Stock upon the execution of a binding letter of intent to agree to negotiate and enter into an exclusive license agreement and collaboration agreement (“LOI”) with a pharmaceutical company with certain desirable proprietary information. The shares issued in this transaction were valued using the stock price at issuance date and amounted to approximately \$120.3 thousand. Pursuant to the LOI, the Company is obligated to issue up to an additional 92,634 shares of unregistered Common Stock upon the occurrence of various milestones. A total of 3,582 shares had been issued as of July 31, 2016 due to achievement of certain milestones. On November 10, 2016, the Company issued an additional 14,327 shares of unregistered Common Stock pursuant to the LOI. The shares issued in this transaction were valued using the stock price at issuance date and amounted to approximately \$85.1 thousand. On March 16, 2017, the Company issued an additional 10,745 shares of unregistered Common Stock pursuant to the LOI. The Company was obligated to issue these shares upon the one year anniversary of receipt by the Company of a milestone payment from Adapt for the first commercial sale of the Company’s product, NARCAN, in the U.S. The shares issued on March 16, 2017 were valued on the date of issuance using the March 16, 2017 closing price of the Company’s Common Stock of \$7.75 per share, which resulted in an aggregate value of approximately \$83.3 thousand. The Company expensed the entire \$83.3 thousand as non-cash expense during the three months ended March 31, 2017.

As of March 31, 2018, the Company was required to issue an additional 37,866 shares of its unregistered Common Stock pursuant to the LOI. The Company was obligated to issue these shares on the receipt of cumulative royalty payments of \$2 million from Adapt and milestone payments from Adapt with respect to first achieving the milestones of the first \$30 million, \$40 million, \$55 million and \$75 million of Net NARCAN Sales. The shares that were issuable as of March 31, 2018, were valued using the March 29, 2018 closing stock price of the Company's Common Stock of \$19.18 per share, which resulted in an aggregate value of approximately \$726 thousand. On April 19, 2018 the Company issued 37,866 shares of Common Stock. For the nine months ended September 30, 2018 the Company recorded total non-cash expense of \$776 thousand, of which \$726 thousand was recorded to research and development expense and \$50 thousand was recorded to other expense.

#### ***Heroin In-License Vaccine***

In October 2016, the Company in-licensed a heroin vaccine from the Walter Reed Army Institute of Research (“Walter Reed”). In consideration for the license the Company agreed to pay a royalty of 3% of net sales if the Company commercializes the vaccine, or 4% if the vaccine is sublicensed. In addition, the Company agreed to pay a minimum annual royalty of \$10 thousand, as well as fixed payments of up to approximately \$715.7 thousand if all of the specified milestones are met. The Company paid \$60 thousand in cash to Walter Reed, of which \$50 thousand was a non-recurring execution fee and the remaining \$10 thousand was the minimum annual royalty for the period of September 2017 through August 2018. The \$10 thousand minimum annual royalty was recorded as a prepaid expense and is being expensed at the rate of \$833 per month, beginning in September 2017 and ending in August 2018. The Company recorded \$5 thousand in expense during the nine months ended September 30, 2018. There was no expense recorded during the nine months ended September 30, 2017.

#### ***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. For the nine months ended September 30, 2018, the Company recorded \$125 thousand of expense associated with the License Agreement.

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).

#### ***Research and Development Agreement***

On July 14, 2017, Renaissance Lakewood, LLC ("Renaissance") and the Company entered into a Research and Development Agreement (the "Renaissance Agreement"). Under the Renaissance Agreement, Renaissance will perform product development work on a naltrexone multi-dose nasal product for the treatment of alcohol use disorder pursuant to the terms set forth in a proposal agreed upon by the parties. The Company will bear the costs of all development services, including all raw materials and packaging components, in connection with the performance of the development work under the Renaissance Agreement and in accordance with financials agreed upon through the proposal. Renaissance will conduct quality control and testing, including non-stability, stability, in-use, raw material, and packaging component testing as part of the services provided to the Company under the Renaissance Agreement. The Company will own all formulations provided to Renaissance and any formulations developed in connection with the Renaissance Agreement. Renaissance will own all know-how developed in connection with the performance of the services that is not solely related to a product. The Company has the right to seek patent protection on any invention or know-how that relates solely to a product developed under the Renaissance Agreement or any our formulation, excluding general manufacturing or product development know-how of Renaissance. The Renaissance Agreement is effective until terminated by either party in accordance with its terms. The Company or Renaissance may terminate the project under a proposal to the Renaissance Agreement due to unforeseen circumstances in the development. The Renaissance Agreement may be terminated by the Company, with or without cause, upon 45 days' written notice. There are also mutual customary termination provisions relating to uncured breaches of material provisions. The Company had previously purchased approximately \$100 thousand of research and development supplies in relation to the Renaissance Agreement (see Note 3 - Prepaid Expenses and Other Current Assets). During the nine months ended September 30, 2018, the Company recorded expense in the amount of \$396 thousand related to the product development work.

#### ***Separation Agreement***

On September 5, 2017, the Company accepted, effective September 11, 2017 (the "Separation Date"), the resignation of Kevin Pollack as (i) the Company's Chief Financial Officer, Treasurer and Secretary, and (ii) a director of Opiant Pharmaceuticals UK Limited, a wholly owned subsidiary of the Company. On September 5, 2017, the Company and Mr. Pollack entered into a Separation Agreement and General Release (the "Separation Agreement"), with such agreement becoming effective on September 12, 2017 (the "Separation Agreement Effective Date"), which represents the date on which Mr. Pollack's seven-day revocation period expired.

Pursuant to the terms of the Separation Agreement, Mr. Pollack received (i) a payment equal to approximately \$1.13 million relating to certain accrued obligations, payable in a cash lump sum within three business days following the Separation Agreement Effective Date; and (ii) a separation payment equal to approximately \$1.44 million, payable in one or two installments in accordance with the terms set forth therein. Mr. Pollack also retained previously granted options to purchase, in the aggregate, 948,000 shares of Common Stock of the Company, which options are fully vested and exercisable. Except as set forth in the Separation Agreement, all other options held by Mr. Pollack were forfeited. Additionally, for a period of no more than 12 months following the Separation Date, Mr. Pollack will cooperate as an adviser with the Company in connection with matters arising out of Mr. Pollack's service with the Company, in accordance with the terms set forth in the Separation Agreement.

During September 2018, the Company paid \$962 thousand to Mr. Pollack which represents the final amount due pursuant to the terms of the Separation Agreement.

#### ***Facility Leases***

The Company's headquarters through August 31, 2017 were located on the 12<sup>th</sup> Floor of 401 Wilshire Blvd., Santa Monica, CA 90401 and were leased for \$5,056 per month. The lease with Premier Business Centers, LLC ("Premier"), was terminated by the Company effective September 30, 2017. On May 29, 2017, the Company entered into a Sublease (the "Sublease") with Standish Management, LLC to sublease office space located at 201 Santa Monica Boulevard, Suite 500, Santa Monica, CA 90401. Per the terms of the Sublease, the term commenced on August 1, 2017 and will end on August 31, 2018. The monthly rent for August 2017 was \$5,000 and the monthly rent for the duration of the term is \$9,000, plus any related operating expenses and taxes. Commencing September 1, 2017, the Company's headquarters are located at this location.

On April 20, 2017, the Company entered into an Office Service Agreement (the "Office Service Agreement") with Regus to lease office space at 83 Baker Street, London, England, W1U 6AG. Per the terms of the Office Service Agreement, the first month's rent is £2,473 with monthly rental payments of £7,521 thereafter. The Company was required to pay a security deposit of £15,042, which is the equivalent of two months of rent. The Office Service Agreement commenced on May 22, 2017 and effective May 31, 2018 continues on a month-to-month basis with either party being able to terminate the agreement by providing three months' advance written notice of termination.

During the nine months ended September 30, 2018, the Company incurred approximately \$226 thousand of rent expense as compared to approximately \$131 thousand during the nine months ended September 30, 2017.

#### **Note 10. Subsequent Events**

From October 1, 2018 through November 5, 2018 the Company issued 39,113 shares of its Common Stock related to stock option exercises.

On October 25, 2018, Emergent BioSolutions' Adapt subsidiaries and Opiant (collectively, the "Plaintiffs") filed a complaint for patent infringement against Perrigo UK FINCO Limited Partnership ("Perrigo") in the United States District Court for the District of New Jersey arising from Perrigo's Abbreviated New Drug Application ("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 Court. 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 BioSolution Inc. continues to vigorously enforce the intellectual property portfolio related to NARCAN<sup>®</sup> Nasal Spray.

On October 29, 2018 Craig Collard joined the Board of Directors of the Company. Mr. Collard will serve as a Class I director, with a term expiring at the annual meeting of stockholders to be held in 2021. Mr. Collard will serve on the Audit Committee and Nominating and Corporate Governance Committee of the Board. In addition, the Board determined that Mr. Collard qualifies as independent under the rules of the Nasdaq Stock Market.

## 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-KT for the five months ended December 31, 2017 (the "Form 10-KT"). 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-KT Risk Factors below and elsewhere in this Report could cause actual results to differ materially from historical results or anticipated results.*

### Change in Fiscal Year

On December 8, 2017, the Board of Directors of Opiant Pharmaceuticals, Inc. ("we", "our" or the "Company"), acting pursuant to Section 5.1 of our Bylaws, approved a resolution changing our fiscal year-end from July 31 to December 31. We made this change to align our fiscal year end with other companies within our industry.

### Overview

We are a specialty pharmaceutical company developing pharmacological treatments for addiction and drug overdose. We were incorporated in the State of Nevada in June 2005 as Madrona Ventures, Inc. and, in September 2009, we changed our name to Lightlake Therapeutics Inc. In January 2016, we again changed our name to Opiant Pharmaceuticals, Inc. Our fiscal year end is December 31.

On October 2, 2017, we changed our state of incorporation from the State of Nevada to the State of Delaware pursuant to an Agreement and Plan of Merger, dated October 2, 2017, whereby we merged with and into our recently formed, wholly-owned Delaware subsidiary, Opiant Pharmaceuticals, Inc. Pursuant to the Agreement and Plan of Merger, (i) we merged with and into our Delaware subsidiary, (ii) our separate corporate existence in Nevada ceased to exist, (iii) our Delaware subsidiary became the surviving corporation, (iv) each share of our Common Stock, \$0.001 par value per share ("Common Stock"), outstanding immediately prior to the effective time was converted into one fully-paid and non-assessable share of Common Stock of Opiant Pharmaceuticals, Inc., a Delaware corporation, and (v) the certificate of incorporation and bylaws of our Delaware subsidiary were adopted as our certificate of incorporation and bylaws at the effective time of the merger. The merger and the Agreement and Plan of Merger were approved by our Board of Directors and stockholders representing a majority of our outstanding Common Stock.

We developed NARCAN® (naloxone hydrochloride) Nasal Spray, a treatment to reverse opioid overdose. This product was conceived, developed and licensed by Opiant and approved by the U.S. Food and Drug Administration ("FDA") in November 2015. It is commercialized by Adapt Pharma Operations Limited ("Adapt"), an Ireland based pharmaceutical company. In October 2018, Emergent BioSolutions, Inc. completed its acquisition of Adapt. We plan to continue to develop pharmacological treatments for addiction and drug overdose. We primarily aim to identify and progress those drug development opportunities that have the potential to file additional New Drug Applications ("NDA") with the FDA within three to five years, with large market opportunities and with the potential to self-commercialize.

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.

Our current pipeline of product candidates includes pharmacological treatments for Bulimia Nervosa ("BN"), Alcohol Use Disorder ("AUD"), Opioid Use Disorder ("OUD") and a long acting Opioid Overdose Reversal ("OOR") product. We are also pursuing other treatment opportunities.

## 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,		
	2018	2017	Change	2018	2017	Change
<b>Revenues</b>						
Royalty and licensing revenue	\$ 4,185	\$ —	\$ 4,185	\$ 8,887	\$ 3,750	\$ 5,137
Treatment investment revenue	63	22	41	170	54	116
Grant revenue	118	—	118	163	—	163
Total revenue	4,366	22	4,344	9,220	3,804	5,416
<b>Operating expenses</b>						
General and administrative	3,398	2,175	1,223	9,220	6,295	2,925
Research and development	1,908	691	1,217	5,945	2,963	2,982
License fees	—	—	—	5,625	—	5,625
Total operating expenses	5,306	2,866	2,440	20,790	9,258	11,532
Loss from operations	(940)	(2,844)	1,904	(11,570)	(5,454)	(6,116)
<b>Other income (expense)</b>						
Interest income, net	20	7	13	31	29	2
Loss on settlement of liability	—	(33)	33	(50)	(33)	(17)
Gain (Loss) on foreign exchange	2	11	(9)	(36)	41	(77)
Total other income (expense)	22	(15)	37	(55)	37	(92)
Loss before provision for income taxes	(918)	(2,859)	1,941	(11,625)	(5,417)	(6,208)
Provision for income taxes	—	550	(550)	33	550	(517)
Net loss	\$ (918)	\$ (3,409)	\$ 2,491	\$ (11,658)	\$ (5,967)	\$ (5,691)

### Comparison of Three Months ended September 30, 2018 to the Three Months ended September 30, 2017

#### Revenues

We recognized \$4.4 million and \$22 thousand of revenue during the three months ended September 30, 2018 and 2017, respectively. For the three months ended September 30, 2018 we recognized approximately \$4.2 million of revenue from the license agreement between us and Adapt, \$63 thousand from treatment investment revenue from our BED program, and \$118 thousand from our grant with NIDA. For the three months ended September 30, 2017 we recognized \$22 thousand of revenue from treatment investment revenue.

#### General and Administrative Expenses

Our general and administrative expenses were \$3.4 million and \$2.2 million for the three months ended September 30, 2018 and 2017, respectively. The increase of \$1.2 million was primarily due to a \$0.7 million increase associated with stock based compensation expense and a \$0.5 million increase for general corporate expenses, including investor relations during the three months ended September 30, 2018, as compared to the three months ended September 30, 2017.

#### Research and Development Expenses

Our research and development expenses were \$1.9 million and \$0.7 million during the three months ended September 30, 2018 and 2017, respectively. Stock based compensation expense increased by \$0.4 million, development and clinical trial expense increased by \$0.5 million, and personnel and related expense increased by \$0.3 million.

#### *License fees*

There were no license fees during the three months ended September 30, 2018 and September 30, 2017.

#### *Other Income (expense)*

During the three months ended September 30, 2018, other income was \$22 thousand compared to other expense of \$15 thousand for the three months ended September 30, 2017.

### **Comparison of Nine Months ended September 30, 2018 to the Nine Months ended September 30, 2017**

#### *Revenues*

We recognized \$9.2 million and \$3.8 million of revenue for the nine months ended September 30, 2018 and 2017, respectively. During the nine months ended September 30, 2018 we recognized \$8.9 million of revenue from the license agreement between us and Adapt, \$0.2 million from treatment investment revenue from our BED program, and \$163 thousand from our grant with NIDA. During the nine months ended September 30, 2017 we earned \$3.75 million from the sale to SWK of our right to receive royalties arising from the sale, by Adapt, of our NARCAN® Nasal Spray, and \$54 thousand from treatment investment revenue.

#### *General and Administrative Expenses*

Our general and administrative expenses were \$9.2 million and \$6.3 million for the nine months ended September 30, 2018 and September 30, 2017, respectively. The increase of \$2.9 million was primarily due to a \$2.3 million increase associated with stock based compensation expense, a \$0.5 million increase in corporate expenses including investor relations and insurance expense and \$0.1 million in personnel and related expenses.

#### *Research and Development Expenses*

Our research and development expenses were \$5.9 million and \$3.0 million during the nine months ended September 30, 2018 and 2017, respectively. The increase of \$2.9 million was attributed to a \$1.1 million increase in stock based compensation expense, a \$1.1 million increase in personnel and related expense, and a \$0.7 million increase in third party expenses associated with research and development programs.

#### *License fees*

We recorded \$5.6 million associated with license fees incurred during the nine months ended September 30, 2018. The license fees relate to the License Agreement with Adapt. There were no license fees for the nine months ended September 30, 2017.

#### *Other Income (expense)*

During the nine months ended September 30, 2018, other expense was \$55 thousand as compared to other income of \$37 thousand during the nine months ended September 30, 2017. The increase of \$92 thousand in comparable period over period expense was due to a \$17 thousand increase in loss of liability settlement and a \$77 thousand increase in loss on foreign exchange, which was partially offset by a \$2 thousand increase in interest income.

### **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:

(in thousands)	Nine Months Ended September 30,	
	2018	2017
Net cash used in operating activities	\$ (305)	\$ (6,446)
Net cash provided by financing activities	\$ 17,014	\$ —

#### Net cash used in operating activities

During the nine months ended September 30, 2018, net cash used in operating activities was \$0.3 million, which was primarily due to the net loss of \$11.7 million and a decrease in accounts payable and accrued liabilities of \$2.4 million mostly offset by \$4.6 million associated with stock based compensation, \$0.8 million for issuance of stock for services and a \$8.4 million increase in other working capital items.

During the nine months ended September 30, 2017, net cash used in operating activities was \$6.4 million which was primarily due to the net loss of approximately \$6.0 million and a net decrease of \$2.1 million in working capital items which was partially offset by stock based compensation of options and warrants and stock issued for services of \$1.7 million.

#### Net cash provided by financing activities

During the nine months ended September 30, 2018, net cash provided by financing activities was approximately \$17.0 million and was primarily attributable to the sale of Common Stock. There were no financing activities for the nine months ended September 30, 2017.

#### Plan of Operation

During the fiscal year ending December 31, 2018, we plan to broaden our product pipeline and anticipate commencing further trials based on our existing, as well as potential, patents.

In March 2017, we initiated a Phase II clinical trial evaluating our novel nasally-delivered opioid antagonist candidate, OPNT001, as a potential treatment for BN. We also plan to advance OPNT002, for the treatment of AUD, into additional clinical trials, and progress our drug development program for the heroin vaccine, which is currently in pre-clinical testing.

On February 12, 2018, we announced positive data from a Phase I clinical study of our product candidate OPNT003 (intranasal nalmefene) and provided an update on a meeting held February 8, 2018 with the FDA regarding our planned development program. OPNT003 is in development as a long acting opioid antagonist for the treatment of opioid overdose. Based on feedback from the FDA in connection with this meeting, we intend to pursue a 505(b)(2) development path, with a potential to submit an NDA for the drug and intranasal delivery device combination in 2020. 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 full commercial rights to OPNT003 and on April 17, 2018 we were awarded a grant of approximately \$7.4 million from the National Institutes of Health's National Institute on Drug Abuse. The grant provides us with additional resources for the ongoing development of OPNT003 (intranasal nalmefene), a long-lasting opioid antagonist for the treatment of opioid overdose. The grant includes approximately \$2.6 million to be funded for the period ending March 31, 2019, with the balance to be funded over the subsequent two years, subject to available funds and satisfactory progress on the development of OPNT003.

On September 19, 2018, we 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 our development of OPTN003. The contract will provide potential funding up to a maximum of approximately \$4.6 million and cover activities related to a potential NDA submission for OPTN003 with the FDA. The contract will provide approximately \$611,000 for the project through September 30, 2019, with the balance to be funded over the following two years, subject to satisfactory project progress, availability of funds and certain other conditions.

On September 27, 2018 the Company completed a secondary public offering of 811,764 shares of our Common Stock at \$17.00 per share, resulting in net proceeds to the company of approximately \$13.0 million after deducting the underwriters' discounts.

In October 2017, we entered into a Sales Agreement with Cantor Fitzgerald, pursuant to which we may offer and sell, from time to time through Cantor Fitzgerald, shares of our Common Stock having an aggregate offering price as set forth in the Sales Agreement and a related prospectus supplement filed with the SEC on March 19, 2018. We agreed to pay Cantor Fitzgerald a cash commission of 3.0% of the aggregate gross proceeds from each sale of shares under the Sales Agreement. During the nine months ended September 30, 2018, we sold 239,270 shares of our Common Stock and received net proceeds of \$4.2 million after deducting sales commissions.

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.

### **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 restricted stock to consultants for various services and employees for compensation. Cost for these transactions are measured at the fair value of the consideration received or the fair value of the equity instruments issued, whichever is more reliably measurable. The value of our Common Stock is measured at the earlier of: (i) the date at which a firm commitment for performance by the counterparty to earn the equity instruments is reached or (ii) the date at which the counterparty's performance is complete.

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.

Long-lived assets such as property, equipment, and identifiable intangibles are reviewed for impairment whenever facts and circumstances indicate that the carrying value may not be recoverable. When required, impairment losses on assets to be held and used are recognized based on the fair value of the asset. The fair value is determined based on estimates of future cash flows, market value of similar assets, if available, or independent appraisals, if required. If the carrying amount of the long-lived asset is not recoverable from its undiscounted cash flows, an impairment loss is recognized for the difference between the carrying amount and fair value of the asset. When fair values are not available, we estimate fair value using the expected future cash flows discounted at a rate commensurate with the risk associated with the recovery of the assets. We did not recognize any impairment losses for any periods presented.

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 payable, note payable, and due to related parties. 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**

We recognize revenues from nonrefundable, up-front license fees related to collaboration agreements, on a straight-line basis over the contracted or estimated period of performance. The period of performance over which the revenues are recognized is typically the period over which the research and/or development is expected to occur or manufacturing services are expected to be provided. When the period of performance is based on the period over which research and/or development is expected to occur, we are required to make estimates regarding drug development and commercialization timelines. Because of the many risks

and uncertainties associated with the development of drug candidates, these estimates regarding the period of performance may change.

In addition, we recognize revenue when the transfer of goods or services occurs in an amount that reflects the consideration to which the Company expects to be entitled in exchange for those goods or services. If one or more of the deliverables have a standalone value, then the arrangement would be separated into multiple units of accounting. This normally occurs when the research and development services could contractually and feasibly be provided by other vendors or if the customer could perform the remaining research and development itself, and when we have no further obligations and the right has been conveyed. When the deliverables cannot be separated, any initial payment received is treated like an advance payment for the services and recognized over the performance period, as determined based on all of the items in the arrangement. This period is usually the expected research and development period.

We recognize revenue from milestone payments upon achievement of the milestones and when we have no further involvement or obligation to perform services, as related to that specific element of the arrangement, provided the milestone is meaningful, and provided that collectability is reasonably assured and other revenue recognition criteria are met.

We recognize revenue from royalty and milestone revenue when we have fulfilled the terms of the contractual agreement and has no material future obligation, other than inconsequential and perfunctory support, and the amount of the royalty fee is determinable and collection is reasonably assured. With regard to royalty and milestone revenue, the Licensing Agreement with Adapt has terms that stipulates that royalty and milestone payments to be paid based on the achievement of net sales of NARCAN sold by Adapt. Based on historical experience and collectability, the Company recognizes revenue based on estimates of royalties earned during the applicable period and reflects in future revenue any differences between the estimated and actual royalties. These estimates are based upon information reported to the Company by Adapt. The Company adopted ASU 2014-09, "Revenue from Contracts with Customers (Topic 606)" ("ASU 2014-09") in the first quarter of 2018 and applied the modified retrospective approach.

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 recognize revenues from grants and contracts in the period during which the related costs are incurred, provided that the conditions under which the grants and contracts were provided have been met and only perfunctory obligations are outstanding.

After the adoption of ASU 2014-09, the Company determined the new guidance does not change the Company's policy of revenue recognition. The Company's primary source of revenue is through the recognition of royalty and milestone payments from Adapt. Milestone revenue is recognized upon successful accomplishment of certain sales targets set forth in the Adapt Agreement. Royalty revenue is determined based on the agreed upon royalty rate applied to NARCAN sales reported by Adapt.

There are no performance obligations by the Company and the Company is paid accordingly by the royalty report provided by Adapt on quarterly basis. There is no disaggregation of revenue given that the licensing revenue is based on one agreement and the nature and timing of revenue is predicated on the Adapt's delivery of the royalty report. In regards to treatment revenue, the Company received certain investments from investors in return for an interest in its existing treatments. Investors carry an option to exchange investment into shares of the Company. 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, the Company determined its performance obligations under the agreement which typically is to perform R&D services related to treatments and recognizes revenue over a period of time which is usually the expected research and development period. The treatment revenue is disaggregated by program treatments. (See Note 6 to the Condensed Consolidated Financial Statements - Deferred Revenue).

#### Licensing Agreement

On December 15, 2014, we entered into the License Agreement with Adapt. Pursuant to the License Agreement, we provided a global license to develop and commercialize our intranasal naloxone opioid overdose reversal treatment, now known as NARCAN. In exchange for licensing its treatment, we received a nonrefundable, upfront license fee of \$500 thousand in December 2014. We also received a monthly fee for one year for participation in joint development committee calls and the production and submission of an initial development plan. The initial development plan was completed and submitted in May 2015. Management evaluated the deliverables of this arrangement and determined that the licensing deliverable had a standalone value and therefore, the payments were recognized as revenue. In addition, on the SWK Closing Date, in connection with the SWK Agreement, we entered into the Adapt Amendment which amends the terms of the License Agreement relating to the grant of a commercial sublicense outside of the U.S and diligence efforts for commercialization of our Product. Under the terms of the Adapt Amendment, Adapt is required to use commercially reasonable efforts to commercialize the Product in the U.S. In the event that Adapt wishes to grant a commercial sublicense to a third party in the European Union or the United Kingdom, we have agreed to negotiate an additional amendment to the License Agreement to include reduced financial terms with respect to the commercial

sublicense in such territory. Under such terms, we would receive an escalating double-digit percentage of all net revenue received by Adapt from a commercial sublicensee in the European Union or the United Kingdom. Net revenue received by Adapt from a commercial sublicensee in European Union or the United Kingdom would be included in determining sales-based milestones due to us.

We could also receive additional payments upon reaching various sales and regulatory milestones as well as royalty payments for commercial sales of NARCAN generated by Adapt. During the nine months ended September 30, 2018, we received \$10.8 million in payments and recognized royalty revenues of approximately \$8.9 million pursuant to the License Agreement.

We recognize revenue for fees related to participation in the initial development plan and joint development once the fee is received and we have performed the required services for the period.

#### Effect of Inflation

Inflation did not have a significant impact on our net sales, revenues, or income from continuing operations for the nine months ended September 30, 2018 and 2017.

#### **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 audited consolidated financial statements in the Form 10-KT and in the Form 10-KT 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"), we provided such investors with an interest in any pre-tax profits received by us that were derived from the sale of the Opioid Overdose Reversal Treatment Product less any and all expenses incurred by and payments made by us in connection with the Opioid Overdose Reversal Treatment Product, 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 "OORT Net Profit"). A summary of the investor agreements is below, and categorized by investor:

##### Potomac Construction Limited ("Potomac")

On April 16, 2013, we entered into an agreement with Potomac (as clarified by the letter agreement dated October 15, 2014 ("Potomac Agreement No. 1")) for funding from Potomac for the research, development, marketing and commercialization of the Opioid Overdose Reversal Treatment Product in the amount of \$600 thousand, in exchange for a 6.0% interest in the OORT Net Profit in perpetuity.

On May 30, 2013, we entered into a new agreement with Potomac (as clarified by that certain letter agreement dated October 15, 2014 ("Potomac Agreement No. 2")) for additional funding from Potomac in the amount of \$150 thousand for the research, development, marketing and commercialization of the Opioid Overdose Reversal Treatment Product, in exchange for an additional 1.5% interest in the OORT Net Profit in perpetuity.

On September 9, 2014, we entered into a new agreement with Potomac (as clarified by that certain letter agreement dated October 15, 2014, "Potomac Agreement No. 3") for additional funding from Potomac in the amount of \$500 thousand for use by us for any purpose, in exchange for an additional 0.98% interest in the OORT Net Profit in perpetuity. During the year ended July 31, 2016, we recognized \$500 thousand as revenue because Potomac's option to receive shares of our Common Stock pursuant to the agreement terminated by its terms. On April 12, 2017, we entered into an amendment with Potomac whereby Potomac

granted us the right, during the period from April 12, 2017 until September 30, 2019, to buyback all or any portion of the interest at the price of \$500 thousand for the full 0.98% interest (the “Potomac Interest No. 3 Buyback Amount”); provided, that in the event we exercise this right within 3.25 years of the date of the investment, we will pay Potomac 1.8 times the Potomac Interest No. 3 Buyback Amount; provided, further, that in the event we exercise this right after 3.25 years of the date of the investment and no later than September 30, 2019, we will pay Potomac 3.15 times the Potomac Interest No. 3 Buyback Amount.

On October 31, 2014, we entered into a new agreement with Potomac (as clarified by that certain letter agreement dated October 31, 2014 (“Potomac Agreement No. 4”) for additional funding from Potomac in the amount of \$500 thousand for use by us for any purpose, in exchange for an additional 0.98% interest in the OORT Net Profit in perpetuity. On April 12, 2017, we entered into an amendment with Potomac whereby Potomac granted us the right, during the period from April 12, 2017 until November 28, 2019, to buyback all or any portion of the interest at the price of \$500 thousand for the full 0.98% interest (the “Potomac Interest No. 4 Buyback Amount”); provided, that in the event we exercise this right within 3.25 years of the date of the investment, we will pay Potomac 1.8 times the Potomac Interest No. 4 Buyback Amount; provided, further, that in the event we exercise this right after 3.25 years of the date of the investment and on or prior to November 28, 2019, we will pay Potomac 3.15 times the Potomac Interest No. 4 Buyback Amount.

On December 8, 2015, we entered into a new agreement with Potomac (“Potomac Agreement No. 5”) for additional funding in the amount of \$500 thousand for use by us for any purpose, in exchange for an additional 0.75% interest in the OORT Net Profit in perpetuity. During the year ended July 31, 2016, we recognized \$500 thousand as revenue because the investment did not contain any option to exchange the 0.75% interest for shares of our Common Stock. On April 12, 2017, we entered into an amendment with Potomac whereby Potomac granted us the right, during the period from April 12, 2017 until December 17, 2020, to buyback all or any portion of the interest at the price of \$500 thousand for the full 0.75% interest (the “Potomac Interest No. 5 Buyback Amount”); provided, that in the event we exercise this right within 3.25 years of the date of the investment, we will pay Potomac 1.8 times the Potomac Interest No. 5 Buyback Amount; provided, further, that in the event we exercise this right within after 3.25 years of the date of the Investment and on or prior to December 17, 2020, we will pay Potomac 3.15 times the Potomac Interest No. 5 Buyback Amount.

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 OORT 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 OORT Net Profit in perpetuity. On July 28, 2014, we received an initial investment of \$111.5 thousand from the Foundation in exchange for a 0.22294% interest. On August 13, 2014, September 8, 2014, November 13, 2014 and February 17, 2015, we made capital calls of \$422.0 thousand, \$444.5 thousand, \$1.034 million, and \$988.0 thousand, respectively, from the Foundation in exchange for approximately 0.84%, 0.89%, 2.07% and 1.98% interests, respectively, in the OORT Net Profit. The Opioid Overdose Reversal Treatment Product was approved by the FDA on November 18, 2015, and, as a result of such approval occurring prior to July 22, 2016, the option to exchange its interest for shares of our Common Stock at an exchange rate of 10 shares for every dollar of its investment terminated by its terms.

*Binge Eating Disorder (BED)*

We have entered into agreements with Potomac whereby, in exchange for funding for any purpose, we have provided Potomac with an interest in our BED treatment product (the “BED Treatment Product”) and pay Potomac a percentage of the pre-tax profit generated from the BED Treatment Product after the deduction of all expenses incurred by and payments made by us in connection with the BED Treatment Product, including but not limited to an allocation of our overhead (the “BED Net Profit”).

A summary of the investor agreements is below:

On December 17, 2013, we entered into an agreement with Potomac for additional funding in the amount of \$250 thousand for use by us for any purpose. In exchange for this additional funding, we agreed to provide Potomac with a 0.5% interest in the BED Treatment Product and pay Potomac 0.5% of the BED Net Profit in perpetuity. During the year ended July 31, 2017, we

recognized approximately \$40 thousand as revenue because Potomac's option to receive 31,250 shares of our Common Stock in exchange for its entire 2013 0.5% Investor Interest terminated by its terms. During the nine months ended September 30, 2018, we recognized approximately \$43 thousand as treatment investment revenue.

On September 17, 2014, we entered into an agreement with Potomac for additional funding in the amount of \$500 thousand. In exchange for this funding, we agreed to provide Potomac with an additional 1.0% interest in our BED Treatment Product and pay Potomac an additional 1.0% of the BED Net Profit in perpetuity. During the nine months ended September 30, 2018, we recognized approximately \$118 thousand as treatment investment revenue.

On July 20, 2015, we entered into an agreement with Potomac for additional funding in the amount of \$250 thousand. In exchange for this funding, we agreed to provide Potomac with an additional 0.50% interest in our BED Treatment Product and pay Potomac an additional 0.5% of the BED Net Profit in perpetuity. If the BED Treatment Product is not introduced to the market and not approved by the FDA or an equivalent body in Europe and not marketed by July 20, 2018, Potomac will have a 60-day option to exchange its 0.5% interest for 25,000 shares of our Common Stock. The option expired unexercised. During the nine months ended September 30, 2018, we recognized approximately \$9 thousand as treatment investment revenue.

#### *Other Activities*

In September 2015, we received a \$1.6 million commitment from 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, any other activities connected to our opioid antagonist treatments for addictions and related disorders that materially rely on certain studies funded by the Foundation's investment, excluding the Opioid Overdose Reversal Treatment Product (the "Certain Studies Products"), 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 2.13% interest in any pre-tax revenue received by us that was derived from the sale of the Certain Studies Products less any and all expenses incurred by and payments made by us in connection with the Certain Studies Products (the "Certain Studies Products Net Revenue"). Additionally, we may buyback, in whole or in part, the 2.13% interest from Valour within 2.5 years or after 2.5 years of the initial investment at a price of two times or 3.5 times, respectively, the relevant investment amount represented by the interests to be bought back. If an aforementioned treatment is not introduced to the market by September 22, 2018, Valour will have a 60-day option to exchange its 2.13% interest for shares of our Common Stock at an exchange rate of one-tenth of a share for every dollar of its investment. In October 2015, December 2015 and May 2016, we made capital calls of \$618 thousand, \$716 thousand, and \$267 thousand from the Foundation in exchange for 0.824%, 0.954% and 0.355333% interests in the aforementioned treatments, respectively. We will defer recording revenue until such time as Valour's option expires or milestones are achieved that eliminates Valour's right to exercise the option. Upon expiration of the exercise option, the deliverables of the arrangement will be reviewed and evaluated under ASU 2014-09. In the event Valour chooses to exchange its 2.13% interest, in whole or in part, for shares of our Common Stock, that transaction will be accounted for similar to a sale of shares of Common Stock for cash. During September 2018 Valour elected to exchange its interest for stock and accordingly we issued 160,000 shares of our Common Shares to Valour.

On March 13, 2017, we entered into a third amendment (the "Third Miles Amendment") to the Senior Advisor Agreement with Brad Miles, dated January 22, 2013 (the "Initial Miles Agreement"), as previously amended on February 24, 2015 (the "First Miles Amendment") and March 19, 2015 (the "Second Miles Amendment" and, together with the Initial Miles Agreement, the First Miles Amendment and the Third Miles Amendment, the "Miles Agreement"). As provided by the Third Miles Amendment, and in consideration for Mr. Miles' continued service to us as an advisor through December 31, 2017, we: (i) paid Mr. Miles \$107.8 thousand in cash and issued Mr. Miles 1,875 shares of Common Stock; (ii) granted to Mr. Miles the right to receive, subject to adjustment under the Third Miles Amendment, 1.25% of the Net Profit (as defined by the Third Miles Amendment) generated from the Product (as defined by the Third Miles Amendment) from the Effective Date (as defined by the Third Miles Amendment) (which amounts shall be paid quarterly per the terms of the Third Amendment), and, in the event of a Divestiture (as defined by the Third Miles Amendment), 1.25% of the net proceeds of such sale, subject to adjustments and, in the event of sale of the Company, the Fair Market Value (as defined by the Third Miles Amendment) of the Product; (iii) will pay Mr. Miles \$17 thousand per calendar quarter during 2017; and (iv) granted to Mr. Miles a warrant to purchase 45,000 shares of our Common Stock (the "Miles Warrant"). The Miles Warrant, which is fully vested on the date of grant, has an exercise price of \$10.00, an expiration date of three years from the date of grant and may be exercised solely by payment of cash.

On June 1, 2017 (the “Welmers Effective Date”), we entered into an amendment to the Welmers Agreement with Welmers to provide for our right to buyback the 1.5% interest from Welmers. As provided under the Welmers Amendment, from June 1, 2017 until May 27, 2019, Welmers granted us the right to buyback all or any portion of the interest at the price of \$300 thousand for the full 1.5% interest (the “Welmers Interest Buyback Amount”); provided, that in the event we exercise this right within 3.25 years of the date of the investment, we will pay Welmers 1.8 times the Welmers Interest Buyback Amount; provided, further, that in the event we exercise this right after 3.25 years of the date of the Investment and on or prior to May 27, 2019, we will pay Welmers 3.15 times the Welmers Interest Buyback Amount. In consideration for Welmers entering into the Welmers Amendment, we paid Welmers \$30 thousand. Furthermore, we granted Welmers the right to receive 0.375% of the Net Profit (as defined in the Welmers Agreement) generated from DAVINCI (as defined in the Welmers Amendment) (the “DAVINCI Interest”). In the event that we are sold, Welmers will receive 0.375% of the net proceeds of such sale, after the deduction of all expenses and costs related to such sale. Additionally, from the Welmers Effective Date until June 1, 2021, Welmers granted us the right to buyback all or any portion of the DAVINCI Interest at the price of \$56.25 thousand for the full 0.375% DAVINCI Interest (the “Welmers DAVINCI Interest Buyback Amount”); provided, that in the event we exercise this right within 2.5 years of the Welmers Effective Date, we will pay Welmers two times the Welmers DAVINCI Interest Buyback Amount; provided, further, that, in the event we exercise this right after 2.5 years of the Welmers Effective Date and on or prior to June 1, 2021, we will pay Welmers 3.5 times the Welmers DAVINCI Interest Buyback Amount. Furthermore, upon our receipt after the Welmers Effective Date of at least \$3.0 million from (i) SWK pursuant to the SWK Agreement, and/or (ii) Adapt pursuant to the License Agreement, fifty percent of all actual amounts received by us from SWK shall be used in determining the Net Profit.

#### *Royalty Payable*

As summarized above, we agreed to provide investors with interest in the OORT Net Profit generated from our OORT Product in perpetuity. As of December 31, 2017, we determined an OORT Net Profit as a result of NARCAN sales reported by Adapt. As of September 30, 2018, we had a royalty payable of \$0.8 million to all Net Profit Partners. For the nine months ended September 30, 2018 we paid \$1,145 thousand to certain OORT Net Profit investors based on net milestone and royalty payments of \$10.8 million received from Adapt during the nine months ended September 30, 2018.

**Item 3. Quantitative and Qualitative Disclosures About Market Risk.**

The Company is not required to provide the information required by this Item because the 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 nine months ended September 30, 2018 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 Abbreviated New Drug Application (“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 April 9, 2018, the Plaintiffs filed a complaint for patent infringement against Teva in the United States District Court for the District of New Jersey arising from Teva USA’s filing of the Teva ANDA with the FDA with respect to the ‘644 and ‘226 patents.

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

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. § 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 Court. 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 BioSolution Inc. continues to vigorously enforce the intellectual property portfolio related to NARCAN® Nasal Spray.

Except for above and the litigation described under the section Legal Proceedings in the Company’s 10-KT filed on March 13, 2018, which had no update during the three months ended September 30, 2018, the Company is currently not involved in any litigation that the Company believes could have a materially adverse effect on the Company’s financial condition or results of operations. Furthermore, 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-KT, 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-KT with respect to the Risk Factors. Investors should consider the Risk Factors prior to making an investment decision with respect to our stock.

*Some of our programs are partially supported by government grant awards, which may not be available to us in the future.*

We have received funding under grant award programs funded by governmental agencies, such as the National Institutes of Health’s National Institute on Drug Abuse (NIDA). To fund a portion of our future research and development programs, we may apply for additional grant funding from such or similar governmental agencies. However, funding by these

governmental agencies may be significantly reduced or eliminated in the future for a number of reasons. For example, some programs are subject to a yearly appropriations process in Congress. In addition, we may not receive full funding under current or future grants because of budgeting constraints of the agency administering the program or unsatisfactory progress on the study being funded. Therefore, we cannot assure you that we will receive any future grant funding from any government agencies, or, that if received, we will receive the full amount of the particular grant award. Any such reductions could delay the development of our product candidates and the introduction of new products.

***Our product pipeline includes pre-clinical product candidates, such as a vaccine for heroin addiction. We may not be successful in completing the pre-clinical work required for these product candidates, the clinical trials necessary for obtaining market approval, or being able to commercially launch these product candidates.***

In October 2016, we licensed a vaccine to treat heroin addiction from the Walter Reed Army Institute of Research ("WRAIR"). This is an early stage asset and requires significant additional pre-clinical research and development before human testing may be initiated. We plan to work closely with scientists at WRAIR in order to advance the program into the clinic and determine if this vaccine is safe and effective in a patient population. As a result, we may be unable to obtain sufficient pre-clinical data to apply for, or gain, the requisite authorizations to commence human clinical testing on either this asset or other pre-clinical assets we may pursue. However, even if we are successful moving a pre-clinical program into humans, the ultimate success of any development program is uncertain. If we obtain positive clinical data for either this or other pre-clinical assets we may develop, there will be a significant time lag before the asset gains regulatory approval or commercialization may begin, if ever.

***The expiration or loss of patent protection may adversely affect our future revenues and operating earnings.***

We rely on patent, trademark, trade secret and other intellectual property protection in the discovery, development, manufacturing and sale of our products and product candidates. In particular, patent protection is important in the development and eventual commercialization of our products and product candidates. Patents covering our products and product candidates normally provide market exclusivity, which is important in order for our products and product candidates to become profitable. Certain of our patents will expire in the next 17 years. While we are seeking additional patent coverage which may protect the technology underlying these patents, there can be no assurances that such additional patent protection will be granted, or if granted, that these patents will not be infringed upon or otherwise held enforceable. Even if we are successful in obtaining a patent, patents have a limited lifespan. In the United States, the natural expiration of a utility patent typically is generally 20 years after it is filed. Various extensions may be available; however, the life of a patent, and the protection it affords, is limited. Without patent protection, our products and product candidates, we may be open to competition from generic versions of such methods and devices. In July 2018, Teva obtained tentative regulatory approval from the FDA to market a generic version of NARCAN pending the outcome of the current ongoing litigation that we have with Teva on our NARCAN patents.

***We may not succeed in completing the development of our product candidates, commercializing our products, and generating significant revenues.***

Our pipeline includes a treatment for OOR, a treatment for BN, a treatment for AUD, treatments for OUD, and additional treatment applications. Our products have generated limited revenues. Our ability to generate significant revenues and achieve profitability depends on our ability to successfully complete the development of our product candidates, obtain market approval, successfully launch our products and generate significant revenues. On December 15, 2014, we and Adapt entered into the Adapt Agreement, as amended by the Adapt Amendment entered into between the parties on December 13, 2016, that provides Adapt with a global license to develop and commercialize our intranasal naloxone Opioid Overdose Reversal Treatment Product, now known as NARCAN. The loss for any reason of Adapt as a key partner could have a significant and adverse impact on our business. If we are unable to retain Adapt as a partner on commercially acceptable terms, we may not be able to commercialize NARCAN as planned and we may experience delays in or suspension of the marketing of NARCAN.

The future success of our business cannot be determined at this time, and we do not anticipate generating significant revenues from product sales for the foreseeable future. Notwithstanding the foregoing, we expect to generate revenues from NARCAN, for which we are dependent on many factors, including the performance of our licensing partner Adapt and competition in the market. In addition, we have no experience in commercializing on our own and face a number of challenges with respect to commercialization efforts, including, among other challenges:

- having inadequate financial or other resources to complete the development of our product candidates;
- competition in the market from new competitive drugs or generic drugs, including a generic drug that could be marketed by Teva, for which it recently received approval from the FDA;

- the inability to manufacture our products in commercial quantities, at an adequate quality, at an acceptable cost or in collaboration with third parties;
- experiencing delays or unplanned expenditures in product development, clinical testing or manufacturing;
- the inability to establish adequate sales, marketing and distribution channels;
- healthcare professionals and patients may not accept our treatments;
- we may not be aware of possible complications from the continued use of our products since we have limited clinical experience with respect to the actual use of our products;
- technological breakthroughs in reversing opioid overdoses and treating patients with BN, AUD, and OUD may reduce the demand for our products;
- changes in the market for reversing opioid overdoses and treating patients with BN, AUD, and OUD, new alliances between existing market participants and the entrance of new market participants may interfere with our market penetration efforts;
- third-party payors may not agree to reimburse patients for any or all of the purchase price of our products, which may adversely affect patients' willingness to purchase our products;
- uncertainty as to market demand may result in inefficient pricing of our products;
- we may face third party claims of intellectual property infringement;
- we may fail to obtain or maintain regulatory approvals for our products in our markets or may face adverse regulatory or legal actions relating to our products even if regulatory approval is obtained; and
- we are dependent upon the results of clinical studies relating to our products and the products of our competitors. If data from a clinical trial is unfavorable, we would be reluctant to advance the specific product for the indication for which it was being developed.

If we are unable to meet any one or more of these challenges successfully, our ability to effectively commercialize our products could be limited, which in turn could have a material adverse effect on our business, financial condition and results of operations.

***Under our agreement with Adapt Pharma Operations Limited ("Adapt"), Adapt has the right to license third-party intellectual property which may result in a reduction of our potential royalty and milestone payments.***

Under our license agreement, as amended, with Adapt (the "Adapt Agreement"), Adapt may seek to license certain intellectual property held by a third-party that Adapt reasonably determines would be infringed upon through the performance of the Adapt Agreement or that Adapt otherwise determines is necessary or desirable for Adapt to perform its obligations under the Adapt Agreement. Adapt may deduct a material amount, as provided in the Adapt agreement, of any upfront payment, milestones or royalties paid to such third-party from any regulatory milestone payments, sales-based milestone payments, and royalty payments payable to us under the Adapt Agreement. In accordance with the Adapt Agreement, Adapt may enter into such a licensing arrangement and exercise its right to deduct any payments with respect thereto at any time without the consent of us. On February 28, 2018, we were notified that Adapt had entered into a license agreement with a Third Party with regard to one or more patents pursuant to which Adapt invoked its right under Section 5.5 of the Adapt Agreement to offset 50%, or \$6,250,000, of the payment paid to such Third Party from the amounts payable by Adapt to us under the License Agreement and SWK under the SWK Purchase Agreement. Under the Adapt Agreement, we do not have a contractual right to see the Third Party agreement that Adapt has executed. As such, we cannot determine whether additional payments will be required or the magnitude of those payments under the license agreement with the Third Party.

***Our employment agreements with our named executive officers may require us to pay severance benefits to any of those persons who are terminated in connection with a change in control of us which could harm our financial condition or results.***

Certain of our executive officers are parties to employment agreements that contain change in control and severance provisions providing for aggregate cash payments of up to approximately \$3.5 million for severance and other benefits and acceleration of vesting of stock options with a value of approximately \$6.5 million, in the event of a termination of employment in connection with a change of control of us. The accelerated vesting of options could result in dilution to our existing stockholders and harm the market price of our Common Stock. The payment of these severance benefits could harm our financial conditions and results. In addition, these potential severance payments may discourage or prevent third parties from seeking a business combination with us.

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

On April 19, 2018, the Company issued 37,866 shares of its Common Stock pursuant to the LOI dated November 19, 2015 (see Note 9 - Commitments). The Company received no proceeds from the issuance of these shares.

On September 5, 2018, the Company issued 160,000 shares of its Common Stock to the Valour Fund, LLC, as a result of Valour's exercise of its option to change its interest in certain product revenues for Common Stock of the Company (see Note 6 - Deferred Revenue).

Use of Proceeds

On September 27, 2018, the Company completed a registered public offering with Cantor Fitzgerald as underwriter and sold 811,764 shares its Common stock (including 105,882 shares purchased by Cantor Fitzgerald upon the exercise in full of its right to purchase up to an additional 105,882 shares to cover over-allotments) at a price of \$17.00 per share. The Company received approximately \$13.0 million of net proceeds from the offering after deducting sales commissions and offering expenses. No payments for such expenses were made directly or indirectly to any of the Company's officers or directors, to persons owning 10% or more of any class of our equity securities, or to any of the Company's affiliates.

The shares of Common Stock were offered and sold pursuant to the Company's shelf registration statement on Form S-3 (File No. 333-220976), which was declared effective by the Securities and Exchange Commission (the "SEC") on November 7, 2017, as supplemented by a preliminary prospectus supplement, dated September 24, 2018, and a final prospectus supplement, dated September 25, 2018, filed with the SEC pursuant to Rule 424(b) under the Securities Act of 1933, as amended.

There has been no material change in the planned use of proceeds from the offering as described in the final prospectus supplement filed with the SEC on September 26, 2018.

**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="#"><u>10.84+</u></a>	<a href="#"><u>Development and Manufacturing Agreement between the Company and Aesica Queensborough Limited dated September 7, 2018.</u></a>	8-K	001-38193	10.84	9/10/18
<a href="#"><u>10.85+</u></a>	<a href="#"><u>Agreement for Reimbursement of Capital Expenditures and Service Fees between the Company and Aesica Queensborough Limited dated September 7, 2018.</u></a>	8-K	001-38193	10.85	9/10/18
<a href="#"><u>10.86+</u></a>	<a href="#"><u>Contract between the Company and Biomedical Advanced Research and Development Authority dated September 19, 2018.</u></a>	8-K	001-38193	10.86	9/20/18
<a href="#"><u>10.87</u></a>	<a href="#"><u>Director Agreement, effective June 12, 2018 by and between Opiant Pharmaceuticals, Inc. and Richard Daly.</u></a>	8-K	001-38193	10.1	6/12/18
<a href="#"><u>31.1*</u></a>	<a href="#"><u>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.</u></a>				
<a href="#"><u>31.2*</u></a>	<a href="#"><u>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.</u></a>				
<a href="#"><u>32.1**</u></a>	<a href="#"><u>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.</u></a>				
<a href="#"><u>32.2**</u></a>	<a href="#"><u>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.</u></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.				

+ Confidential treatment has been requested with respect to certain portions of this exhibit. Omitted portions have been filed separately with the SEC.

\* 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 7, 2018

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

November 7, 2018

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





**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, 2018, 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 7, 2018

By:           /s/ Dr. Roger Crystal          

Dr. Roger Crystal  
Chief Executive Officer  
(Principal Executive Officer)



