

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 June 30, 2019
or

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

For the transition period from _____ to _____.

Commission File Number: 001-38193

OPIANT PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of incorporation or organization)

46-4744124

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

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

(Address of principal executive offices)

90401

(Zip Code)

(310)-598-5410

(Registrant's telephone number, including area code)

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

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

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

Large Accelerated Filer

Accelerated Filer

Non-Accelerated Filer

Smaller Reporting Company

Emerging Growth Company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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

As of August 5, 2019, the registrant had 4,041,030 shares of common stock outstanding.

Securities registered pursuant to Section 12(b) of the Act:

| Title of each class | Trading symbol | Name of each exchange on which registered |
|---|----------------|---|
| Common stock, par value \$0.001 per share | OPNT | Nasdaq Stock Market LLC |

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)

| | June 30, 2019 | December 31, 2018 |
|--|---------------|-------------------|
| Assets | (unaudited) | |
| Current assets | | |
| Cash and cash equivalents | \$ 23,917 | \$ 24,614 |
| Accounts receivable | 4,345 | 4,489 |
| Prepaid and other current assets | 493 | 267 |
| Total current assets | 28,755 | 29,370 |
| Other assets | | |
| Property and equipment - net of accumulated depreciation | 55 | — |
| Patents and patent applications - net of accumulated amortization | 15 | 16 |
| Total assets | \$ 28,825 | \$ 29,386 |
| Liabilities and Stockholders' Equity | | |
| Liabilities | | |
| Current liabilities | | |
| Accounts payable and accrued expenses | 1,074 | 1,133 |
| License fees | 4,500 | 5,400 |
| Accrued salaries and wages | 879 | 1,084 |
| Royalty payable | 935 | 998 |
| Deferred revenue | 1,374 | 1,212 |
| Total current liabilities | 8,762 | 9,827 |
| Long-term liabilities | | |
| License fees | — | 2,700 |
| Total long-term liabilities | — | 2,700 |
| Total liabilities | \$ 8,762 | \$ 12,527 |
| Stockholders' equity | | |
| Common stock; par value \$0.001; 200,000,000 shares authorized; 4,025,500 and 3,845,361 shares issued and outstanding at June 30, 2019 and December 31, 2018, respectively | 4 | 4 |
| Additional paid-in capital | 94,638 | 91,276 |
| Accumulated deficit | (74,579) | (74,421) |
| Total stockholders' equity | 20,063 | 16,859 |
| Total liabilities and stockholders' equity | \$ 28,825 | \$ 29,386 |

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

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

Opiant Pharmaceuticals, Inc.
Condensed Consolidated Statements of Stockholders Equity
(unaudited)
(In thousands, except share data)

| | Common Stock | | Additional Paid In Capital | Accumulated Deficit | Total |
|---|--------------|--------|----------------------------------|------------------------|---------|
| | Shares | Amount | | | |
| Balance at December 31, 2018 | 3,845,361 | \$ 4 | \$ 91,276 | \$ (74,421) | 16,859 |
| Exercise of stock options | 80,000 | — | 601 | — | 601 |
| Stock based compensation from issuance of stock options | — | — | 1,066 | — | 1,066 |
| Net loss | — | — | — | (1,736) | (1,736) |
| Balance at March 31, 2019 | 3,925,361 | 4 | 92,943 | (76,157) | 16,790 |
| Exercise of stock options | 100,139 | — | 834 | — | 834 |
| Stock based compensation from issuance of stock options | — | — | 861 | — | 861 |
| Net income | — | — | — | 1,578 | 1,578 |
| Balance at June 30, 2019 | 4,025,500 | 4 | 94,638 | (74,579) | 20,063 |
| Balance at December 31, 2017 | 2,535,766 | 2 | 66,223 | (53,225) | 13,000 |
| Exercise of stock options | — | — | — | — | — |
| Exercise of warrants | 2,400 | — | 24 | — | 24 |
| Issuance of common stock, net of issuance costs | 48,634 | 1 | 641 | — | 642 |
| Stock based compensation from issuance of stock options | — | — | 1,609 | — | 1,609 |
| Net loss | — | — | — | (9,343) | (9,343) |
| Balance at March 31, 2018 | 2,586,800 | 3 | 68,497 | (62,568) | 5,932 |
| Exercise of stock options | 7,063 | — | — | — | — |
| Stock issued for services | 38,166 | — | 782 | — | 782 |
| Issuance of common stock, net of issuance costs | 79,616 | — | 1,527 | — | 1,527 |
| Stock based compensation from issuance of stock options | — | — | 1,532 | — | 1,532 |
| Net loss | — | — | — | (1,397) | (1,397) |
| Balance at June 30, 2018 | 2,711,645 | 3 | 72,338 | (63,965) | 8,376 |

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

| | For the Six Months Ended | |
|--|---------------------------------|----------------------|
| | June 30, 2019 | June 30, 2018 |
| Cash flows from operating activities | | |
| Net loss | \$ (158) | \$ (10,740) |
| Adjustments to reconcile net loss to net cash from operating activities: | | |
| Depreciation and amortization | 5 | 2 |
| Stock based compensation from issuance of options | 1,927 | 3,141 |
| Issuance of common stock for services | — | 782 |
| Change in assets and liabilities: | | |
| Accounts receivable | 144 | 8,727 |
| Prepaid and other current assets | (226) | 174 |
| Accounts payable and accrued expenses | (59) | (1,685) |
| Accrued salaries and wages | (205) | (71) |
| Royalty payable | (63) | — |
| Deferred revenue | 162 | 348 |
| License fees | (3,600) | — |
| Net cash provided by (used in) operating activities | (2,073) | 678 |
| Cash flows from investing activities | | |
| Purchase of property and equipment | (59) | — |
| Net cash used in investing activities | (59) | — |
| Cash flows provided by financing activities | | |
| Proceeds from issuance of warrants | — | 24 |
| Proceeds from issuance of common shares | — | 2,532 |
| Finance costs | — | (105) |
| Proceeds from stock option exercises | 1,435 | — |
| Net cash provided by financing activities | 1,435 | 2,451 |
| Net increase (decrease) in cash and cash equivalents | (697) | 3,129 |
| Cash and cash equivalents, beginning of period | 24,614 | 8,116 |
| Cash and cash equivalents, end of period | \$ 23,917 | \$ 11,245 |
| Non-Cash Transactions | | |
| Offset of deferred financing costs against APIC | \$ — | \$ 365 |
| Deferred financing costs in accounts payable | \$ — | \$ 50 |

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

Opiant Pharmaceuticals, Inc.
Notes to Unaudited Condensed Consolidated Financial Statements

Note 1. Description of Business

Company

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

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

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

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

Basis of Presentation

The accompanying condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America (“GAAP”) and the applicable rules and regulations of the SEC for interim financial information. Accordingly, they do not include all of the information and notes required by GAAP for complete financial statements. The condensed consolidated balance sheet at December 31, 2018 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 June 30, 2019 and December 31, 2018, results of operations for the three and six months ended June 30, 2019 and 2018, statement of stockholders equity for the six months ended June 30, 2019 and 2018, and statement of cash flows for the six months ended June 30, 2019 and 2018. The interim results are not necessarily indicative of the results for any future interim period or for the entire year. Certain prior period amounts have been reclassified to conform to current period presentation. These classifications have no effect on the previously reported net loss or loss per share.

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

The accompanying condensed consolidated financial statements and related financial information should be read in conjunction with the audited consolidated financial statements and the related notes thereto for the year ended December 31, 2018 included in the Company's Annual Report on Form 10-K filed with the SEC on March 21, 2019.

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 \$23.9 million and \$24.6 million at June 30, 2019 and December

31, 2018, 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 six months ended June 30, 2019, the Company has not experienced any losses on its deposits of cash and cash equivalents for the periods presented.

Earnings (Loss) Per Share

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

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

| | For the Three Months Ended June 30, | | For the Six Months Ended June 30, | |
|---|-------------------------------------|------------|-----------------------------------|-------------|
| | 2019 | 2018 | 2019 | 2018 |
| Numerator: | | | | |
| Net income (loss) | \$ 1,578 | \$ (1,397) | \$ (158) | \$ (10,740) |
| Denominator: | | | | |
| Denominator for basic income (loss) | | | | |
| per share - weighted-average shares | 3,995,669 | 2,679,910 | 3,952,773 | 2,611,245 |
| Effect of dilutive securities: | | | | |
| Equity incentive plans | 1,132,906 | — | — | — |
| Denominator for diluted income (loss) per share | 5,128,575 | 2,679,910 | 3,952,773 | 2,611,245 |
| Income (loss) per share - Basic | \$ 0.39 | \$ (0.52) | \$ (0.04) | \$ (4.11) |
| Income (loss) per share - Diluted | \$ 0.31 | \$ (0.52) | \$ (0.04) | \$ (4.11) |

The Company excluded the following securities from the calculation of diluted net income (loss) per share as the effect would have been antidilutive:

| | For the Three Months Ended June 30, | | For the Six Months Ended June 30, | |
|-----------------------------------|-------------------------------------|-----------|-----------------------------------|-----------|
| | 2019 | 2018 | 2019 | 2018 |
| Options to purchase common stock | 477,150 | 3,295,050 | 3,157,650 | 3,295,050 |
| Warrants to purchase common stock | — | 354,610 | 353,610 | 354,610 |
| Total | 477,150 | 3,649,660 | 3,511,260 | 3,649,660 |

Accounting Pronouncements

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

Recently Adopted Accounting Pronouncements

In February 2016, the FASB issued ASU 2016-02, "*Leases*" (Topic 842). The new standard requires lessees to recognize leases on-balance sheet and disclose key information about leasing arrangements. The new standard establishes a right-of-use ("ROU") model that requires a lessee to recognize a ROU asset and lease liability on the balance sheet for all leases with a term longer than 12 months. Leases will be classified as finance or operating, with classification affecting the pattern and classification of expense recognition in the income statement. The standard is effective on January 1, 2019, with early adoption permitted. The Company adopted the new standard on January 1, 2019 using the modified retrospective method. As part of the adoption, the Company elected to utilize the package of practical expedients included in this guidance, which permitted the Company to not reassess (i) whether any expired or existing contracts contain leases; (ii) the lease classification for any expired or existing leases; and (iii) the initial direct costs for existing leases. In conjunction with the adoption of the new lease standard, the Company adopted the following policy; an election not to recognize short-term leases (i.e., a lease that is less than 12 months and contains no purchase option) within the unaudited Condensed Consolidated Balance Sheets, with the expense related to these short-term leases recorded within total operating expenses within the unaudited Condensed Consolidated Statements of Operations. As the Company's current operating leases are less than 12 months the Company has concluded there is no impact on its consolidated financial statements.

In June 2018, the FASB issued ASU No. 2018-07, "Compensation-Stock Compensation (Topic 718): Improvements to Non-employee Share-Based Payment Accounting," ("ASU 2018-07"), which expands the scope of Topic 718 to include share-based payment transactions for acquiring goods and services from non-employees. ASU 2018-07 is effective for financial statements issued for annual periods beginning after December 15, 2018, and for the interim periods therein. The Company adopted this ASU effective January 1, 2019 and has concluded it did not have a material impact on its consolidated financial statements.

In 2018, the FASB issued ASU No. 2018-02, *Income Statement-Reporting Comprehensive Income* (Topic 220): Reclassification of Certain Tax Effects from Accumulated Other Comprehensive Income. This new standard permits entities to reclassify to retained earnings the tax effects stranded in accumulated other comprehensive income ("AOCI") as a result of U.S. tax reform. The amendments in this update are effective for all entities for fiscal years beginning after December 15, 2018, and interim periods within those fiscal years. The Company adopted this ASU effective January 1, 2019 and has concluded it did not have a material impact on its consolidated financial statements.

Recent accounting pronouncements pending adoption

In November 2018, the FASB issued ASU No. 2018-18, *Collaborative Arrangements (Topic 808): Clarifying the Interaction between Topic 808 and Topic 606*. This standard resolves the diversity in practice concerning whether certain transactions between collaborative arrangement participants should be accounted for as revenue under Accounting Standards Codification 606, *Revenue from Contracts with Customers* ("Topic 606"). This standard specifies when a participant is a customer in a collaboration, adds unit of account guidance to align with Topic 606 and provides presentation guidance for collaborative arrangements. This guidance is effective for public entities for fiscal years beginning after December 15, 2019, and for interim periods within those fiscal years, with early adoption permitted. The Company is currently evaluating the timing of the adoption and its impact on the Company's consolidated financial statements.

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

Note 3. Prepaid Expenses and Other Current Assets

As of June 30, 2019, the Company had approximately \$0.5 million recorded as prepaid expenses and other current assets. The Company's prepaid amounts are primarily for insurance, advance research and development payments, software licenses, prepaid rent, and other amounts paid that relate to future periods of service. Other current assets are primarily items such as security deposits and other receivables.

Note 4. Accounts Receivable

As of June 30, 2019, the Company had accounts receivable of \$4.3 million, which relates to royalty revenue from the sales of NARCAN®. As of December 31, 2018 the Company had accounts receivable of \$4.5 million, which relates to royalty revenue from the sales of NARCAN®.

Note 5. 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. During June 2019 the Company determined it would not continue development efforts on the BED Treatment Product. The Company recognized approximately \$115.9 thousand and \$29.0 thousand of revenue relating to the agreement for the six months ended June 30, 2019 and 2018, 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. During June 2019 the Company determined it would not continue development efforts on the BED Treatment Product. During the six months ended June 30, 2019 and 2018, the Company recognized revenue of approximately \$313.7 thousand and \$78.4 thousand in each period related to this agreement.

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. During June 2019 the Company determined it would not continue development efforts on the BED Treatment Product. During the six months ended June 30, 2019 and 2018, the Company recognized revenue of approximately \$214.3 thousand and zero, respectively related to this agreement.

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. Of the \$7.4 million, approximately \$5.6 million has been awarded up until March 31, 2020, with the balance to be funded the subsequent year, 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 six months ended June 30, 2019 the Company recognized revenue of \$1.6 million 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 \$0.6 million 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. During the six months ended June 30, 2019 the Company recognized revenue of \$96,823 related to this contract.

As of June 30, 2019 the Company had recorded all of its deferred revenue as a current liability because the Company expects to recognize all such deferred revenue as revenue during the next 12 months.

The following is a summary of the Company's deferred revenue activity as of June 30, 2019:

| (in thousands) | BED | | Grants | | Total |
|---------------------------------|-----|-------|--------|---------|----------|
| Balance as of December 31, 2018 | \$ | 644 | \$ | 568 | \$ 1,212 |
| Additions to deferred revenue | | — | | 2,400 | 2,400 |
| Recognized as revenue | | (644) | | (1,594) | (2,238) |
| Balance as of June 30, 2019 | \$ | — | \$ | 1,374 | \$ 1,374 |

Note 6. License Fee Payable

On February 28, 2018, the Company was notified that Adapt, now a subsidiary of Emergent BioSolutions ("EBS"), had entered into a license agreement with a Third Party (as defined in the License Agreement) with regard to one or more patents pursuant to which Adapt invoked its right under Section 5.5 of the License Agreement, dated as of December 15, 2014, by and between the Company and Adapt, as amended (the "License Agreement"), to offset 50% of certain payments paid to such Third Party from the amounts payable by Adapt to the Company under the License Agreement, and SWK under the SWK Purchase Agreement. On March 1, 2018, the Company received net milestone payments of \$6.1 million, which was net of 50% of a license fee payment Adapt made to the Third Party. The portion of the milestone payment that the Company would have otherwise received was reduced by \$5.6 million.

As provided in Amendment No. 2 to the License Agreement, which the parties entered into on March 18, 2019, Adapt has made and will in the future make payments to the Third Party Licensee (as defined in Amendment No. 2) and will be allowed to reduce the royalties and milestones that the Company would be due under the License Agreement by a maximum of \$9.0 million in relation to such payments. Under the SWK Purchase Agreement, the Company retains 90% of the royalties payable under the License Agreement, with SWK entitled to 10%. The maximum amount payable by the Company is therefore \$8.1 million (90% of \$9 million), of which the Company recorded \$5.4 million as a current liability and \$2.7 million as a long-term liability at December 31, 2018. As provided in Amendment No. 2, Adapt will be allowed to reduce the royalties and milestones that the Company would be due under the License Agreement during the year ending December 31, 2019 by a maximum of \$1.8 million each quarter. As provided in the License Agreement, if Net NARCAN® Sales (as defined in the License Agreement) exceed \$200 million in any calendar year, the Company and SWK will be due a milestone of \$15.0 million. Under Amendment No. 2, if this \$15.0 million milestone becomes payable to the Company and SWK, Adapt may deduct \$2.7 million from the \$13.5 million (90% of \$15.0 million) milestone payable to the Company.

As of June 30, 2019, the Company has recorded \$4.5 million of license fees as a current liability, as it expects the remaining amounts to be paid, by a reduction of the royalties or milestones payable, within twelve months of June 30, 2019.

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 Opioid Overdose Reversal Treatment Product ("OORTP"). In exchange for this funding, the Company agreed to provide investors with interest in the OORTP Net Profit generated from its OORTP in perpetuity. As of December 31, 2018, the Company determined an OORTP Net Profit as a result of NARCAN® sales by Adapt and recorded a royalty payable of \$1.0 million. As of June 30, 2019, the Company has a royalty payable of approximately \$0.9 million.

Note 8. Stockholders' Equity

Common Stock

During the six months ended June 30, 2019, the Company issued 180,139 shares of Common Stock as a result of employee stock option exercises, and received net cash proceeds of approximately \$1.4 million.

Stock Options

On September 8, 2017, the Company held its Annual Meeting of Stockholders (the "Annual Meeting"), at which time the 2017 Long-Term Incentive Plan ("2017 Plan") was approved by stockholder vote. The 2017 Plan allows the Company to grant both incentive stock options ("ISOs") and non-qualified stock options ("NSOs") to purchase a maximum of 400,000 shares of the Company's Common Stock. Under the terms of the 2017 Plan, ISOs may only be granted to Company employees and directors, while NSOs may be granted to employees, directors, advisors, and consultants. The Board has the authority to determine to whom

options will be granted, the number of options, the term, and the exercise price. Options are to be granted at an exercise price not less than fair value for an ISO or an NSO. The vesting period is normally over a period of four years from the vesting date. The contractual term of an option is no longer than ten years.

As provided in the 2017 Plan, on January 1, 2019 the number of options available for issuance was increased by 4% of the outstanding stock as of December 31, 2018, which represents an increase of 153,814 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, 2018, the Company had outstanding Pre-2017 Non-Qualified Stock Options to purchase, in the aggregate, 2,885,500 shares of the Company's Common Stock. During the six months ended June 30, 2019, 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 six months ended June 30, 2019 is presented in the table below:

| | Number of Shares | Weighted-average Exercise Price | Weighted-average Remaining Contractual Term (years) | Aggregate Intrinsic Value |
|----------------------------------|-------------------------|--|--|--------------------------------------|
| Outstanding at December 31, 2018 | 2,885,500 | \$ 7.30 | 6.04 | \$ 20,633,100 |
| Exercised | (180,139) | 7.79 | | |
| Forfeited | (4,861) | 10.00 | | |
| Outstanding at June 30, 2019 | 2,700,500 | \$ 7.27 | 5.49 | \$ 16,195,750 |
| Exercisable at June 30, 2019 | 2,612,436 | \$ 7.19 | 5.49 | \$ 15,865,094 |

A summary of the status of the Company's non-vested Pre-2017 Non-Qualified Stock Options as of June 30, 2019 is presented below:

| | Number of Options | Weighted Average Grant Date Fair Value |
|-----------------------------|--------------------------|---|
| Non-vested at June 30, 2019 | 88,064 | \$ 7.75 |

During the six months ended June 30, 2019 and 2018, the Company recognized approximately \$115 thousand and \$570 thousand, respectively, of non-cash expense related to Pre-2017 Non-Qualified Stock Options granted in prior periods. As of June 30, 2019, there was approximately \$74 thousand of unrecognized compensation costs related to non-vested Pre-2017 Non-Qualified Stock Options.

The 2017 Plan

During 2019, the Company granted options to a number of employees to purchase 117,200 shares of the Company's Common Stock at exercise prices from \$12.75 to \$14.62 per share, which represents the closing price of the Company's Common Stock on the date of the grants. These options were issued under the Company's 2017 Plan and have ten-year terms. The options contain various vesting schedules as follows: one year from date of grant; 25% on the one year anniversary of the grant date and then 1/48th 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 aggregate fair value on the dates of grant to be \$1.4 million.

The assumptions used in the valuation of options granted under the 2017 Plan during the six months ended June 30, 2019 are as follows:

| | For the Six Months Ended June 30, 2019 |
|---|---|
| Market value of stock on measurement date | \$12.75 to \$14.62 |
| Risk-free interest rate | 1.88% to 2.57% |
| Dividend yield | — |
| Volatility factor | 105% to 121% |
| Term | 5.50 to 6.25 Years |

Stock option activity for options granted under the 2017 Plan during the six months ended June 30, 2019 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 |
|--------------------------------------|---------------------------------------|--|---|---|--------------------------------------|
| Balance at December 31, 2018 | 157,881 | 343,550 | \$ 28.97 | 8.95 | \$ 840 |
| Annual additional options authorized | 153,814 | — | — | | |
| Granted | (117,200) | 117,200 | \$ 13.60 | | |
| Exercised | — | — | — | | |
| Forfeited | 3,600 | (3,600) | \$ 17.91 | | |
| Balance at June 30, 2019 | <u>198,095</u> | <u>457,150</u> | \$ 25.12 | 8.75 | \$ 6,250 |

A summary of the status of the Company's non-vested options granted under the 2017 Plan as of June 30, 2019 is presented in the following table:

| | Number of Shares | Weighted Average Grant Date Fair Value Per Share |
|-----------------------------|-------------------------|---|
| Balance at June 30, 2019 | 457,150 | \$ 24.29 |
| Vested | (143,554) | 28.41 |
| Non-vested at June 30, 2019 | <u>313,596</u> | <u>\$ 22.70</u> |

During the six months ended June 30, 2019 and 2018, the Company recognized approximately \$1.9 million and \$2.6 million of non-cash expense related to options granted under the 2017 Plan. As of June 30, 2019, there was approximately \$3.1 million of unrecognized compensation costs related to non-vested stock options that were granted under the 2017 Plan.

Warrants

During the six months ended June 30, 2019, the Company did not issue any warrants.

Warrant activity for the six months ended June 30, 2019 is presented in the table below:

| | Number of Shares | Weighted- average Exercise Price | Weighted- average Remaining Contractual Term (years) | Aggregate Intrinsic Value |
|----------------------------------|-----------------------------|---|---|--------------------------------------|
| Outstanding at December 31, 2018 | 353,610 | \$ 9.78 | 4.36 | \$ 1,226,833 |
| Exercised | — | \$ — | | |
| Outstanding at June 30, 2019 | <u>353,610</u> | \$ 9.78 | 4.11 | \$ 1,226,833 |
| Exercisable at June 30, 2019 | <u>353,610</u> | \$ 9.78 | 4.11 | \$ 1,226,833 |

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:

Torreya Agreement

On December 18, 2014, the Company entered into a consulting agreement with Torreya (the "2014 Agreement"), a financial advisory firm, under which Torreya 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 Torreya, under which Torreya 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 Torreya. Torreya'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 Torreya 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. As provided in the SWK agreement, Torreya currently receives 3.375% of the Total Consideration (as defined in the 2014 Agreement). 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, Torreya will receive 3.5625% of the Total Consideration thereafter.

During the six months ended June 30, 2019 and 2018, the Company recorded \$212 thousand and zero, respectively of expense related to Torreya, and has recorded a liability of \$146 thousand as of June 30, 2019 related to Torreya.

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, of which a total of 66,520 shares with a value of approximately \$0.9 million have been issued through December 31, 2018. No shares were required to be issued during the six months ended June 30, 2019.

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 six months ended June 30, 2019, and 2018 the Company recorded \$0.2 million and zero 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. During the six months ended June 30, 2019 and 2018, the Company recorded expense in the amount of \$0.9 million and \$0.2 million related to the product development work.

Facility Leases

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 original term commenced on August 1, 2017 and ended on August 31, 2018, after which the lease term was month-to-month. The Company provided notice to terminate the lease effective July 31, 2019.

On May 7, 2019, the Company entered into a Sub-Sublease with PERL Mortgage, Inc. to sublease office space located at 233 Wilshire Blvd., Suite 280, Santa Monica, CA 90401, and this is the Company's headquarters. The lease commenced on July 1, 2019 and expires August 31, 2021.

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. The Company provided notice to terminate the lease effective July 31, 2019.

During the six months ended June 30, 2019 and 2018, the Company incurred approximately \$235 thousand and \$144 thousand of rent expense, respectively.

Note 10. Subsequent Events

From July 1, 2019 through August 6, 2019, the Company issued 25,530 shares of its Common Stock related to stock option exercises.

On July 11, 2019, the Company entered into an Office Service Agreement with Regus to lease office space at One Kingdom Street, London, England, W2 6BD. The lease commences on August 1, 2019 and ends May 31, 2021 with monthly rent of 20,000 GBP.

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

The interim consolidated financial statements included in this Quarterly Report on Form 10-Q (this "Report") and this Management’s Discussion and Analysis of Financial Condition and Results of Operations should be read in conjunction with the financial statements and notes thereto in this Report, and the related Management’s Discussion and Analysis of Financial Condition and Results of Operations, contained in the Company’s Form 10-K for the year ended December 31, 2018 (the "Form 10-K"). In addition to historical information, this discussion and analysis contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). These forward-looking statements are subject to risks and uncertainties, including those set forth in Part II - Other Information, Item 1A and in the Form 10-K. Risk Factors below and elsewhere in this Report could cause actual results to differ materially from historical results or anticipated results.

Overview

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

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

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

Our current pipeline includes medicines in development for Opioid Overdose Reversal ("OOR"), Alcohol Use Disorder ("AUD"), Opioid Use Disorder ("OUD"), and Acute Cannabinoid Overdose ("ACO"). We are also pursuing other treatment opportunities within the addiction and drug overdose field.

Results of Operations

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

| (in thousands) | For the Three Months Ended June 30, | | | For the Six Months Ended June 30, | | |
|-----------------------------------|-------------------------------------|------------|----------|-----------------------------------|-------------|-----------|
| | 2019 | 2018 | Change | 2019 | 2018 | Change |
| Revenues | | | | | | |
| Royalty and licensing revenue | \$ 6,129 | \$ 3,053 | \$ 3,076 | \$ 9,875 | \$ 4,702 | \$ 5,173 |
| Treatment investment revenue | 564 | 53 | 511 | 644 | 107 | 537 |
| Grant and contract revenue | 82 | 44 | 38 | 1,691 | 44 | 1,647 |
| Total revenue | 6,775 | 3,150 | 3,625 | 12,210 | 4,853 | 7,357 |
| Operating expenses | | | | | | |
| General and administrative | 3,731 | 2,857 | (874) | 7,427 | 5,822 | 1,605 |
| Research and development | 1,634 | 1,616 | (18) | 5,201 | 4,036 | 1,165 |
| License fees | — | — | — | — | 5,625 | (5,625) |
| Total operating expenses | 5,365 | 4,473 | (892) | 12,628 | 15,483 | (2,855) |
| Income (loss) from operations | 1,410 | (1,323) | 2,733 | (418) | (10,630) | 10,212 |
| Other income (expense) | | | | | | |
| Interest income | 122 | 6 | 116 | 244 | 11 | 233 |
| Loss on settlement of liability | — | (50) | 50 | — | (50) | 50 |
| Loss on foreign exchange | (11) | (30) | 19 | (41) | (38) | (3) |
| Total other income (expense) | 111 | (74) | 185 | 203 | (77) | 280 |
| Income (loss) before income taxes | 1,521 | (1,397) | 2,918 | (215) | (10,707) | 10,492 |
| Income tax (expense) benefit | 57 | — | (57) | 57 | (33) | 90 |
| Net income (loss) | \$ 1,578 | \$ (1,397) | \$ 2,975 | \$ (158) | \$ (10,740) | \$ 10,582 |

Comparison of Three Months ended June 30, 2019 to the Three Months ended June 30, 2018

Revenues

We recognized \$6.8 million and \$3.2 million of revenue during the three months ended June 30, 2019 and 2018, respectively. For the three months ended June 30, 2019 we recognized approximately \$6.1 million of revenue from the license agreement between us and Adapt, \$0.1 million from grant and contract revenue, and \$0.6 million from treatment investment revenue. For the three months ended June 30, 2018, we recognized \$3.1 million of revenue from the license agreement between us and Adapt, \$44 thousand from grant and contract revenue, and \$53 thousand of revenue from treatment investment revenue.

General and Administrative Expenses

Our general and administrative expenses were \$3.7 million and \$2.9 million for the three months ended June 30, 2019 and 2018, respectively. The increase of \$0.8 million was primarily due to a \$1.0 million increase associated with royalty and related expense, a \$0.1 million increase in legal, accounting and professional fees, partially offset by a \$0.3 million decrease in stock based compensation expense.

Research and Development Expenses

Our research and development expenses were \$1.6 million and \$1.6 million during the three months ended June 30, 2019 and 2018, respectively. Stock based compensation expenses decreased by approximately \$0.4 million which was offset by increased expenses of approximately \$0.4 million primarily associated with external development expense.

License fees

There were no license fees recorded for the three months ended June 30, 2019 and 2018.

Other Income (expense)

During the three months ended June 30, 2019, other income was \$111 thousand compared to other expense of \$74 thousand for the three months ended June 30, 2018.

Comparison of Six Months ended June 30, 2019 to the Six Months ended June 30, 2018

Revenues

We recognized \$12.2 million and \$4.9 million of revenue during the six months ended June 30, 2019 and 2018, respectively. For the six months ended June 30, 2019 we recognized approximately \$9.9 million of revenue from the license agreement between us and Adapt, \$1.7 million from grant and contract revenue, and \$0.6 million from treatment investment revenue. For the six months ended June 30, 2018, we recognized \$4.7 million of revenue from the license agreement between us and Adapt, \$44 thousand from grant and contract revenue, and \$107 thousand of revenue from treatment investment revenue.

General and Administrative Expenses

Our general and administrative expenses were \$7.4 million and \$5.8 million for the six months ended June 30, 2019 and 2018, respectively. The increase of \$1.6 million was primarily due to a \$1.5 million increase in royalty and related expense, a \$0.6 million increase in legal, accounting, and professional fees, a \$0.3 million increase in personnel and related expense including recruiting, partially offset by a \$0.8 million decrease in stock based compensation expense for the six months ended June 30, 2019, compared to the six months ended June 30, 2018.

Research and Development Expenses

Our research and development expenses were \$5.2 million and \$4.0 million during the six months ended June 30, 2019 and 2018, respectively. The increase of \$1.2 million resulted from an increase in third party clinical trial and development expense of \$1.4 million, an increase in personnel and related expense of \$0.2 million, partially offset by a \$0.4 million decrease in stock based compensation expense.

License fees

There were no license fees recorded for the six months ended June 30, 2019. We recorded \$5.6 million in license fees during the six months ended June 30, 2018 related to our License Agreement with Adapt.

Other Income (expense)

During the six months ended June 30, 2019, other income was \$203 thousand compared to other expense of \$77 thousand for the six months ended June 30, 2018.

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) | Six Months Ended June 30, | |
|---|----------------------------------|-------------|
| | 2019 | 2018 |
| Net cash (used in) provided by operating activities | \$ (2,073) | \$ 678 |
| Net cash provided by financing activities | \$ 1,435 | \$ 2,451 |

Net cash used in operating activities

During the six months ended June 30, 2019, net cash used in operating activities was \$2.1 million, which was primarily due to the net loss of \$0.2 million and a \$3.8 million change in other assets and liabilities, partially offset by approximately \$1.9 million associated with stock based compensation expense.

During the six months ended June 30, 2018, net cash provided by operating activities was \$0.7 million, which was primarily due to a \$8.7 million reduction of accounts receivable, \$3.1 million associated with stock based compensation, and \$0.8 million for issuance of stock for services, offset by the net loss of \$10.7 million and a \$1.2 million decrease in other assets and liabilities.

Net cash provided by financing activities

During the six months ended June 30, 2019, net cash provided by financing activities was approximately \$1.4 million primarily attributable to proceeds received from stock option exercises.

During the six months ended June 30, 2018, net cash provided by financing activities was \$2.5 million, primarily attributed to the sale of Common Stock.

Plan of Operation

During the fiscal year ending December 31, 2019, we plan to broaden our product pipeline and anticipate commencing further trials based on our existing, as well as potential, patents.

On February 12, 2018, we announced positive data from a Phase 1 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 the potential to submit a 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 expect to receive approximately \$7.4 million from the National Institute of Health ("NIH") and approximately \$4.6 million from the Biological Advance Research and Development Agency ("BARDA") from 2018 through 2021, subject to availability of funds and satisfactory progress on OPNT003, to fund development of this project through NDA submission.

As of June 30, 2019 we had cash and cash equivalents of \$23.9 million. We believe that we have sufficient capital resources to sustain operations through at least the next 12 months from the date of the filing of this Report.

Critical Accounting Policies and Estimates

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

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

We issue options and warrants to consultants, directors, and officers as compensation for services. These options and warrants are valued using the Black-Scholes option pricing model, which focuses on the current stock price and the volatility of moves to predict the likelihood of future stock moves. This method of valuation is typically used to accurately price stock options and warrants based on the price of the underlying stock.

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

Revenue Recognition

In May 2014, the FASB issued an accounting standard update ("ASU"), 2014-09, Revenue from Contracts with Customers (Topic 606). This ASU amends the existing accounting standards for revenue recognition and is based on the principle that revenue should be recognized to depict the transfer of goods or services to a customer at an amount that reflects the consideration a company expects to receive in exchange for those goods or services. On January 1, 2018, we adopted the new Accounting Standards Codification ("ASC") 606, Revenue from Contracts with Customers using the modified retrospective method, and we determined the new guidance does not change our policy of revenue recognition. Our primary source of revenue is through the recognition of royalty and milestone payments from 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 us and we recognize revenue according to the royalty report provided to us by Adapt on quarterly basis.

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

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

Licensing Agreement

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

Effect of Inflation

Inflation did not have a significant impact on our net sales, revenues, or income from continuing operations for the three and six months ended June 30, 2019 and 2018.

Off-Balance Sheet Arrangements

We have no off-balance sheet arrangements.

Recent Accounting Pronouncements

We reviewed accounting pronouncements and interpretations thereof that have effectiveness dates during the periods reported and in future periods. We have carefully considered the new pronouncements that alter previous generally accepted accounting principles and do not believe that any new or modified principles will have a material impact on our reported financial position or operations in the near term. The applicability of any standard is subject to the formal review of our financial management and certain standards are under consideration. Those standards have been addressed in the notes to the condensed consolidated financial statements contained herein, and in the notes to the audited consolidated financial statements in the Annual Form 10-K and in the Form 10-K itself.

Net Profit Interests

NARCAN®

We have entered into agreements with certain investors whereby, in exchange for funding for the research, development, marketing and commercialization of a product relating to our treatment to reverse opioid overdoses (the "Opioid Overdose Reversal Treatment Product or OORTP), we provided such investors with an interest in any pre-tax profits received

by us that were derived from the sale of the OORTP less any and all expenses incurred by and payments made by us in connection with the OORTP, including but not limited to an allocation of our overhead devoted by us to product-related activities, which allocation shall be determined in good faith by us (the "OORTP Net Profit").

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

Potomac Construction Limited ("Potomac")

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 OORTP 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 OORTP, in exchange for an additional 1.5% interest in the OORTP 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 OORTP 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 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 OORTP 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 OORTP 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 OORTP Net Profit in perpetuity. On June 1, 2017, we entered into an amendment with Welmers whereby Welmers granted us certain buyback rights that have expired as of December 31, 2018.

Valour Fund, LLC ("Valour")

On July 22, 2014, we received a \$3.0 million commitment from a foundation (the "Foundation") which later assigned its interest to Valour, from which we had the right to make capital calls from the Foundation for the research, development, marketing, commercialization and any other activities connected to the Opioid Overdose Reversal Treatment Product, certain

operating expenses and any other purpose consistent with the goals of the Foundation. In exchange for funds invested by the Foundation, Valour currently owns a 6.0% interest in the OORTP Net Profit in perpetuity. 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 0.844687%, 0.888906%, 2.067228% and 1.976085% interests, respectively, in the OORTP Net Profit. The OORTP 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.

LYL Holdings Inc. ("LYL")

On June 1, 2017 (the "LYL Effective Date"), we entered into an amendment with LYL (the "LYL Amendment") to the Amended and Restated Consulting Agreement, dated October 25, 2016 and effective as of July 17, 2013 (the "LYL Agreement"). Pursuant to the LYL Amendment, LYL granted us certain buyback provisions that have expired as of December 31, 2018.

Binge Eating Disorder (BED)

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

Other Activities

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% OORTP Net Profit 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.

Royalty Payable

We entered into various agreements and subsequently received funding from investors for use by us for any purpose. In exchange for this funding, we agreed to provide investors with interest in the OORTP Net Profit generated from the OORTP in perpetuity. We recorded a royalty payable of \$0.9 million at June 30, 2019 and \$1.0 million at December 31, 2018, related to the various OORTP agreements as a result of net NARCAN® sales by Adapt/EBS.

License Fee Payable

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

As provided in Amendment No. 2 to the License Agreement, which the parties entered into on March 18, 2019, EBS made certain payments in October of 2018 to the Third Party Licensee (as defined in Amendment No. 2) and will be allowed to reduce the royalties and milestones that we would be due under the License Agreement by a maximum of \$9.0 million. Under the SWK Purchase Agreement, we retain 90% of the royalties payable under the License Agreement, with SWK entitled to 10%. The maximum amount payable by us is therefore \$8.1 million (90% of \$9 million), of which we have recorded \$6.3 million as a current liability at June 30, 2019.

As provided in Amendment No. 2, EBS will be allowed to reduce the royalties and milestones we would be due under the License Agreement during the year ending December 31, 2019 by a maximum of \$2.0 million each quarter. As provided in the License Agreement, if net NARCAN® Sales (as defined in the License Agreement) exceed \$200 million in any calendar year, we and SWK will be due a milestone payment of \$15.0 million. Under Amendment No. 2, if this \$15.0 million milestone becomes payable to us and SWK, EBS may deduct \$2.5 million from the \$13.5 million (90% of \$15.0 million) milestone payable to us.

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 three months ended June 30, 2019 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II— OTHER INFORMATION

Item 1. Legal Proceedings.

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

On September 14, 2018, the Company and Adapt Pharma, Inc. (“Adapt”) received notice from Perrigo UK FINCO Limited Partnership (“Perrigo”), pursuant to 21 U.S.C. § 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.

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

On or about February 19, 2019, Emergent BioSolutions’ Adapt subsidiaries and Opiant received notice from a company called Nalox-1 Pharmaceuticals LLC (“Nalox-1”) that it had filed fifteen petitions for *inter partes* review of U.S. Patent Nos. 9,211,253, 9,468,747, 9,561,177, 9,629,965, and 9,775,838 (IPR Nos. 2019-00685, 2019-00686, 2019-00687, 2019-00688, 2019-00689, 2019-00690, 2019-00691, 2019-00692, 2019-00693, 2019-00694, 2019-00695, 2019-00696, 2019-00697, 2019-00698, 2019-00699) with the Patent Trial and Appeal Board of the United States Patent and Trademark Office. Nalox-1’s petitions assert that each of the foregoing patents are invalid as obvious in view of prior art. An initial response to the petitions is due three months from the filing date of the petitions. Opiant continues to be confident in the intellectual property portfolio related to NARCAN® Nasal Spray.

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

Item 1A. Risk Factors.

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

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

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

Two separate companies, (i) Teva Pharmaceuticals Industries Ltd. and its wholly owned subsidiary Teva Pharmaceuticals USA, Inc. (collectively “Teva”), and (ii) Perrigo UK FINCO Limited Partnership sent us and our partner Adapt Pharma Operations Limited (“Adapt”), notices that they had filed ANDAs with the FDA seeking approval to market a generic version of NARCAN®, and we, along with Adapt, filed patent lawsuits against each of these companies in the District Court for New Jersey. We cannot predict the timing or outcome of this or the other ANDA litigation proceedings against the ANDA filers. For more information about these litigation matters, see Part I, Item 3: Legal Proceedings, in our Form 10-K.

On April 19, 2019, the FDA announced approval of Teva’s ANDA for a generic version of NARCAN®. The timing of any potential commercial launch of a generic version of NARCAN® is uncertain. However, after any introduction of a generic competitor, a significant percentage of the prescriptions written for NARCAN® may be filled with the generic version, resulting in a loss in sales of NARCAN®. Generic competition often also results in decreases in the prices at which branded products can be sold, particularly when there is more than one generic available in the marketplace. In addition, certain U.S. state laws allow for, and in some instances in the absence of specific instructions from the prescribing physician mandate, the dispensing of generic products rather than branded products where a generic version is available. We cannot predict whether we will be able to maintain the validity of any of our patents or will otherwise obtain a judicial determination that a generic naloxone hydrochloride product infringes any of our patents. However, we expect that the launch of a generic version of NARCAN®, or the approval and launch of other products that compete with NARCAN®, would have a material adverse effect on our licensing partner’s sales of NARCAN® and as a result have a material adverse effect on the royalties that we would receive from such sales of NARCAN®, on our business, financial condition, results of operations and growth prospects.

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

None.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

None.

Item 6. Exhibits.

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

EXHIBIT INDEX

| Exhibit Number | Description of Document | Incorporation by Reference | | | |
|-------------------------------|--|-----------------------------------|-----------------|----------------|--------------------|
| | | Form | File No. | Exhibit | Filing Date |
| <u>31.1*</u> | <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> | | | | |
| <u>31.2*</u> | <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> | | | | |
| <u>32.1**</u> | <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> | | | | |
| <u>32.2**</u> | <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> | | | | |
| 101.INS* | XBRL Instance Document. | | | | |
| 101.SCH* | XBRL Taxonomy Extension Schema Document. | | | | |
| 101.CAL* | XBRL Taxonomy Extension Calculation Linkbase Document. | | | | |
| 101.DEF* | XBRL Taxonomy Extension Definition Linkbase Document. | | | | |
| 101.LAB* | XBRL Taxonomy Extension Label Linkbase Document. | | | | |
| 101.PRE* | XBRL Taxonomy Extension Presentation Linkbase Document. | | | | |

* Filed herewith

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

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

OPIANT PHARMACEUTICALS, INC.

August 8, 2019

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

August 8, 2019

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

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

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

1. I have reviewed this Quarterly Report on Form 10-Q of Opiant Pharmaceuticals, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 8, 2019

By: /s/ Dr. Roger Crystal

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

