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

FORM 10-K

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

For the fiscal year ended December 31, 2019

OR

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

Commission file number: 001-38193

OPIANT PHARMACEUTICALS, INC.

(Exact name of Registrant as specified in its charter)

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

Registrant's telephone number, including area code:

(310)-598-5410

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

Title of each class	Name of exchange on which registered
Common Stock, par value $0.001 per share	Nasdaq Stock Market LLC

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☑

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☑

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 if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of this chapter) is not contained herein, and will not be contained herein, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth 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 Act). Yes ☐ No ☑

As of June 28, 2019, the aggregate market value of the voting and non-voting common stock held by non-affiliates of the registrant, computed by reference to the closing price of the shares of common stock on the NASDAQ Capital Market was approximately $50,427,380.

As of March 2, 2020, the registrant had 4,238,595 shares of common stock issued and outstanding.

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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K (this "Report") contains "forward-looking statements" within the meaning of the 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. These forward-looking statements are found at various places throughout this Report and include information concerning: possible or assumed future results of our operations; business strategies; future cash flows; financing plans; plans and objectives of management; any other statements regarding future operations, future cash needs, business plans and future financial results; and any other statements that are not historical facts.

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.

From time to time, forward-looking statements also are included in our other periodic reports on Forms 10-Q 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.

For discussion of factors that we believe could cause our actual results to differ materially from expected and historical results see "Item 1A — Risk Factors" below.

PART I

Item 1. Business.

Our Company

Opiant Pharmaceuticals, Inc. (“we”, “our” or the “Company”) is a specialty pharmaceutical company developing medicines for addictions and drug overdose. We were incorporated in the State of Nevada in June 2005 as Madrona Ventures, Inc. and, in September 2009, we changed our name to Lightlake Therapeutics Inc. In January 2016, we again changed our name to Opiant Pharmaceuticals, Inc.

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

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 was originally marketed by Adapt. In October 2018, Emergent BioSolutions, Inc. ("EBS") completed its acquisition of Adapt.

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.

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.

Principal Products or Services and Markets

Opioid Overdose Reversal

Naloxone is a medicine that can reverse opioid overdose and until November 2015, was only approved by the FDA as an injection. Administered as a nasal spray, naloxone can be used more widely to prevent opioid overdose deaths.

There is a large and growing addressable market for opioid overdose reversal agents driven by sales into first responder institutions, and patients via pharmacies. The current institutional market is substantial, to ensure an opioid overdose reversal agent is available for all first responders, including fire departments, emergency medical services, federal law enforcement and local law enforcement. The co-prescribing of opioid overdose reversal agents alongside prescription opioids, has also driven growth. It is estimated that only 5 percent of at risk patients have a naloxone prescription. Currently there are only nine state that have some form of mandatory co-prescription legislation in place.

We believe that U.S. sales of opioid reversal agents could exceed $1.0 billion by 2022, with approximately fifty percent from institutional sales and fifty percent from retail sales, which includes primarily pharmacy sales and co-prescription.

In December 2014, we entered into a license agreement with Adapt (the “Adapt Agreement”). The Adapt Agreement has no set duration but may be terminated, among other ways, by Adapt/EBS in its sole discretion, either in its entirety or in respect of one or more countries, at any time by providing 60 days prior notice to us. Pursuant to the Adapt Agreement, Adapt received our global license to develop and commercialize our intranasal naloxone Opioid Overdose Reversal Treatment Product. In exchange for licensing our treatment to Adapt/EBS, we could receive total potential regulatory and sales milestone payments of more than $55 million, plus up to double-digit percentage royalties on net sales. In February 2015, Adapt received “Fast Track” designation

by the FDA and in July 2015, Adapt submitted a New Drug Application ("NDA") to the FDA for NARCAN®. In November 2015, NARCAN® was approved by the FDA for the emergency treatment of a known or suspected opioid overdose. In May 2016, Adapt submitted a new drug submission ("NDS") for NARCAN® to Health Canada. In October 2016, Health Canada approved Adapt's naloxone hydrochloride nasal spray to treat opioid overdose, to be marketed as NARCAN®.

In October 2016, one of our patents for NARCAN® became listed in the FDA publication, Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book, patent number 9468747, which patent expires on March 16, 2035.

On December 13, 2016, we entered into a Purchase and Sale Agreement (the "SWK Purchase Agreement") with SWK Funding LLC ("SWK") pursuant to which we sold, and SWK purchase, our right to receive, commencing on October 1, 2016, all Royalties (as defined in the SWK Purchase Agreement) arising from the sale by Adapt, pursuant to the Adapt Agreement, of NARCAN® or any other product, subject to certain conditions and limitations. As of December 31, 2017, all amounts due SWK under the SWK Purchase Agreement have been paid. SWK retains a 10% interest for all royalties and milestones that the Company received in the years ended December 31, 2019 and 2018 and will receive in future years.

In addition, on December 13, 2016, in connection with the SWK Purchase Agreement, we entered into Amendment No. 1 to the Adapt Agreement (the "Adapt Amendment") which amends the terms of the Adapt Agreement relating to the grant of a commercial sublicense outside of the U.S and diligence efforts for commercialization of our intranasal naloxone opioid overdose reversal treatment ("OORT"). Under the terms of the Adapt Amendment, Adapt/EBS is required to use commercially reasonable efforts to commercialize OORT in the United States In the event that Adapt/EBS wishes to grant a commercial sublicense to a third party in the European Union or the United Kingdom, we have agreed to negotiate an additional amendment to the Adapt Agreement to include reduced financial terms with respect to the commercial sublicense in such territory. Under such terms, we would receive an escalating double-digit percentage of all net revenue received by Adapt/EBS from a commercial sublicensee in the European Union or the United Kingdom. Net revenue received by Adapt/EBS from a commercial sublicensee in European Union or the United Kingdom would be included in determining sales-based milestones due to us.

In January 2017, the FDA approved the 2mg formulation of NARCAN® for opioid-dependent patients expected to be at risk for severe opioid withdrawal in situations where there is a low risk for accidental or intentional opioid exposure by household contacts.

In March 2017, the U.S. Patent and Trademark Office ("USPTO") issued U.S. Patent Numbers 9,480,644 and 9,561,177 covering methods of use for NARCAN®. In December 2018, the USPTO issued U.S. Patent, No. 10,085,937, covering methods of use for the four-milligram formulation of NARCAN® for the treatment of opioid overdose. These patents are listed in the FDA publication, Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book, and expire on March 16, 2035.

OPNT003 - Intranasal Nalmefene for OOR

On February 12, 2018, we announced positive data from a Phase 1 clinical study of OPNT003 (intranasal nalmefene) and provided an update at a meeting held on February 8, 2018 with the FDA regarding our planned development program. OPNT003 is in development as a potent 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 safety and efficacy for a previously approved FDA product and to supplement this data 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.

Data generated in a Phase 1 study completed under a clinical trial agreement with the National Institute on Drug Abuse ("NIDA") provided the basis for the FDA meeting. These preliminary data demonstrate that our intranasal nalmefene formulation containing a proprietary absorption enhancer (Intravail®, from Aegis Therapeutics) resulted in rapid increases in plasma levels with an onset faster than an intramuscular injection and a comparatively long half-life (6.7-7.8 hours). Naloxone, the only FDA medication currently approved to treat opioid overdose, has a half-life of approximately 2 hours.

On January 27, 2020, the Company received a letter from the FDA formalizing the "clinical hold", which was discussed during a telephone conversation on January 16, 2020, on the clinical study for the Company's product candidate OPNT003 (intranasal nalmefene) as a potent long-acting opioid antagonist for the treatment of opioid overdose. The FDA has requested additional information be provided to evaluate the sensitization and irritation endpoints of the final finished device.

We have full commercial rights to OPNT003 and we were awarded a grant of approximately $7.4 million from the National Institutes of Health (“NIH”). The grant provides us with additional resources for the ongoing development of OPNT003. We have been awarded approximately $5.6 million funded through the period ended March 31, 2021, with the balance of $1.8 million expected to be funded, subject to available funds and satisfactory progress on the development of OPNT003. We have also received a contract for approximately $4.6 million from the Biological Advance Research and Development Agency (“BARDA”) to fund development of this project through NDA submission. BARDA has awarded approximately $3.0 million of the contract through December 20, 2021, with the balance expected to be funded, subject to satisfactory project progress, availability of funds and certain other conditions. In 2017, NIH leadership called for the development of a stronger, longer-acting formulations of antagonists to counteract the very high potency synthetic opioids that are now claiming thousands of lives each year.

Synthetic opioids, such as fentanyl, are now responsible for more overdose deaths than both heroin and prescription opioids, with over 31,000 fatalities linked to synthetic opioids in 2018. Fentanyl and derivatives, such as carfentanil, are especially dangerous because of a long half-life of seven to ten hours that may require continuous monitoring of overdose victims and repeated dosing with naloxone to initially resuscitate a patient and to prevent relapse. A long-acting opioid overdose reversal drug may reduce this burden.

An easy-to-use nasal formulation of nalmefene with a rapid onset and long duration of action would be suitable for non-medically trained persons to administer. If approved by the FDA, OPNT003 may also be especially useful in rural areas, where a rapidly growing number of overdoses are occurring, and where access to emergency medical response may be delayed by hours. In addition, since high potency synthetic opioids, such as fentanyl, can be weaponized, OPNT003 may also be suitable as an antidote in a civilian mass casualty event.

OPNT002 - Nasal Naltrexone for Alcohol Use Disorder ("AUD")

We are developing OPNT002, nasal naltrexone for AUD. Alcohol triggers the release of naturally occurring endorphins, which then bind to the opioid receptors in the brain, leading to dopamine release in the brain's reward center. Opioid antagonists are anticipated to reduce heavy drinking because they block these opioid receptors, which results in dampening of alcohol-induced dopamine release and reward. Naltrexone is currently approved by the FDA for the treatment of AUD as a tablet and depot injection. However, in contrast to current naltrexone formulations OPNT002 will be taken nasally on an "as needed" basis, in anticipation of drinking or once drinking has started in order to reduce alcohol intake. We anticipate that taking our product on an as-needed basis could improve patient compliance and enable a patient to regain control of their drinking, especially in situations where heavy drinking is otherwise habitual. Furthermore, we expect patients to have high rates of adherence, because they will not be required to abstain and potentially go through detoxification and withdrawal prior to initiating OPNT002 therapy, unlike the typical situation with existing medicines for AUD.

We have generated encouraging Phase 1 clinical data demonstrating rapid intranasal absorption of OPNT002, which confirms its suitability for use on an as needed basis. High levels of naltrexone can be delivered within minutes, which is very important during a period of craving. The Company has also received feedback from the FDA on our proposed 505(b)(2) development plan, which accepts a harm reduction-based primary endpoint rather than a primary endpoint based on abstinence.

In October of 2019, we completed a dose ranging study, confirming the suitability of our OPNT002 formulation of AUD. During 2020, we plan to begin patient enrollment for a double blind, placebo controlled Phase 2 study of OPNT002 in AUD. This study will enroll approximately 300 patients in Europe and the United Kingdom.

There are approximately 16.3 million people in the U.S. who suffer from some form of AUD. According to the National Institute on Alcohol Abuse and Alcoholism, only 2.5% of these individuals receive pharmacotherapy for this condition. Feedback from our primary market research strongly supports nasal naltrexone as a product that could also be used in a primary care setting as well as by addiction specialists and in addiction treatment centers.

OPNT004 - Drinabant Injection for Acute Cannabinoid Overdose ("ACO")

On December 26, 2018, we entered into an exclusive global licensing agreement with Sanofi for the development and commercialization of drinabant for the treatment of acute cannabinoid overdose ("ACO"). We intend to develop drinabant, a selective, high affinity cannabinoid CB-1 receptor antagonist, as an injectable for administration in an emergency department setting. In a proof of principle study that Sanofi completed with 36 patients, oral drinibant blocked both subjective and objective psychological effects of inhaled delta9-tetrahydrocannabinol ("THC"). Sanofi also generated extensive safety data in Phase 1 and 2 studies with more than 700 subject for up to 24 weeks.

ACO is most frequently linked to the ingestion of “edibles” containing large quantities of THC and synthetic cannabinoids (often referred to as “K2” and “Spice”) that are more potent and less expensive than cannabis. Edibles, sold as brownies, cookies and candies, pose particular risks for children, who can consume these by accident. Based on 2014 rates from the National Emergency Department sample and United States Census Bureau figures, we estimate that ACO resulted in more than one million emergency department visits in the United States in 2016. With an increasing number of states legalizing cannabis for personal and recreational use, ACO rates are expected to rise. Features of ACO produced by edibles and synthetic cannabinoids can include psychosis, panic and anxiety, feelings of paranoia, agitation, hallucinations, nausea, vomiting and cardiac arrhythmias. These symptoms often require emergency medical attention and can take hours to days to resolve. There are currently no FDA approved treatments for ACO.

In January 2020, we signed a Letter of Intent with the National Center for Advancing Translational Sciences ("NCATS") to collaborate on the development of OPNT004. NCATS is one of 27 divisions and centers of the NIH. NCATS will provide development resources around certain pre-clinical activities and studies to support our planned filing of an Investigational New Drug ("IND") application for OPNT004. This collaboration will be carried out under a Cooperative Research and Development Agreement with the Company and the NIH.

Opioid Use Disorder

OUD is a major global health issue, particularly in the United States, where opioid misuse, in particular involving opioid painkillers and subsequent addiction, has become widespread. Given the increase in prevalence, OUD has now been classified in the United States as a public health crisis. As prescription opioid painkillers have become more difficult to obtain due to tighter controls for distribution and prescribing, and abuse deterrent formulations have become available, there has been an increase in heroin use, which is cheaper and often easier to obtain than painkillers. At the same time, the availability and abuse of synthetic opioids, including fentanyl and its derivatives (fentanyl has been estimated to be at least 50 times more potent than heroin) has become more widespread, further driving the recent increase in deaths from opioid overdose in the U.S.

Current FDA approved treatments for opioid addiction are methadone-based and buprenorphine-based substitution therapies, and the use of naltrexone (an opioid antagonist), available as both a tablet and depot injection. Most substitution therapies, are opioid-based treatments, which for many patients is undesirable, as there is frequently diversion and misuse of these treatments amongst patients with OUD. With respect to naltrexone based therapies, patients must undergo detoxification before initiating treatment, which for many patients severely limits compliance and willingness to undergo this method of treatment. Therefore, being able to provide a vaccine to patients that potentially provides specific immunity against heroin and its metabolites without the need for prior detoxification and enabling patients to remain opioid-free is an attractive solution.

In October 2016, we in-licensed OPNT005, a heroin vaccine from Walter Reed Army Institute of Research (“WRAIR”). This is an early stage pre-clinical asset and requires further pre-clinical research before human testing. In October 2018, researchers at the U.S. Military HIV Research Program at the WRAIR and SUNY Upstate Medical University in Syracuse, NY, were awarded a grant by NIH to advance OPNT005, through Phase 1/2a clinical trials to assess its safety and efficacy.

Other Activities

On June 22, 2017, we entered into a license agreement with Aegis Therapeutics LLC ("Aegis") (the “Aegis License Agreement”) and a related supply agreement (the “Supply Agreement”) pursuant to which we were 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 Aegis 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 Aegis License Agreement restricts our 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 we shall obtain all supply of such Excipients from Aegis under the Supply Agreement. The Aegis License Agreement also restricts Aegis’s ability to compete with us worldwide with respect to the Exploitation (as defined in the Aegis License Agreement) of any therapeutic containing a Compound or derivative or active metabolite of a Compound without our prior written consent. The effective date of the Aegis License Agreement and the Supply Agreement is January 1, 2017.

As consideration for the grant of the License, we agreed to pay Aegis two upfront payments, of which we may elect to pay up to 50% by issuing our Common Stock to Aegis, with the number of shares to be issued equal to 75% of the average closing price of our Common Stock over the 20 trading days preceding the date of payment. The Aegis 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 Aegis License Agreement) of all Products during the Royalty Term (as defined in the Aegis License Agreement) according to a tiered royalty rate based on Annual Net Sales of the Products by us, our sublicensees and affiliates. We shall also pay to Aegis a sublicense fee based on a sublicense rate to be negotiated in good faith by the parties. The Aegis License Agreement contains customary representations and warranties, ownership, patent rights, confidentiality, indemnification and insurance provisions. The Aegis License Agreement shall expire upon the expiration of our obligation to pay royalties under such Aegis License Agreement; provided, however, that we shall have the right to terminate the License granted on a product-by-product or country-by-country basis upon 30 days' prior written notice to Aegis.

Under the terms of the Supply Agreement, Aegis shall deliver to us 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 Aegis 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 us to manufacture such Excipients. We do 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 us (subject to a 60-day cure period).

On December 3, 2018, Neurelis, Inc. completed its acquisition of Aegis. As a result of the acquisition, Neuralis succeeded to all obligations under the Aegis License Agreement.

On July 14, 2017, we entered into a Research and Development Agreement (the "Renaissance Agreement") with Renaissance Lakewood, LLC ("Renaissance"). Under the Renaissance Agreement, Renaissance will perform product development work on a naltrexone multi-dose nasal product for the treatment of AUD (the "Renaissance Product") as provided in a proposal agreed upon by the parties. We 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 us under the Renaissance Agreement. We 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. We have 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. We have agreed to indemnify Renaissance in connection with claims arising out of any clinical trials, ownership, testing, use, application, consumption, distribution, marketing or sale of the Renaissance Product, or any violation or infringement of any patent, copyright or trademark from the use of our designated formula, component or artwork related to the Renaissance Product irrespective of whether we had knowledge of such infringement or violation. The Renaissance Agreement is effective until terminated by either party in accordance with its terms. We 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 us, with or without cause, upon 45 days' written notice. There are also mutual customary termination provisions relating to uncured breaches of material provisions. Renaissance may terminate the Renaissance Agreement in the event of bankruptcy of us or our failure for a period of 180 consecutive days to use commercially reasonable efforts to undertake or further activities to advance the possibility of the commercialization of a Renaissance Product.

On September 10, 2018, we entered into a development and manufacturing agreement for OPNT003 (intranasal nalmefene), a potent, long-acting opioid antagonist for the treatment of opioid overdose with Consort Medical plc ("Consort"), a leading contract development and manufacturing organization. Under this agreement, Aesica and Bespak, wholly-owned subsidiaries of Consort, will work with us to produce a pre-filled delivery nasal spray with nalmefene. As part of the agreement, Aesica will supply Opiant with clinical samples and registration batches for the purposes of performing clinical studies and obtaining regulatory approvals. Further, upon approval by the FDA, Aesica and Bespak will manufacture and supply the commercial device for us.

In November 2016, Opiant Pharmaceuticals UK Limited ("OPUK") was incorporated under the Companies Act of 2006 as a private company. OPUK is a wholly-owned subsidiary of the Company and Dr. Roger Crystal, our Chief Executive Officer and a director, and David O'Toole, our Chief Financial Officer and Secretary, serve as the sole directors of OPUK.

Competition

The specialty pharmaceutical industry is intensely competitive and is characterized by rapid technological progress. Certain pharmaceutical and biopharmaceutical companies and academic and research organizations currently engage in, or have

engaged in, efforts related to the discovery and development of new medicines for the treatment of substance use, addictive and eating disorders. Significant levels of research in chemistry and biotechnology occur in universities and other nonprofit research institutions. These entities have become increasingly active in seeking patent protection and licensing revenues for their research results. They also compete with us in recruiting skilled scientific talent. Some of these companies are larger and better-funded than us and there are no assurances that we can effectively compete with these competitors. Potential competitors include Emergent BioSolutions Inc., Amphastar, Indivior PLC, Alkermes PLC, H. Lundbeck A/S, Teva, Shire PLC, Orexo AB, BioDelivery Services International, Inc., Braeburn Pharmaceuticals, Inc., and BioCorRx, Inc.

With respect to NARCAN®, we face competition from other treatments, including injectable naloxone, auto-injectors and improvised nasal kits. Amphastar Pharmaceuticals, Inc. competes with NARCAN® with their naloxone injection. Kaléo competes with NARCAN® with their auto-injector known as EVZIO™ (naloxone HCl injection) Auto-Injector. In 2015, Indivior PLC received a Complete Response Letter from the FDA with respect to a naloxone nasal spray. Between 2016 and 2018, TEVA has filed abbreviated new drug applications ("ANDAs") with the FDA seeking regulatory approval to market a generic version of NARCAN® before the expiration of the ‘253, '747, '177, '965, '644, and '226 patents, and in 2018 Perrigo UK FINCO Limited Partnership ("Perrigo") filed an ANDA with the FDA seeking regulatory approval to market a generic version of NARCAN® before the expiration of the '253, '747, '177, '965, and '838 patents. Although NARCAN® was the first FDA-approved naloxone nasal spray for the emergency reversal of opioid overdoses and has advantages over certain other treatments, we expect the treatment to face additional competition. For example, during 2018, INSYS Therapeutics, Inc., Orexo AB and Harm Reduction Therapeutics have announced the development of novel naloxone nasal spray formulations intended for use in opioid overdose reversal.

Patents and Proprietary Information

We have obtained and intend to actively seek to obtain, when appropriate, protection for our products and proprietary technology by means of United States and foreign patents, trademarks and contractual arrangements. In addition, we rely upon trade secrets and contractual agreements to protect certain of our proprietary technology and products. We have issued United States patents and pending United States patent applications, as well as pending foreign patent applications or issued foreign patents, relating to our marketed products and product candidates. We also have United States and foreign patent applications pending relating to novel product concepts. There can be no assurance that our patent applications will issue as patents or, with respect to our issued patents, that they will provide us with significant protection. The following provides a general description of our patent portfolio and is not intended to represent an assessment of claim limitations or claim scope:

Product Group	Patent No.	Description	Patent Expiration	Publication No.
NARCAN® Nasal	10,085,937	IN naloxone for treatment of opioid overdose	March 16, 2035	US20170071851
NARCAN® Nasal	9,211,253	IN naloxone for treatment of opioid overdose	March 16, 2035	US20150258019
NARCAN® Nasal	9,468,747	IN naloxone for treatment of opioid overdose	March 16, 2035	US20160184294
NARCAN® Nasal	9,480,644	IN naloxone for treatment of opioid overdose	March 16, 2035	US20160166503
NARCAN® Nasal	9,561,177	IN naloxone for treatment of opioid overdose	March 16, 2035	US20160303041
NARCAN® Nasal	9,629,965	IN naloxone for treatment of opioid overdose	March 16, 2035	US20170043107
NARCAN® Nasal	9,707,226	IN naloxone for treatment of opioid overdose	March 16, 2035	US20170151231
NARCAN® Nasal	9,775,838	IN naloxone for treatment of opioid overdose	March 16, 2035	US20170239241
NARCAN® Nasal	2,538,682	IN naloxone for treatment of opioid overdose	March 16, 2035	UK
NARCAN® Nasal	2,942,611	IN naloxone for treatment of opioid overdose	March 16, 2035	Canada
NARCAN® Nasal	365,383	IN naloxone for treatment of opioid overdose	March 16, 2035	Mexico
NARCAN® Nasal	2,631,504	IN naloxone for treatment of opioid overdose	March 16, 2035	Spain

In addition to the patents and applications listed above, we have several pending, unpublished applications drawn to formulations, devices, and treatments of disorders, as well as additional continuation and divisional applications claiming the benefit of priority of applications listed above.

Research and Development

During the years ended December 31, 2019 and December 31, 2018, we incurred research and development expenses of $9.1 million and $8.5 million, respectively.

Regulation

Government Regulation and Product Approval

Government authorities in the United States, at the federal, state, and local levels, and in other countries and jurisdictions, including the European Union, extensively regulate, among other things, the research, development, testing, product approval, manufacture, quality control, safety, effectiveness, manufacturing changes, packaging, storage, record-keeping, labeling, promotion, advertising, sales, distribution, marketing, and import and export of drugs and biologic products. All of our foreseeable product candidates are expected to be regulated as drugs. In particular, therapeutic product candidates for human use are subject to rigorous preclinical and clinical testing and other requirements of the Federal Food, Drug and Cosmetic Act (“FFDCA”), implemented by the FDA, as well as similar statutory and regulatory requirements of foreign countries. The processes for obtaining regulatory approval in the United States. and in foreign countries and jurisdictions, along with ongoing compliance with applicable statutes and regulations and other regulatory authorities both pre- and post-commercialization, are a significant factor in the production and marketing of our products and our R&D activities and require the expenditure of substantial time and financial resources. Any failure by us or our collaborators, licensors or licensees to obtain, or any delay in obtaining, regulatory approvals or in complying with other regulatory requirements could adversely affect the commercialization of product candidates then being developed by us and our ability to receive product or royalty revenues.

The processes for obtaining regulatory approvals in the United States and in foreign countries, along with subsequent compliance with applicable statutes and regulations, require the expenditure of substantial time and financial resources. In the United States, the FDA regulates drugs under the FFDCA and the FDA's implementing regulations. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process, or after approval, may subject an applicant to administrative or judicial sanctions. These sanctions could include the FDA's refusal to approve pending applications, withdrawal of an approval, a clinical hold, untitled or warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement or civil or criminal penalties. The process required by the FDA before a drug may be marketed in the United States generally involves the following:

- completion of preclinical laboratory tests, animal studies and formulation studies according to Good Laboratory Practices regulations;
- submission to the FDA of an IND, which must become effective before human clinical studies may begin;
- approval by an independent internal review board ("IRB"), at each clinical site before each trial may be initiated;
- performance of adequate and well-controlled human clinical studies according to Good Clinical Practice ("GCP") regulations, to establish the safety and efficacy of the proposed drug for its intended use;
- preparation and submission to the FDA of an NDA;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the product, or components thereof, are produced to assess compliance with current Good Manufacturing Practice ("cGMP") to assure that the facilities, methods, and controls are adequate to preserve the drug's identity, strength, quality, and purity; and
- FDA review and approval of the NDA.

The testing and approval process requires substantial time, effort and financial resources, and we cannot be certain that any approvals for our product candidates (or those of our collaborators or licensees) will be granted on a timely basis, if at all.

An IND sponsor must submit the results of the preclinical tests, together with manufacturing information, analytical data and any available clinical data or literature, to the FDA as part of the IND. The sponsor must also include a protocol detailing, among other things, the objectives of the initial clinical study, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated if the initial clinical study lends itself to an efficacy evaluation. Some preclinical testing may continue even after the IND is submitted. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA raises concerns or questions related to a proposed clinical study and places the study on a clinical hold within that 30-day time period. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical

study can begin. Clinical holds also may be imposed by the FDA at any time before or during clinical studies due to safety concerns or non-compliance, and may be imposed on all product candidates within a certain pharmaceutical class. The FDA also can impose partial clinical holds, for example, prohibiting the initiation of clinical studies of a certain duration or for a certain dose.

All clinical studies must be conducted under the supervision of one or more qualified investigators in accordance with GCP regulations. These regulations include the requirement that all research subjects provide informed consent in writing before their participation in any clinical study. Further, an IRB must review and approve the plan for any clinical study before it commences at any institution, and the IRB must conduct continuing review and re-approve the study at least annually. An IRB considers, among other things, whether the risks to individuals participating in the clinical study are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the information regarding the clinical study and the consent form that must be provided to each clinical study subject or his or her legal representative and must monitor the clinical study until completed. Each new clinical protocol and any amendments to the protocol must be submitted for FDA review, and to the IRBs for approval. Protocols detail, among other things, the objectives of the clinical study, dosing procedures, subject selection and exclusion criteria, and the parameters to be used to monitor subject safety. Study sites are subject to inspection for compliance with GCP.

Information about certain clinical trials must be submitted within specific timeframes to the NIH, for public dissemination on their ClinicalTrials.gov website.

Human clinical studies are typically conducted in three sequential phases that may overlap or be combined:

- Phase 1. The product is initially introduced into a small number of healthy human subjects or patients and tested for safety, dosage tolerance, absorption, metabolism, distribution and excretion and, if possible, to gain early evidence on effectiveness. In the case of some products for severe or life-threatening diseases, especially when the product is suspected or known to be unavoidably toxic, the initial human testing may be conducted in patients.

- Phase 2. Involves clinical studies in a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance and optimal dosage and schedule.

- Phase 3. Clinical studies are undertaken to further evaluate dosage, clinical efficacy and safety in an expanded patient population at geographically dispersed clinical study sites. These clinical studies are intended to establish the overall risk/benefit relationship of the product and provide an adequate basis for product labeling.

Progress reports detailing the results of the clinical studies must be submitted at least annually to the FDA and safety reports must be submitted to the FDA and the investigators for serious and unexpected suspected adverse events. Phase 1, Phase 2 and Phase 3 testing may not be completed successfully within any specified period, if at all. The FDA or the sponsor may suspend or terminate a clinical study at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical study at its institution if the clinical study is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to patients.

U.S. Review and Approval Processes

Assuming successful completion of the required clinical testing, the results of product development, preclinical studies and clinical studies, along with descriptions of the manufacturing process, analytical tests conducted on the drug, proposed labeling and other relevant information, are submitted to the FDA as part of an NDA for a new drug, requesting approval to market the product.

The submission of an NDA is subject to the payment of a substantial application user fee although a waiver of such fee may be obtained under certain limited circumstances. For example, the agency will waive the application fee for the first human drug application that a small business or its affiliate submits for review. The sponsor of an approved NDA is also subject to annual program user fees.

In addition, under the Pediatric Research Equity Act of 2003, an NDA application (or supplements to an application) for a new active ingredient, new indication, new dosage form, new dosing regimen, or new route of administration must contain data that are adequate to assess the safety and effectiveness of the drug for the claimed indications in all relevant pediatric subpopulations, and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective, unless the applicant has obtained a waiver or deferral.

In 2012, the FDASIA amended the FDCA to require that a sponsor who is planning to submit a marketing application for a drug that includes a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration submit an initial Pediatric Study Plan ("PSP"), within sixty days of an End-of-Phase II meeting or as may be agreed between the sponsor and the FDA. The initial PSP must include an outline of the pediatric study or studies that the sponsor plans to conduct, including study objectives and design, age groups, relevant endpoints and statistical approach, or a justification for not including such detailed information, and any request for a deferral of pediatric assessments or a full or partial waiver of the requirement to provide data from pediatric studies along with supporting information. The FDA may, on its own initiative or at the request of the applicant, grant deferrals for submission of data or full or partial waivers. The FDA and the sponsor must reach agreement on the PSP. A sponsor can submit amendments to an agreed upon initial PSP at any time if changes to the pediatric plan need to be considered based on data collected from preclinical studies, early phase clinical studies, and/or other clinical development programs.

The FDA also may require submission of a Risk Evaluation and Mitigation Strategy ("REMS") to mitigate any identified or suspected serious risks. The REMS could include medication guides, physician communication plans, assessment plans, and elements to assure safe use, such as restricted distribution methods, patient registries, or other risk minimization tools.

The FDA reviews all NDAs submitted to ensure that they are sufficiently complete for substantive review before it accepts them for filing. The FDA may request additional information rather than accept an application for filing. In this event, the application must be re-submitted with the additional information. The re-submitted application also is subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review to determine whether the product is safe and effective for its intended use.

The FDA may refer the NDA to an advisory committee for review, evaluation and recommendation as to whether the application should be approved and under what conditions. An advisory committee is a panel of experts, including clinicians and other scientific experts, who provide advice and recommendations when requested by the FDA. The FDA is not bound by the recommendation of an advisory committee, but it considers such recommendations when making decisions.

Additionally, before approving an NDA, the FDA will typically inspect one or more clinical sites to assure clinical data supporting the submission were developed in compliance with GCP.

The approval process is lengthy and difficult and the FDA may refuse to approve an NDA if the applicable regulatory criteria are not satisfied, or may require additional clinical data or other data and information. Even if such data and information are submitted, the FDA may ultimately decide that the NDA does not satisfy the criteria for approval. Data obtained from clinical studies are not always conclusive and the FDA may interpret data differently than an applicant interprets the same data.

After the FDA's evaluation of an application, the FDA may issue an approval letter, or, in some cases, a complete response letter to indicate that the review cycle is complete and that the application is not ready for approval. A complete response letter generally contains a statement of specific conditions that must be met to secure final approval of the application and may require additional clinical or preclinical testing for the FDA to reconsider the application. The deficiencies identified may be minor, for example, requiring labeling changes, or major, for example, requiring additional clinical studies. Additionally, the complete response letter may include recommended actions that the applicant might take to place the application in a condition for approval. If a complete response letter is issued, the applicant may either resubmit the application, addressing all of the deficiencies identified in the letter, or withdraw the application or request an opportunity for a hearing.

Even with submission of additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval. If and when those conditions have been met to the FDA's satisfaction, the FDA will typically issue an approval letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications.

If a product receives regulatory approval, the approval may be significantly limited to specific diseases and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. Further, the FDA may require that certain contraindications, warnings or precautions be included in the product labeling. In addition, the FDA may require post-approval studies, including Phase 4 clinical studies, to further assess safety and effectiveness after approval and may require testing and surveillance programs to monitor the safety of approved products that have been commercialized. After approval, some types of changes to the approved product, such as adding new indications, manufacturing changes, and additional labeling claims, are subject to further testing requirements and FDA review and approval.

Abbreviated New Drug Applications ("ANDAs") and Section 505(b)(2) New Drug Applications

Most drug products obtain FDA marketing approval pursuant to an NDA for innovator products, or an ANDA for generic products. Relevant to ANDAs, the Hatch-Waxman amendments to the FDCA established a statutory procedure for submission and FDA review and approval of ANDAs for generic versions of branded drugs previously approved by the FDA (such previously approved drugs are also referred to as listed drugs). Because the safety and efficacy of listed drugs have already been established by the brand company (sometimes referred to as the innovator), the FDA does not require a demonstration of safety and efficacy of generic products. However, a generic manufacturer is typically required to conduct bioequivalence studies of its test product against the listed drug. The bioequivalence studies for orally administered, systemically available drug products assess the rate and extent to which the API is absorbed into the bloodstream from the drug product and becomes available at the site of action. Bioequivalence is established when there is an absence of a significant difference in the rate and extent for absorption of the generic product and the listed drug. In addition to the bioequivalence data, an ANDA must contain patent certifications and chemistry, manufacturing, labeling and stability data.

The third alternative is a special type of NDA, commonly referred to as a Section 505(b)(2) NDA, which enables the applicant to rely, in part, on the FDA's findings of safety and efficacy of an existing product, or published literature, in support of its application. Section 505(b)(2) NDAs often provide an alternate path to FDA approval for new or improved formulations or new uses of previously approved products. Section 505(b)(2) permits the filing of an NDA where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. The applicant may rely upon the FDA's findings with respect to certain preclinical or clinical studies conducted for an approved product. The FDA may also require companies to perform additional studies or measurements to support the change from the approved product. The FDA may then approve the new product candidate for certain label indications for which the referenced product has been approved, as well as for any new indication sought by the Section 505(b)(2) applicant.

In seeking approval for a drug through an NDA, including a 505(b)(2) NDA, applicants are required to list with the FDA certain patents of the applicant or that are held by third parties whose claims cover the applicant's product. Upon approval of an NDA, each of the patents listed in the application for the drug is then published in the Orange Book. Any subsequent applicant who files an ANDA seeking approval of a generic equivalent version of a drug listed in the Orange Book or a 505(b)(2) NDA referencing a drug listed in the Orange Book must make one of the following certifications to the FDA concerning patents: (1) the patent information concerning the reference listed drug product has not been submitted to the FDA; (2) any such patent that was filed has expired; (3) the date on which such patent will expire; or (4) such patent is invalid or will not be infringed upon by the manufacture, use or sale of the drug product for which the application is submitted. This last certification is known as a paragraph IV certification. A notice of the paragraph IV certification must be provided to each owner of the patent that is the subject of the certification and to the holder of the approved NDA to which the ANDA or 505(b)(2) application refers. The applicant may also elect to submit a "section viii" statement certifying that its proposed label does not contain (or carves out) any language regarding the patented method-of-use rather than certify to a listed method-of-use patent.

If the reference NDA holder or patent owners assert a patent challenge directed to one of the Orange Book listed patents within 45 days of the receipt of the paragraph IV certification notice, the FDA is prohibited from approving the application until the earlier of 30 months from the receipt of the paragraph IV certification expiration of the patent, settlement of the lawsuit or a decision in the infringement case that is favorable to the applicant. The ANDA or 505(b) (2) application also will not be approved until any applicable non-patent exclusivity listed in the Orange Book for the branded reference drug has expired as described in further detail below. Thus approval of a Section 505(b)(2) NDA or ANDA can be stalled until all the listed patents claiming the referenced product have expired, until any non-patent exclusivity, such as exclusivity for obtaining approval of a new chemical entity, listed in the Orange Book for the referenced product has expired, and, in the case of a Paragraph IV certification and subsequent patent infringement suit, until the earlier of 30 months, settlement of the lawsuit or a decision in the infringement case that is favorable to the ANDA or Section 505(b)(2) applicant.

Post-Approval Requirements

Drugs manufactured or distributed pursuant to FDA approvals are subject to extensive and continuing regulation by the FDA, including, among other things, requirements relating to recordkeeping (including certain electronic record and signature requirements), periodic reporting, product sampling and distribution, advertising and promotion and reporting of certain adverse experiences, deviations, and other problems with the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims are subject to prior FDA review and approval. There also are continuing, annual user fee requirements for any marketed products, as well as new application fees for supplemental applications with clinical data.

The FDA strictly regulates labeling, advertising, promotion and other types of information on products that are placed on the market. Products may be promoted only for the approved indications and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability. Further, manufacturers must continue to comply with cGMP requirements, which are extensive and require considerable time, resources and ongoing investment to ensure compliance. In addition, changes to the manufacturing process generally require prior FDA approval before being implemented and other types of changes to the approved product, such as adding new indications and additional labeling claims, are also subject to further FDA review and approval.

Manufacturers and certain other entities involved in the manufacturing and distribution of approved products are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP and other laws. The cGMP requirements apply to all stages of the manufacturing process, including the production, processing, sterilization, packaging, labeling, storage and shipment of the product.

Changes to the manufacturing process are strictly regulated and often require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting and documentation requirements upon the sponsor and any third party manufacturers that the sponsor may decide to use. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance.

The FDA may impose a number of post-approval requirements as a condition of approval of an application. For example, the FDA may require post-marketing testing, including Phase 4 clinical trials, and surveillance to further assess and monitor the product's safety and effectiveness after commercialization.

The FDA may withdraw a product approval if compliance with regulatory requirements is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, problems with manufacturing processes, or failure to comply with regulatory requirements, may result in restrictions on the product or even complete withdrawal of the product from the market.

Potential implications include required revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical trials to assess new safety risks; or imposition of distribution or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- warning letters or holds on post-approval clinical trials;
- refusal of the FDA to approve pending NDAs or supplements to approved NDAs, or suspension or revocation of product license approvals;
- product seizure or detention, or refusal to permit the import or export of products; or
- injunctions or the imposition of civil or criminal penalties.

In addition, the distribution of prescription drugs is subject to the Prescription Drug Marketing Act ("PDMA"), which regulates the distribution of the products and product samples at the federal level, and sets minimum standards for the registration and regulation of distributors by the states. Both the PDMA and state laws limit the distribution of prescription pharmaceutical product samples and impose requirements to ensure accountability in distribution.

From time to time, legislation is drafted, introduced and passed in Congress that could significantly change the statutory provisions governing the approval, manufacturing and marketing of products regulated by the FDA. In addition to new legislation, FDA regulations, guidance, and policies are often revised or reinterpreted by the agency in ways that may significantly affect our business and our product candidates. It is impossible to predict whether further legislative or FDA regulation or policy changes will be enacted or implemented and what the impact of such changes, if any, may be.

Pharmaceutical Coverage, Pricing and Reimbursement

In the United States, sales of any products for which we (or our collaborators or licensees) may receive regulatory approval for commercial sale will depend in part on the availability of coverage and reimbursement from third-party payors. Third-party payors include government authorities, managed care providers, private health insurers and other organizations.

Significant uncertainty exists as to the coverage and reimbursement status of any products for which we may obtain regulatory approval. The process for determining whether a payor will provide coverage for a drug may be separate from the process for setting the reimbursement rate that the payor will pay for the product. Some of the additional requirements and restrictions on coverage and reimbursement levels imposed by third-party payors influence the purchase of healthcare services and products.

Third-party payors may limit coverage to specific drugs on an approved list, or formulary, which might not include all of the FDA-approved drugs for a particular indication, or place drugs at certain formulary levels that result in lower reimbursement levels and higher cost-sharing obligation imposed on patients. Moreover, a payor's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development. Further, one payor's determination to provide coverage does not assure that other payors will also provide coverage and reimbursement for the product, and the level of coverage and reimbursement may differ significantly from payor to payor. Third-party payors are increasingly challenging the price and examining the medical necessity and cost-effectiveness of medical products and services, in addition to their safety and efficacy. In order to obtain and maintain coverage and reimbursement for any product that might be approved for sale, we may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of any products, in addition to the costs required to obtain regulatory approvals. Our product candidates may not be considered medically necessary or cost-effective. If third-party payors do not consider a product to be cost-effective compared to other available therapies, they may not cover the product after approval as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow a company to sell its products at a profit.

The United States government and state legislatures have shown significant interest in implementing cost containment programs to limit the growth of government-paid healthcare costs, including price controls, restrictions on reimbursement and coverage and requirements for substitution of generic products for branded prescription drugs. Adoption of government controls and measures, and tightening of restrictive policies in jurisdictions with existing controls and measures, could exclude or limit our drugs and product candidates from coverage and limit payments for pharmaceuticals.

In addition, we expect that the increased emphasis on managed care and cost containment measures in the United States by third-party payors and government authorities to continue and will place pressure on pharmaceutical pricing and coverage. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

Employees

As of March 1, 2020, we had 21 full-time employees and one part-time employee. In addition, we have a number of outside consultants that are not on our payroll.

ITEM 1A. RISK FACTORS

An investment in our securities involves a high degree of risk. Prior to making a decision about investing in our securities, you should carefully consider all of the information in this Report on Form 10-K, including our consolidated financial statements and related notes. The risks and uncertainties we have described are not the only ones we face. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also affect our operations. The occurrence of any of these known or unknown risks might cause you to lose all or part of your investment.

Risks Related to our Business, Financial Condition and Capital Requirements

We have historically generated limited revenue to date and expect to incur significant operating losses for the foreseeable future.

As of December 31, 2019, we have an accumulated deficit of $62.8 million. The likelihood of our future success must be considered in light of the expenses, difficulties, complications and delays often encountered in connection with the clinical trials that will be conducted and on the development of new solutions to common addictions and related disorders. These potential challenges include, but are not limited to, unanticipated clinical trial delays, poor data, changes in the regulatory and competitive landscape and additional costs and expenses that may exceed current budget estimates. In order to complete certain clinical trials and otherwise operate pursuant to our current business strategy, we anticipate that we will incur increased operating expenses. In addition, we expect to incur significant losses for the foreseeable future and we also expect to experience negative cash flow for the foreseeable future as we fund the operating losses and capital expenditures. We recognize that if we are unable to generate sufficient revenues or source funding, we will not be able to continue operations as currently contemplated, complete planned clinical trials and/or achieve profitability. Our failure to achieve or maintain profitability will also negatively impact the value of our securities. If we are unsuccessful in addressing these risks, then the Company will most likely fail.

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

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

Two separate companies, (i) Teva Pharmaceuticals Industries Ltd. and its wholly owned subsidiary Teva Pharamceuticals USA, Inc. (collectively “Teva”), and (ii) Perrigo UK FINCO Limited Partnership sent us and our partner 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.

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.

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

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

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

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

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

Given our lack of sufficient revenue and cash flow, we may need to raise additional capital, which may be unavailable to us or, even if consummated, may cause dilution or place significant restrictions on our ability to operate.

Since we may be unable to generate sufficient revenue or cash flow to fund our operations for the foreseeable future, we may need to seek additional equity or debt financing to provide the capital required to maintain or expand our operations. We may also need additional funding to continue the development of our product candidates, build our sales and marketing capabilities, promote brand identity or develop or acquire complementary technologies, assets and companies, as well as for working capital requirements and other operating and general corporate purposes.

Other than the Open Market Sale Agreement[SM] dated November 14, 2019, we do not currently have any arrangements or credit facilities in place as a source of funds, and there can be no assurance that we will be able to raise sufficient additional capital if needed on acceptable terms, or at all. If such financing is not available on satisfactory terms, or is not available at all, we may be required to delay, scale back or eliminate the development of our product candidates and other business opportunities

and our ability to achieve our business objectives, our competitiveness and our operations and financial condition may be materially adversely affected. Our inability to fund our business could thus lead to the loss of your investment.

If we raise additional capital by issuing equity securities and/or equity-linked securities, the percentage ownership of our existing stockholders may be reduced, and accordingly these stockholders may experience substantial dilution. We may also issue equity securities and/or equity-linked securities that provide for rights, preferences and privileges senior to those of Common Stock. Given our need for cash and that equity and equity-linked issuances are very common types of fundraising for companies like us, the risk of dilution is particularly significant for our stockholders.

Debt financing, if obtained, may involve agreements that include liens on our assets and covenants limiting or restricting our ability to take specific actions such as incurring additional debt. Debt financing could also be required to be repaid regardless of our operating results.

If we raise additional funds through collaborations and licensing arrangements, we may be required to relinquish some rights to our products or to grant licenses on terms that are not favorable to us.

We depend on third parties in connection with our pre-clinical studies and clinical trials, which may result in costs and delays that prevent us from obtaining regulatory approval or successfully commercializing our product candidates.

We engage third parties to perform various aspects of our pre-clinical studies and clinical trials. For instance, on September 10, 2018, we entered into a development and manufacturing agreement for OPNT003 (intranasal nalmefene), a potent, long-acting opioid antagonist for the treatment of opioid overdose with Consort Medical plc ("Consort"), a leading contract development and manufacturing organization. Under this agreement, Aesica and Bespak, wholly-owned subsidiaries of Consort, will work with us to produce a pre-filled delivery nasal spray with nalmefene. As part of the agreement, Aesica will supply Opiant with clinical samples and registration batches for the purposes of performing clinical studies and obtaining regulatory approvals. We depend on these third parties to perform these activities on a timely basis in accordance with the protocol, good laboratory practices, good clinical practices, and other regulatory requirements. Our reliance on these third parties for pre-clinical and clinical development activities reduces our control over these activities. Accordingly, if these parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, our pre-clinical studies and clinical trials may be extended, delayed, terminated or our data may be rejected by the FDA. For example, if Consort were to cease to be able to supply the device to us, our OPNT003 program would be delayed until we obtained an alternative source, which could take a considerable length of time. If there are delays in testing or obtaining regulatory approvals as a result of a third party’s failure to perform, our drug discovery and development costs will likely increase, and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates.

Further, upon approval by the FDA, Aesica and Bespak will manufacture and supply the commercial device for us. Third parties’ abilities to adequately and timely manufacture and supply our product candidates is dependent on the operation of their facilities which may be impacted by, among other things:

- availability, performance, or contamination of raw materials and components used in the manufacturing process, particularly those for which we have no other source or supplier;
- capacity of our facility and those of contract manufacturer;
- the performance of information technology systems;
- compliance with regulatory requirements;
- inclement weather and natural disasters;
- changes in forecasts of future demand for product components;
- timing and actual number of production runs for product components;
- potential facility contamination by microorganisms or viruses;
- updating of manufacturing specifications; and
- product quality success rates and yields.

If the efficient manufacture and supply of our product candidates is interrupted, we may experience delayed shipments or supply constraints, which may materially impact our ongoing and future pre-clinical studies and clinical trials.

Any contract manufacturer must undergo a potentially lengthy FDA approval process, as well as other regulatory approval processes, and are subject to continued review by the FDA and other regulatory authorities. It is a multi-year process to build and license a new manufacturing facility and it can take significant time to qualify and license a contract manufacturer.

If regulatory authorities determine that we or our contract manufacturer or certain of our third-party service providers have violated regulations or if they restrict, suspend or revoke our prior approvals, they could prohibit us from manufacturing our products or conducting clinical trials or selling our marketed products until we or the affected third-party service providers comply, or indefinitely. Because our third-party service providers are subject to the FDA and, potentially, in the future, foreign
regulatory authorities, alternative qualified third-party service providers may not be available on a timely basis or at all. If we or our third-party service providers cease or interrupt production or if our third-party service providers fail to supply materials, products or services to us, we may experience delayed shipments, and supply constraints for our products.

Our current and future operations substantially depend on our Chief Executive Officer and our ability to hire other key personnel, the loss of any of whom could disrupt our business operations.

Our business depends and will continue to depend in substantial part on the continued service of Dr. Roger Crystal, the Company's Chief Executive Officer. The loss of the services of Dr. Crystal would significantly impede implementation and execution of our business strategy and may result in the failure to reach our goals.

Our future viability and ability to achieve sales and profits will also depend on our ability to attract, train, retain and motivate highly qualified personnel in the diverse areas required for continuing operations. There is a risk that we will be unable to attract, train, retain or motivate qualified personnel, both near term or in the future, and the failure to do so may severely damage its prospects.

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

Certain of our executive officers are parties to employment agreements that contain change in control and severance provisions providing for aggregate cash payments of up to approximately $5.1 million for severance and other benefits and acceleration of vesting of stock options with a value of approximately $3.2 million, in the event of a termination of employment in connection with a change of control of the Company. The accelerated vesting of options and restricted stock units could result in dilution to our existing stockholders and harm the market price of our Common Stock. The payment of these severance benefits could harm our financial conditions and results. In addition, these potential severance payments may discourage or prevent third parties from seeking a business combination with us.

Under the Company's agreement with Adapt/EBS, they have the right to license third-party intellectual property which may result in a reduction of our potential royalty and milestone payments.

Under the Company's license agreement, with Adapt/EBS (the "Adapt Agreement"), Adapt/EBS may seek to license certain intellectual property held by a third-party that Adapt/EBS reasonably determines would be infringed upon through the performance of the Adapt Agreement or that Adapt/EBS otherwise determines is necessary or desirable for Adapt/EBS to perform its obligations under the Adapt Agreement. On March 18, 2019, the Company and Adapt/EBS entered into an amendment to the Adapt Agreement that clarifies the circumstances under which Adapt/EBS may enter into such licenses and deduct a material amount, as provided in the Adapt Agreement, of any upfront payment, milestones or royalties paid to such third-party from any regulatory milestone payments, sales-based milestone payments, and royalty payments payable to the Company under the Adapt Agreement. Following the execution of the amendment, in most situations, in order to exercise its right to deduct any payments with respect thereto, Adapt/EBS will need the consent of the Company that the licensing arrangement is acceptable.

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

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

Exposure to United Kingdom political developments, including the outcome of its withdrawal from membership in the European Union, could be costly and difficult to comply with and could seriously harm our business.

We have based a significant portion of our non-U.S. operations in the United Kingdom. In June 2016, a referendum was held in the U.K. which resulted in a majority voting in favor of the U.K. withdrawing from the E.U. (commonly referred to as "Brexit"). Pursuant to legislation approved by the U.K. Parliament and the E.U. Parliament in January 2020, the U.K. withdrew from the E.U. with effect from 11 p.m. (GMT) on January 31, 2020 on the terms of a withdrawal agreement agreed between the U.K. and the E.U. in October 2019 (the "Withdrawal Agreement"). The Withdrawal Agreement provides that the U.K.'s withdrawal is followed by a "transition period", during which, in summary, the U.K. is not a member of the E.U. but most E.U. rules and regulations continue to apply to the U.K. During the transition period, the U.K. and the E.U. will seek to negotiate the terms of a long-term trading relationship between the U.K. and the E.U. based on a "Political Declaration" agreed between the U.K. and the E.U. in October 2019. The transition period provided for in the Withdrawal Agreement will expire on December 31, 2020 (unless both the U.K. and the E.U. agree to extend the period of transition by one or two years). The political negotiation surrounding the terms of the U.K.'s withdrawal from the E.U. has created significant uncertainty about the future relationship between the U.K. and the E.U., including with respect to the laws and regulations that will apply. This is because, once the "transition period" expires then, subject to the terms of any long-term trading relationship agreed between the U.K. and the E.U., the U.K. will determine which E.U.-derived laws to replace or replicate. If no long-term trading relationship is agreed between the U.K. and the E.U. by the end of the transition period provided for in the Withdrawal Agreement, the U.K.'s membership of the E.U. could ultimately terminate under a so-called "hard Brexit." The full effect of Brexit is uncertain and depends on any agreements the U.K. may make to retain access to E.U. markets. Consequently, no assurance can be given about the impact of the outcome and our business, including operational and tax policies, may be seriously harmed or require reassessment if our European operations or presence become a significant part of our business.

Risks Related to our Intellectual Property

If we are unable to obtain and maintain patent protection for our products and product candidates, or if the scope of the patent protection obtained is not sufficiently broad, our competitors could develop and commercialize products and product candidates that are similar or identical to ours, and our ability to successfully commercialize our products and product candidates may be adversely affected.

Our commercial success will depend, in part, on our ability to obtain and maintain patent protection in the United States and other countries with respect to our products and product candidates. We seek to protect our proprietary position by filing patent applications in the United States and abroad related to our products and product candidates that are important to our business, as appropriate. We cannot be certain that patents will be issued or granted with respect to applications that are currently pending or that we may apply for in the future with respect to one or more of our products and product candidates, or that issued or granted patents will not later be found to be invalid and/or unenforceable.

The patent prosecution process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Although we may enter into non-disclosure and confidentiality agreements with parties who have access to patentable aspects of our research and development output, such as our employees, distribution partners, consultants, advisors and other third parties, any of these parties may breach the agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection.

The patent position of pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued, and even if issued, the patents may not meaningfully protect our products or product candidates, effectively prevent competitors and third parties from commercializing competitive products or otherwise provide us with any competitive advantage. Our competitors or other third parties may be able to circumvent our patents by developing similar or alternative products in a non-infringing manner.

Changes in either the patent laws, implementing regulations or interpretation of the patent laws in the U.S. and other countries may also diminish the value of our patents or narrow the scope of our patent protection. The laws of foreign countries may not protect our rights to the same extent as the laws of the U.S., and many companies have encountered significant difficulties in protecting and defending such rights in foreign jurisdictions.

We cannot be certain that our patents and patent rights will be effective in protecting our products, product candidates and technologies. Failure to protect such assets may have a material adverse effect on our business, operations, financial condition and prospects.

We may face litigation from third parties claiming that our products or business infringe, misappropriate, or otherwise violate their intellectual property rights, or seeking to challenge the validity of our patents.

Our future success is also dependent in part on the strength of our intellectual property, trade secrets and know-how, which have been developed from years of research and development, and on our ability, and the ability of our future collaborators, to develop, manufacture, market and sell our products and product candidates, if approved, and use our proprietary technologies without alleged or actual infringement, misappropriation or other violation of the patents and other intellectual property rights of third parties.

In addition to the litigation with TEVA and Perrigo discussed below, we may be exposed to, or be threatened with, adversarial proceedings or additional future litigation by third parties regarding intellectual property rights with respect to our current and any future product candidates and technology, including interference or derivation proceedings, post grant review and *inter partes* review before the USPTO or similar adversarial proceedings or litigation in other jurisdictions seeking to challenge the validity of our intellectual property rights, claiming that we have misappropriated the trade secrets of others, or claiming that our technologies, products or activities infringe the intellectual property rights of others.

There have been many lawsuits and other proceedings involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, oppositions and reexamination proceedings before the USPTO, and corresponding foreign patent offices. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may be subject to claims of infringement of the intellectual property rights of third parties. We actively track third-party applications with claims that, if valid, could be construed to read upon the use our NARCAN® product(s) for the treatment of opioid overdose, or other products and indications. Certain of these applications could be granted in the future. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future including, perhaps, the aforementioned allowed patent application, regardless of their merit. There is a risk that third parties may choose to engage in litigation with us to enforce or to otherwise assert their patent rights against us. Even if we believe such claims are without merit, a court of competent jurisdiction could hold that these third-party patents are valid, enforceable and infringed, and the holders of any such patents may be able to block our ability to commercialize such product candidate unless we obtained a license under the applicable patents, or until such patents expire or are finally determined to be invalid or unenforceable. Similarly, if any third-party patents were held by a court of competent jurisdiction to cover aspects of our compositions, formulations, or methods of treatment, prevention or use, the holders of any such patents may be able to block our ability to develop and commercialize the applicable product candidate unless we obtained a license or until such patent expires or is finally determined to be invalid or unenforceable. In either case, such a license may not be available on commercially reasonable terms, or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. Some claimants may have substantially greater resources than we do and may be able to sustain the costs of complex intellectual property litigation to a greater degree and for longer periods of time than we could. In addition, patent holding companies that focus solely on extracting royalties and settlements by enforcing patent rights may target us. Furthermore, even in the absence of litigation, we may need to obtain licenses from third parties to advance our research or to enable the commercialization of our product candidates. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In such an event, we would be unable to further practice our technologies or develop and commercialize any of our product candidates at issue, which could harm our business significantly.

Parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize one or more of our product candidates, if approved. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of management and employee time and resources from our business. Third parties making such claims may have the ability to dedicate substantially greater resources to these legal actions than we or our licensors or collaborators can. In the event of a successful claim of infringement, misappropriation or other violation against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, pay royalties, redesign our infringing products or obtain one or more licenses from third parties, which may be impossible or require substantial time and monetary expenditure.

Similarly, we or our licensors or collaborators may initiate such proceedings or litigation against third parties, e.g., to challenge the validity or scope of intellectual property rights controlled by third parties. In order to successfully challenge the validity of any U.S. patent in federal court, we would need to overcome a presumption of validity. As this burden is a high one

requiring us to present clear and convincing evidence as to the invalidity of any such United States patent claim, there is no assurance that a court would invalidate the claims of any such United States patent.

Patent litigation and other proceedings may also absorb significant management time. The cost to us of any patent litigation or other proceeding, even if resolved in our favor, could be substantial. During the course of any patent or other intellectual property litigation or other proceeding, there could be public announcements of the results of hearings, rulings on motions, and other interim proceedings or developments and if securities analysts or investors regard these announcements as negative, the perceived value of our product candidates or intellectual property could be diminished. Accordingly, the market price of our common stock may decline. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our business, ability to compete in the marketplace, financial condition, results of operations and growth prospects.

We may become involved in lawsuits to protect or enforce our patents or other intellectual property, which could be expensive, time consuming and unsuccessful.

Competitors may infringe, misappropriate or otherwise violate our patents, trademarks, copyrights or other intellectual property, or those of our licensors. To counter infringement, misappropriation, unauthorized use or other violations, we may be required to file legal claims, which can be expensive and time consuming and divert the time and attention of our management and scientific personnel.

For example, within the last 24 months, we along with Adapt (collectively, the “Plaintiffs”) have filed six separate complaints for patent infringement against Teva Pharmaceuticals Industries Ltd. (“Teva Ltd.”) and Teva Pharmaceuticals USA, Inc., a wholly owned subsidiary of Teva Ltd. (“Teva USA” and, together with Teva Ltd., “Teva”) in the United States District Court for the District of New Jersey arising from Teva USA’s filing of ANDA with the FDA seeking regulatory approval to market a generic version of NARCAN before the expiration of the Company’s patents. Additionally, on October 25, 2018, Plaintiffs filed a similar complaint for patent infringement against Perrigo UK FINCO Limited Partnership (“Perrigo”) in the United States District Court for the District of New Jersey arising from Perrigo’s ANDA filing with the FDA.

For more information about these litigation matters, see Part I, Item 3: Legal Proceedings. We maintain full confidence in our intellectual property portfolio related to NARCAN® and expect that the Company’s patents will continue to be vigorously defended from any infringement. However, there can be no assurances that we will be successful with respect to these litigation matters or any other litigation matters which may arise in the ordinary course of our business. Such a failure may have a material impact on our business, results of operations and financial condition in the future.

We may not be able to prevent, alone or with our licensees or any future licensors, infringement, misappropriation or other violations of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the United States. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their patents. In addition, in a patent infringement proceeding, there is a risk that a court will decide that a patent of ours is invalid or unenforceable, in whole or in part, and that we do not have the right to stop the other party from using the invention at issue. There is also a risk that, even if the validity of such patents is upheld, the court will construe the patent’s claims narrowly or decide that we do not have the right to stop the other party from using the invention at issue on the grounds that our patents do not cover the invention. An adverse outcome in a litigation or proceeding involving our patents could limit our ability to assert our patents against those parties or other competitors, and may curtail or preclude our ability to exclude third parties from making and selling similar or competitive products. Any of these occurrences could adversely affect our competitive business position, business prospects and financial condition. Similarly, if we assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks.

In any infringement, misappropriation or other intellectual property litigation, any award of monetary damages we receive may not be commercially valuable. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during litigation. Moreover, there can be no assurance that we will have sufficient financial or other resources to file and pursue such infringement claims, which typically last for years before they are concluded. Even if we ultimately prevail in such claims, the monetary cost of such litigation and the diversion of the attention of our management and scientific personnel could outweigh any benefit we receive as a result of the proceedings.

We may not be able to protect our intellectual property rights throughout the world, which could negatively impact our business.

Filing, prosecuting and defending patents covering NARCAN®, and any future product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Further, licensing partners may not prosecute patents in certain jurisdictions in which we may obtain commercial rights, thereby precluding the possibility of later obtaining patent protection in these countries. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and may also export infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our product candidates, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to biotechnology products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license. Furthermore, while we intend to protect our intellectual property rights in our expected significant markets, we cannot ensure that we will be able to initiate or maintain similar efforts in all jurisdictions in which we may wish to market our product candidates. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate, which may have an adverse effect on our ability to successfully commercialize our product candidates in all of our expected significant foreign markets.

Additionally, the requirements for patentability may differ in certain countries, particularly developing countries. For example, unlike other countries, China has a heightened requirement for patentability, and specifically requires a detailed description of medical uses of a claimed drug. In India, unlike the United States, there is no link between regulatory approval of a drug and its patent status. Furthermore, generic or biosimilar drug manufacturers or other competitors may challenge the scope, validity or enforceability of our or our licensors' patents, requiring us or our licensees or any future licensors to engage in complex, lengthy and costly litigation or other proceedings. In addition, certain countries in Europe and developing countries, including China and India, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In those countries, we and our licensees or any future licensors may have limited remedies if patents are infringed or if we or our licensees or any future licensors are compelled to grant a license to a third party, which could materially diminish the value of those patents. This could limit our potential revenue opportunities. Accordingly, our and our licensees' or any future licensors' efforts to enforce intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we own or license.

We may be subject to claims that we or our employees, consultants, contractors or advisors have infringed, misappropriated or otherwise violated the intellectual property of a third party, or claiming ownership of what we regard as our own intellectual property.

Many of our employees were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees do not use the intellectual property and other proprietary information, know-how or trade secrets of others in their work for us, we may be subject to claims that we or these employees have used or disclosed such intellectual property or other proprietary information. Litigation may be necessary to defend against these claims.

In addition, while we typically require our employees, consultants and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that we regard as our own. To the extent that we fail to obtain such assignments, such assignments do not contain a self-executing assignment of intellectual property rights or such assignments are breached, we may be forced to bring claims against third parties, or defend claims they

may bring against us, to determine the ownership of what we regard as our intellectual property. If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Such intellectual property rights could be awarded to a third party, and we could be required to obtain a license from such third party to commercialize our technology or products. Such a license may not be available on commercially reasonable terms or at all. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to our management and scientific personnel.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance and annuity fees on any issued patent are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we or our licensors fail to maintain the patents and patent applications covering our products, our competitors might be able to enter the market, which would have a material adverse effect on our business, financial conditions, results of operations and growth prospects.

If we are unable to protect the confidentiality of our trade secrets, the value of our technology could be materially adversely affected and our business would be harmed.

In addition to seeking patents for some of our technology and products, we also rely on trade secrets, including unpatented know-how, technology and other proprietary information, in seeking to develop and maintain a competitive position. We seek to protect these trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, consultants, independent contractors, advisors, corporate collaborators, outside scientific collaborators, contract manufacturers, suppliers and other third parties. We also enter into confidentiality and invention or patent assignment agreements with employees and certain consultants. We also seek to preserve the integrity and confidentiality of our data, trade secrets and know-how by maintaining physical security of our premises and physical and electronic security of our information technology systems. Monitoring unauthorized uses and disclosures is difficult, and we do not know whether the steps we have taken to protect our proprietary technologies will be effective.

Since our inception, we have sought to contract with manufacturers to supply commercial quantities of pharmaceutical formulations and products. As a result, we have disclosed, under confidentiality agreements, various aspects of our technology with potential manufacturers and suppliers. We believe that these disclosures, while necessary for our business, may have resulted and may result in the attempt by potential manufacturers and suppliers to improperly assert ownership claims to our technology in an attempt to gain an advantage in negotiating manufacturing and supplier rights.

We cannot guarantee that our trade secrets and other proprietary and confidential information will not be disclosed or that competitors will not otherwise gain access to our trade secrets. Any party with whom we have executed such an agreement may breach that agreement and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts both within and outside the United States may be less willing or unwilling to protect trade secrets. Further, if any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent such third party, or those to whom they communicate such technology or information, from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor, our business and competitive position could be harmed.

Trade secrets and know-how can be difficult to protect as trade secrets and know-how will over time be disseminated within the industry through independent development, the publication of journal articles, and the movement of personnel skilled in the art from company to company or academic to industry scientific positions. If we fail to prevent material disclosure of the know-how, trade secrets and other intellectual property related to our technologies to third parties, we will not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, results of operations and financial condition. Even if we are able to adequately protect our trade secrets and proprietary information, our trade secrets could otherwise become known or could be independently discovered by our competitors. For

example, competitors could purchase our products and attempt to replicate some or all of the competitive advantages we derive from our development efforts, design around our protected technology or develop their own competitive technologies that fall outside of our intellectual property rights. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, in the absence of patent protection, we would have no right to prevent them, or those to whom they communicate, from using that technology or information to compete with us.

We may not be able to prevent misappropriation of our intellectual property, trade secrets or confidential information, particularly in countries where the laws may not protect those rights as fully as in the United States. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation.

Intellectual property rights do not necessarily address all potential threats to our business.

Once granted, patents may remain open to opposition, interference, re-examination, post-grant review, *inter partes* review, nullification or derivation action in court or before patent offices or similar proceedings for a given period after allowance or grant, during which time third parties can raise objections against such grant. In the course of such proceedings, which may continue for a protracted period of time, the patent owner may be compelled to limit the scope of the allowed or granted claims thus attacked, or may lose the allowed or granted claims altogether. In addition, the degree of future protection afforded by our intellectual property rights is uncertain because even granted intellectual property rights have limitations, and may not adequately protect our business. The following examples are illustrative:

- others may be able to make formulations that are similar to our NARCAN® or other formulations but that are not covered by the claims of our patent rights;
- the patents of third parties may have an adverse effect on our business;
- we or our licensors or any future strategic partners might not have been the first to conceive or reduce to practice the inventions covered by the issued patent or pending patent application that we own or have exclusively licensed;
- we or our licensors or any future strategic partners might not have been the first to file patent applications covering certain of our inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that our pending patent applications will not lead to issued patents;
- issued patents that we may own or that we exclusively license in the future may not provide us with any competitive advantage, or may be held invalid or unenforceable, as a result of legal challenges by our competitors;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- third parties performing manufacturing or testing for us using our product candidates or technologies could use the intellectual property of others without obtaining a proper license;
- we may not develop additional proprietary technologies that are patentable; and
- the patents of others may have an adverse effect on our business.

Should any of these events occur, they could have a material adverse effect on our business, financial condition, results of operations and prospects.

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

We rely on patent, trademark, trade secret and other intellectual property protection in the discovery, development, manufacturing and sale of our products and product candidates. In particular, patent protection is important in the development and eventual commercialization of our products and product candidates. Patents covering our products and product candidates normally provide market exclusivity, which is important in order for our products and product candidates to become profitable.

Certain of our patents will expire in the next 15 years. While we are seeking additional patent coverage which may protect the technology underlying these patents, there can be no assurances that such additional patent protection will be granted, or if granted, that these patents will not be infringed upon or otherwise held enforceable. Even if we are successful in obtaining a patent, patents have a limited lifespan. In the U.S., the natural expiration of a utility patent typically is generally 20 years after it is filed. Various extensions may be available; however, the life of a patent, and the protection it affords, is limited. Without patent protection, our products and product candidates, we may be open to competition from generic versions of such methods and devices

Risks Related to Product Development, Regulatory Approval, Manufacturing and Commercialization

Delays in the completion of, or the termination of, any clinical for any drug candidates could adversely affect our business.

Clinical trials are very expensive, time consuming, unpredictable and difficult to design and implement. The results of clinical trials may be unfavorable, they may continue for several years, and they may take significantly longer to complete and involve significantly more costs than expected. Delays in the commencement or completion of clinical testing could significantly affect product development costs and plans with respect to any of our drug candidates. The commencement and completion of clinical trials can be delayed and experience difficulties for a number of reasons, including delays and difficulties caused by circumstances over which we may have no control. For instance, approvals of the scope, design or trial site may not be obtained from the FDA and other required bodies in a timely manner or at all, agreements with acceptable terms may not be reached in a timely manner or at all with contract research organizations ("CROs"), to conduct the trials, a sufficient number of subjects may not be recruited and enrolled in the trials, and third-party manufacturers of the materials for use in the trials may encounter delays and problems in the manufacturing process, including failure to produce materials in sufficient quantities or of an acceptable quality to complete the trials.

In January 2020, we were notified by the FDA that it was placing the PK study for OPNT003 on clinical hold and the FDA requested additional information in regards to the drug delivery device that we intend to use in this clinical trial. We currently expect to submit the requested data to the FDA and resume the clinical study in the first quarter of 2020. However, if we are unable to satisfactorily address the FDA's requests or we were to experience delays in the commencement or completion of, or if we were to terminate, any clinical or non-clinical trials we pursue in the future, the commercial prospects for the applicable drug candidates may be limited or eliminated, which may prevent us from recouping our investment in research and development efforts for the drug candidate and would have a material adverse effect on our business, results of operations, financial condition and prospects.

If we are not able to obtain any required regulatory approvals for our drug candidates, we will not be able to commercialize our drug candidates and our ability to generate revenue will be limited.

Our current pipeline includes medicines in development for OOR, AUD, OUD, ACO and additional treatment applications. Our products have generated limited revenues. We must successfully complete clinical trials for our drug candidates before we can apply for marketing approval. Even if we complete our clinical trials, it does not assure marketing approval. Our clinical trials may be unsuccessful, which would materially harm our business. Even if our initial clinical trials are successful, we are required to conduct additional clinical trials to establish our drug candidates' safety and efficacy, before an NDA or Biologics License Application ("BLA"), or their foreign equivalents can be filed with the FDA or comparable foreign regulatory authorities for marketing approval of our drug candidates.

Clinical testing is expensive, is difficult to design and implement, can take many years to complete and is uncertain as to outcome. Success in early phases of pre-clinical and clinical trials does not ensure that later clinical trials will be successful, and interim results of a clinical trial do not necessarily predict final results. A failure of one or more of our clinical trials can occur at any stage of testing. We may experience numerous unforeseen events during, or as a result of, the clinical trial process that could delay or prevent our ability to receive regulatory approval or commercialize our drug candidates. The research, testing, manufacturing, labeling, packaging, storage, approval, sale, marketing, advertising and promotion, pricing, export, import and distribution of drug products are subject to extensive regulation by the FDA and other regulatory authorities in the United States and other countries, which regulations differ from country to country. We are not permitted to market our drug in the United States until we receive approval of an NDA from the FDA, or in any foreign countries until we receive the requisite approval from such countries. In the United States, the FDA generally requires the completion of clinical trials of each drug to establish its safety and efficacy and extensive pharmaceutical development to ensure its quality before an NDA is approved. Regulatory authorities in other jurisdictions impose similar requirements. Of the large number of drugs in development, only a small percentage result in the submission of an NDA to the FDA and even fewer are eventually approved for commercialization. If our development efforts for our drug candidates, including regulatory approval, are not successful for their planned indications, or if adequate demand for our drug candidates is not generated, our business will be materially adversely affected.

Our success depends on the receipt of regulatory approval and the issuance of such regulatory approvals is uncertain and subject to a number of risks, including the following:

- the results of toxicology studies may not support the filing of an IND for our drug candidates;
- the FDA or comparable foreign regulatory authorities or Institutional Review Boards, or "IRB", may disagree with the design or implementation of our clinical trials;

- we may not be able to provide acceptable evidence of our drug candidates' safety and efficacy;
- the results of our clinical trials may not be satisfactory or may not meet the level of statistical or clinical significance required by the FDA or other regulatory agencies for marketing approval;
- the dosing of our drug candidates in a particular clinical trial may not be at an optimal level;
- patients in our clinical trials may suffer adverse effects for reasons that may or may not be related to our drug candidates;
- the data collected from clinical trials may not be sufficient to support the submission of an NDA, BLA or other submission or to obtain regulatory approval in the United States or elsewhere;
- the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

Failure to obtain regulatory approval for our drug candidates for the foregoing, or any other reasons, will prevent us from commercializing our drug candidates, and our ability to generate revenue will be materially impaired. We cannot guarantee that regulators will agree with our assessment of the results of the clinical trials we intend to conduct in the future or that such trials will be successful. The FDA and other regulators have substantial discretion in the approval process and may refuse to accept any application or may decide that our data is insufficient for approval and require additional clinical trials, or pre-clinical or other studies. In addition, varying interpretations of the data obtained from pre-clinical and clinical testing could delay, limit or prevent regulatory approval of our drug candidates.

Excluding any activities related to NARCAN®, we have not submitted an NDA or received regulatory approval to market our drug candidates in any jurisdiction. We have only limited experience in filing the applications necessary to gain regulatory approvals and expect to rely on consultants and third party CROs, with expertise in this area to assist us in this process. Securing regulatory approvals to market a product requires the submission of pre-clinical, clinical, and/or pharmacokinetic data, information about product manufacturing processes and inspection of facilities and supporting information to the appropriate regulatory authorities for each therapeutic indication to establish a drug candidate's safety and efficacy for each indication. Our drug candidates may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude us from obtaining regulatory approval or prevent or limit commercial use with respect to one or all intended indications.

The process of obtaining regulatory approvals is expensive, often takes many years, if approval is obtained at all, and can vary substantially based upon, among other things, the type, complexity and novelty of the drug candidates involved, the jurisdiction in which regulatory approval is sought and the substantial discretion of the regulatory authorities. Changes in regulatory approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for a submitted product application may cause delays in the approval or rejection of an application. Regulatory approval obtained in one jurisdiction does not necessarily mean that a drug candidate will receive regulatory approval in all jurisdictions in which we may seek approval, but the failure to obtain approval in one jurisdiction may negatively impact our ability to seek approval in a different jurisdiction. Failure to obtain regulatory marketing approval for our drug candidates in any indication will prevent us from commercializing the drug candidate, and our ability to generate revenue will be materially impaired.

If we fail to successfully commercialize any of our drug candidates, we may need to acquire additional drug candidates and our business will be adversely affected.

We have never directly commercialized any drug candidates and do not have any other compounds in pre-clinical testing, lead optimization or lead identification stages beyond our current drug candidates. We cannot be certain that any of our drug candidates will prove to be sufficiently effective and safe to meet applicable regulatory standards for any indication. If we fail to successfully commercialize any of our drug candidates for their targeted indications, whether as stand-alone therapies or in combination with other therapeutic agents, our business would be adversely affected.

Even if we receive regulatory approval for any of our drug candidates, we may not be able to successfully commercialize the product and the revenue that we generate from its sales, if any, may be limited.

If approved for marketing, the commercial success of our drug candidates will depend upon each product's acceptance by the medical community, including physicians, patients and health care payors. The degree of market acceptance for any of our drug candidates will depend on a number of factors, including:

- demonstration of clinical safety and efficacy;
- relative convenience, dosing burden and ease of administration;

- the prevalence and severity of any adverse effects;
- the willingness of physicians to prescribe our drug candidates, and the target patient population to try new therapies;
- efficacy of our drug candidates compared to competing products;
- the introduction of any new products that may in the future become available targeting indications for which our drug candidates may be approved;
- new procedures or therapies that may reduce the incidences of any of the indications in which our drug candidates may show utility;
- pricing and cost-effectiveness;
- the inclusion or omission of our drug candidates in applicable therapeutic and vaccine guidelines;
- the effectiveness of our own or any future collaborators' sales and marketing strategies;
- limitations or warnings contained in approved labeling from regulatory authorities;
- our ability to obtain and maintain sufficient third-party coverage or reimbursement from government health care programs, including Medicare and Medicaid, private health insurers and other third-party payors or to receive the necessary pricing approvals from government bodies regulating the pricing and usage of therapeutics; and
- the willingness of patients to pay out-of-pocket in the absence of third-party coverage or reimbursement or government pricing approvals.

If any of our drug candidates are approved, but do not achieve an adequate level of acceptance by physicians, health care payors, and patients, we may not generate sufficient revenue and we may not be able to achieve or sustain profitability. Our efforts to educate the medical community and third-party payors on the benefits of our drug candidates may require significant resources and may never be successful.

In addition, even if we obtain regulatory approvals, the timing or scope of any approvals may prohibit or reduce our ability to commercialize our drug candidates successfully. For example, if the approval process takes too long, we may miss market opportunities and give other companies the ability to develop competing products or establish market dominance. Any regulatory approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render our drug candidates not commercially viable. For example, regulatory authorities may approve any of our drug candidates for fewer or more limited indications than we request, may not approve the price we intend to charge for any of our drug candidates, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve any of our drug candidates with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that indication. Further, the FDA or comparable foreign regulatory authorities may place conditions on approvals or require risk management plans or a Risk Evaluation and Mitigation Strategy, ("REMS"), to assure the safe use of the drug. If the FDA concludes a REMS is needed, the sponsor of the NDA must submit a proposed REMS; the FDA will not approve the NDA without an approved REMS, if required. A REMS could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. The FDA may also require a REMS for an approved product when new safety information emerges. Any of these limitations on approval or marketing could restrict the commercial promotion, distribution, prescription or dispensing of our drug candidates. Moreover, product approvals may be withdrawn for non-compliance with regulatory standards or if problems occur following the initial marketing of the product. Any of the foregoing scenarios could materially harm the commercial success of our drug candidates.

Even if we obtain marketing approval for any of our drug candidates, we will be subject to ongoing obligations and continued regulatory review, which may result in significant additional expense. Additionally, our drug candidates could be subject to labeling and other restrictions and withdrawal from the market and we may be subject to penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with our drug candidates.

Even if we obtain regulatory approval for any of our drug candidates for an indication, the FDA or foreign equivalent may still impose significant restrictions on their indicated uses or marketing or the conditions of approval, or impose ongoing requirements for potentially costly and time-consuming post-approval studies, including Phase 4 clinical trials, and post-market surveillance to monitor safety and efficacy. Our drug candidates will also be subject to ongoing regulatory requirements governing the manufacturing, labeling, packaging, storage, distribution, safety surveillance, advertising, promotion, recordkeeping and reporting of adverse events and other post-market information. These requirements include registration with the FDA, as well as continued compliance with current Good Clinical Practices regulations ("cGCPs"), for any clinical trials that we conduct post-approval. In addition, manufacturers of drug products and their facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with current cGMP, requirements relating to quality control, quality assurance and corresponding maintenance of records and documents.

The FDA has the authority to require a REMS as part of an NDA or after approval, which may impose further requirements or restrictions on the distribution or use of an approved drug, such as limiting prescribing to certain physicians or medical centers

that have undergone specialized training, limiting treatment to patients who meet certain safe-use criteria or requiring patient testing, monitoring and/or enrollment in a registry.

With respect to sales and marketing activities by us or any future partner, advertising and promotional materials must comply with FDA rules in addition to other applicable federal, state and local laws in the United States and similar legal requirements in other countries. In the United States, the distribution of product samples to physicians must comply with the requirements of the U.S. Prescription Drug Marketing Act. Application holders must obtain FDA approval for product and manufacturing changes, depending on the nature of the change. We may also be subject, directly or indirectly through our customers and partners, to various fraud and abuse laws, including, without limitation, the U.S. Anti-Kickback Statute, U.S. False Claims Act, and similar state laws, which impact, among other things, our proposed sales, marketing, and scientific/educational grant programs. If we participate in the U.S. Medicaid Drug Rebate Program, the Federal Supply Schedule of the U.S. Department of Veterans Affairs, or other government drug programs, we will be subject to complex laws and regulations regarding reporting and payment obligations. All of these activities are also potentially subject to U.S. federal and state consumer protection and unfair competition laws. Similar requirements exist in many of these areas in other countries.

In addition, if any of our drug candidates are approved for a particular indication, our product labeling, advertising and promotion would be subject to regulatory requirements and continuing regulatory review. The FDA strictly regulates the promotional claims that may be made about prescription products. In particular, a product may not be promoted for uses that are not approved by the FDA as reflected in the product's approved labeling. If we receive marketing approval for our drug candidates, physicians may nevertheless legally prescribe our products to their patients in a manner that is inconsistent with the approved label. If we are found to have promoted such off-label uses, we may become subject to significant liability and government fines. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant sanctions. The federal government has levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees of permanent injunctions under which specified promotional conduct is changed or curtailed.

If we or a regulatory agency discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, problems with the facility where the product is manufactured, or we or our manufacturers fail to comply with applicable regulatory requirements, we may be subject to the following administrative or judicial sanctions:

- restrictions on the marketing or manufacturing of the product, withdrawal of the product from the market, or voluntary or mandatory product recalls;
- issuance of warning letters or untitled letters;
- clinical holds;
- injunctions or the imposition of civil or criminal penalties or monetary fines;
- suspension or withdrawal of regulatory approval;
- suspension of any ongoing clinical trials;
- refusal to approve pending applications or supplements to approved applications filed by us, or suspension or revocation of product license approvals;
- suspension or imposition of restrictions on operations, including costly new manufacturing requirements; or
- product seizure or detention or refusal to permit the import or export of product.

The occurrence of any event or penalty described above may inhibit our ability to commercialize our drug candidates and generate revenue. Adverse regulatory action, whether pre- or post-approval, can also potentially lead to product liability claims and increase our product liability exposure.

Obtaining and maintaining regulatory approval of our drug candidates in one jurisdiction does not mean that we will be successful in obtaining regulatory approval of our drug candidates in other jurisdictions.

Obtaining and maintaining regulatory approval of our drug candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction, but a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. For example, even if the FDA grants marketing approval of a drug candidate, comparable regulatory authorities in foreign jurisdictions must also approve the manufacturing, marketing and promotion of the drug candidate in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from those in the United States, including additional preclinical studies or clinical trials, as clinical studies conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, a drug candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval.

Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. If we fail to comply with the regulatory requirements in international markets and/ or to receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our drug candidates will be harmed.

Current and future legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize our drug candidates and affect the prices we may obtain.

In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval for our drug candidates, restrict or regulate post-approval activities and affect our ability to profitably sell our drug candidates. Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We do not know whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our drug candidates, if any, may be. In addition, increased scrutiny by the U.S. Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements.

In the United States, the Medicare Modernization Act, or ("MMA"), changed the way Medicare covers and pays for pharmaceutical products. The legislation expanded Medicare coverage for drug purchases by the elderly and introduced a new reimbursement methodology based on average sales prices for drugs. In addition, this legislation authorized Medicare Part D prescription drug plans to use formularies where they can limit the number of drugs that will be covered in any therapeutic class. As a result of this legislation and the expansion of federal coverage of drug products, we expect that there will be additional pressure to contain and reduce costs. These cost reduction initiatives and other provisions of this legislation could decrease the coverage and price that we receive for our drug candidates and could seriously harm our business. While the MMA applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates, and any reduction in reimbursement that results from the MMA may result in a similar reduction in payments from private payors.

The Affordable Care Act ("ACA") is a sweeping law intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. The ACA revised the definition of "average manufacturer price" for reporting purposes, which could increase the amount of Medicaid drug rebates to states. Further, the law imposed a significant annual fee on companies that manufacture or import branded prescription drug products.

The ACA remains subject to legislative efforts to repeal, modify or delay the implementation of the law. Efforts to date have generally been unsuccessful. If the ACA is repealed or modified, or if implementation of certain aspects of the Health Care Reform Law are delayed, such repeal, modification or delay may materially adversely impact our business, strategies, prospects, operating results or financial condition. We are unable to predict the full impact of any repeal or modification in the implementation of the ACA on us at this time.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted. We expect that additional federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, and in turn could significantly reduce the projected value of certain development projects and reduce or eliminate our profitability.

Our drug candidates may face competition sooner than expected.

Our success will depend in part on our ability to obtain and maintain patent protection for our certain of our drug candidates and technologies and to prevent third parties from infringing upon our proprietary rights. We must also operate without infringing upon patents and proprietary rights of others, including by obtaining appropriate licenses to patents or other proprietary rights held by third parties, if necessary. However, the applications we have filed or may file in the future may never yield patents that protect our inventions and intellectual property assets. Failure to obtain patents that sufficiently cover our formulations and technologies would limit our protection against compounding pharmacies, outsourcing facilities, generic drug manufacturers, pharmaceutical companies and other parties who may seek to copy our products, produce products substantially similar to ours or use technologies substantially similar to those we own.

While the FDA has confirmed a 505(b)(2) pathway for OPNT 003, we also intend to seek data exclusivity or market exclusivity for our other drug candidates provided under the FDCA, and similar laws in other countries. The FDCA provides three years of marketing exclusivity for an NDA, 505(b)(2) NDA or supplement to an existing NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example, for new indications, dosages, or strengths of an existing drug. This three-year exclusivity covers only the conditions associated with the new clinical investigations and does not prohibit the FDA from approving ANDAs for drugs containing the original active agent. Even if our drug candidates are considered to be reference products eligible for three years of exclusivity under the FDCA, another company could market competing products if the FDA approves a full NDA for such product containing the sponsor's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of the products. Moreover, an amendment or repeal of the FDCA could result in a shorter exclusivity period for our drug candidates, which would have a material adverse effect on our business.

If we market any of our drug candidates in a manner that violates healthcare fraud and abuse laws, or if we violate government price reporting laws, we may be subject to civil or criminal penalties.

The FDA enforces laws and regulations which require that the promotion of pharmaceutical products be consistent with the approved prescribing information. While physicians may prescribe an approved product for a so-called "off label" use, it is unlawful for a pharmaceutical company to promote its products in a manner that is inconsistent with its approved label and any company which engages in such conduct can subject that company to significant liability. Similarly, industry codes in the EU and other foreign jurisdictions prohibit companies from engaging in off-label promotion and regulatory agencies in various countries enforce violations of the code with civil penalties. While we intend to ensure that our promotional materials are consistent with our label, regulatory agencies may disagree with our assessment and may issue untitled letters, warning letters or may institute other civil or criminal enforcement proceedings. In addition to FDA restrictions on marketing of pharmaceutical products, several other types of state and federal healthcare fraud and abuse laws have been applied in recent years to restrict certain marketing practices in the pharmaceutical industry. These laws include the U.S. Anti-Kickback Statute, U.S. False Claims Act and similar state laws. Because of the breadth of these laws and the narrowness of the safe harbors, it is possible that some of our business activities could be subject to challenge under one or more of these laws.

The U.S. Anti-Kickback Statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce, or in return for, purchasing, leasing, ordering or arranging for the purchase, lease or order of any healthcare item or service reimbursable under Medicare, Medicaid or other federally financed healthcare programs. This statute has been interpreted broadly to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers and formulary managers on the other. Although there are several statutory exemptions and regulatory safe harbors protecting certain common activities from prosecution, the exemptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchasing or recommending may be subject to scrutiny if they do not qualify for an exemption or safe harbor. Our practices may not, in all cases, meet all of the criteria for safe harbor protection from anti-kickback liability. Moreover, recent health care reform legislation has strengthened these laws. For example, the Health Care Reform Law, among other things, amends the intent requirement of the U.S. Anti-Kickback Statute and criminal health care fraud statutes; a person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it. In addition, the Health Care Reform Law provides that the government may assert that a claim including items or services resulting from a violation of the U.S. Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the U.S. False Claims Act. Federal false claims laws prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government or knowingly making, or causing to be made, a false statement to get a false claim paid.

Over the past few years, several pharmaceutical and other healthcare companies have been prosecuted under these laws for a variety of alleged promotional and marketing activities, such as: allegedly providing free trips, free goods, sham consulting fees and grants and other monetary benefits to prescribers; reporting to pricing services inflated average wholesale prices that were then used by federal programs to set reimbursement rates; engaging in off-label promotion that caused claims to be submitted to Medicare or Medicaid for non-covered, off-label uses; and submitting inflated best price information to the Medicaid Rebate Program to reduce liability for Medicaid rebates. Most states also have statutes or regulations similar to the U.S. Anti-Kickback Statute and the U.S. False Claims Act, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor. Sanctions under these federal and state laws may include substantial civil monetary penalties, exclusion of a manufacturer's products from reimbursement under government programs, substantial criminal fines and imprisonment.

We will be completely dependent on third parties to manufacture our drug candidates, and our commercialization of our drug candidates could be halted, delayed or made less profitable if those third parties fail to obtain manufacturing approval from the FDA or comparable foreign regulatory authorities, fail to provide us with sufficient quantities of our drug candidates or fail to do so at acceptable quality levels or prices.

We do not currently have, nor do we plan to acquire, the capability or infrastructure to manufacture the active pharmaceutical ingredient, ("API"), in our drug candidates for use in our clinical trials or for commercial product, if any. In addition, we do not have the capability to encapsulate any of our drug candidates as a finished drug product for commercial distribution. As a result, we will be obligated to rely on contract manufacturers, if and when any of our drug candidates are approved for commercialization. We have not entered into an agreement with any contract manufacturers for commercial supply and may not be able to engage a contract manufacturer for commercial supply of any of our drug candidates on favorable terms to us, or at all.

The facilities used by our contract manufacturers to manufacture our drug candidates must be approved by the FDA or comparable foreign regulatory authorities pursuant to inspections that will be conducted after we submit an NDA or BLA to the FDA or their equivalents to other relevant regulatory authorities. We will not control the manufacturing process of, and will be completely dependent on, our contract manufacturing partners for compliance with cGMPs for manufacture of both active drug substances and finished drug products. These cGMP regulations cover all aspects of the manufacturing, testing, quality control and record keeping relating to our drug candidates. If our contract manufacturers do not successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or others, they will not be able to secure and/or maintain regulatory approval for their manufacturing facilities. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our drug candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our drug candidates, if approved.

Our contract manufacturers will be subject to ongoing periodic unannounced inspections by the FDA and corresponding state and foreign agencies for compliance with cGMPs and similar regulatory requirements. We will not have control over our contract manufacturers' compliance with these regulations and standards. Failure by any of our contract manufacturers to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, failure to grant approval to market any of our drug candidates, delays, suspensions or withdrawals of approvals, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect our business. In addition, we will not have control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. Failure by our contract manufacturers to comply with or maintain any of these standards could adversely affect our ability to develop, obtain regulatory approval for or market any of our drug candidates.

If, for any reason, these third parties are unable or unwilling to perform, we may not be able to terminate our agreements with them, and we may not be able to locate alternative manufacturers or formulators or enter into favorable agreements with them and we cannot be certain that any such third parties will have the manufacturing capacity to meet future requirements. If these manufacturers or any alternate manufacturer of finished drug product experiences any significant difficulties in its respective manufacturing processes for our API or finished products or should cease doing business with us, we could experience significant interruptions in the supply of any of our drug candidates or may not be able to create a supply of our drug candidates at all. Were we to encounter manufacturing issues, our ability to produce a sufficient supply of any of our drug candidates might be negatively affected. Our inability to coordinate the efforts of our third-party manufacturing partners, or the lack of capacity available at our third party manufacturing partners, could impair our ability to supply any of our drug candidates at required levels. Because of the significant regulatory requirements that we would need to satisfy in order to qualify a new bulk or finished product manufacturer, if we face these or other difficulties with our current manufacturing partners, we could experience significant interruptions in the supply of any of our drug candidates if we decided to transfer the manufacture of any of our drug candidates to one or more alternative manufacturers in an effort to deal with the difficulties.

Any manufacturing problem or the loss of a contract manufacturer could be disruptive to our operations and result in lost sales. Additionally, we rely on third parties to supply the raw materials needed to manufacture our potential products. Any reliance on suppliers may involve several risks, including a potential inability to obtain critical materials and reduced control over production costs, delivery schedules, reliability and quality. Any unanticipated disruption to a future contract manufacturer caused by problems at suppliers could delay shipment of any of our drug candidates, increase our cost of goods sold and result in lost sales.

We cannot guarantee that our future manufacturing and supply partners will be able to reduce the costs of commercial scale manufacturing of any of our drug candidates over time. If the commercial-scale manufacturing costs of any of our drug candidates are higher than expected, these costs may significantly impact our operating results. In order to reduce costs, we may need to develop and implement process improvements. However, in order to do so, we will need, from time to time, to notify or make submissions with regulatory authorities, and the improvements may be subject to approval by such regulatory authorities.

We cannot be sure that we will receive these necessary approvals or that these approvals will be granted in a timely fashion. We also cannot guarantee that we will be able to enhance and optimize output in our commercial manufacturing process. If we cannot enhance and optimize output, we may not be able to reduce our costs over time.

Any termination or suspension of, or delays in the commencement or completion of, any necessary studies of any of our drug candidates for any indications could result in increased costs to us, delay or limit our ability to generate revenue and adversely affect our commercial prospects.

The commencement and completion of clinical studies can be delayed for a number of reasons, including delays related to:

- the FDA or a comparable foreign regulatory authority failing to grant permission to proceed and placing the clinical study on hold;
- subjects for clinical testing failing to enroll or remain in our trials at the rate we expect;
- a facility manufacturing any of our drug candidates being ordered by the FDA or other government or regulatory authorities to temporarily or permanently shut down due to violations of cGMP requirements or other applicable requirements, or cross-contaminations of drug candidates in the manufacturing process;
- any changes to our manufacturing process that may be necessary or desired;
- subjects choosing an alternative treatment for the indications for which we are developing our drug candidates, or participating in competing clinical studies;
- subjects experiencing severe or unexpected drug-related adverse effects;
- reports from clinical testing on similar technologies and products raising safety and/or efficacy concerns;
- third-party clinical investigators losing their license or permits necessary to perform our clinical trials, not performing our clinical trials on our anticipated schedule or employing methods consistent with the clinical trial protocol, cGMP requirements, or other third parties not performing data collection and analysis in a timely or accurate manner;
- inspections of clinical study sites by the FDA, comparable foreign regulatory authorities, or IRBs finding regulatory violations that require us to undertake corrective action, result in suspension or termination of one or more sites or the imposition of a clinical hold on the entire study, or that prohibit us from using some or all of the data in support of our marketing applications;
- third-party contractors becoming debarred or suspended or otherwise penalized by the FDA or other government or regulatory authorities for violations of regulatory requirements, in which case we may need to find a substitute contractor, and we may not be able to use some or any of the data produced by such contractors in support of our marketing applications;
- one or more IRBs refusing to approve, suspending or terminating the study at an investigational site, precluding enrollment of additional subjects, or withdrawing its approval of the trial; reaching agreement on acceptable terms with prospective CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- deviations of the clinical sites from trial protocols or dropping out of a trial;
- adding new clinical trial sites;
- the inability of the CRO to execute any clinical trials for any reason; and
- government or regulatory delays or "clinical holds" requiring suspension or termination of a trial.

Product development costs for any of our drug candidates will increase if we have delays in testing or approval or if we need to perform more or larger clinical studies than planned. Additionally, changes in regulatory requirements and policies may occur and we may need to amend study protocols to reflect these changes. Amendments may require us to resubmit our study protocols to the FDA, comparable foreign regulatory authorities, and IRBs for reexamination, which may impact the costs, timing or successful completion of that study. If we experience delays in completion of, or if we, the FDA or other regulatory authorities, the IRB, or other reviewing entities, or any of our clinical study sites suspend or terminate any of our clinical studies of any of our drug candidates, its commercial prospects may be materially harmed and our ability to generate product revenues will be delayed. Any delays in completing our clinical trials will increase our costs, slow down our development and approval process and jeopardize our ability to commence product sales and generate revenues. Any of these occurrences may harm our business, financial condition and prospects significantly. In addition, many of the factors that cause, or lead to, termination or suspension of, or a delay in the commencement or completion of, clinical studies may also ultimately lead to the denial of regulatory approval of our drug candidates. In addition, if one or more clinical studies are delayed, our competitors may be able to bring products to market before we do, and the commercial viability of any of our drug candidates could be significantly reduced.

Clinical drug development involves a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results.

Clinical testing of drug candidates is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. The results of pre-clinical studies and early clinical trials may not be predictive of the results of later-stage clinical trials. We cannot assure you that the FDA or comparable foreign regulatory authorities will view the results as we do or that any future trials of any of our drug candidates will achieve positive results. Drug candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through pre-clinical studies and initial clinical trials. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials. Any future clinical trial results for our drug candidates may not be successful.

In addition, a number of factors could contribute to a lack of favorable safety and efficacy results for any of our drug candidates. For example, such trials could result in increased variability due to varying site characteristics, such as local standards of care, differences in evaluation period and surgical technique, and due to varying patient characteristics including demographic factors and health status.

Although we may pursue expedited regulatory approval pathways for a drug candidate, it may not qualify for expedited development or, if it does qualify for expedited development, it may not actually lead to a faster development or regulatory review or approval process.

We are pursuing track approval under 505(b)(2) for OPNT 003 and we believe there may be an opportunity to accelerate the development of certain of our other drug candidates through one or more of the FDA's expedited programs, such as fast track, breakthrough therapy, accelerated approval or priority review. However, we cannot be assured that any of our drug candidates will qualify for such programs.

For example, a drug may be eligible for designation as a breakthrough therapy if the drug is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening condition and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints. Although breakthrough designation or access to any other expedited program may expedite the development or approval process, it does not change the standards for approval. If we apply for breakthrough therapy designation or any other expedited program for our drug candidates, the FDA may determine that our proposed target indication or other aspects of our clinical development plans do not qualify for such expedited program. Even if we are successful in obtaining a breakthrough therapy designation or access to any other expedited program, we may not experience faster development timelines or achieve faster review or approval compared to conventional FDA procedures. Access to an expedited program may also be withdrawn by the FDA if it believes that the designation is no longer supported by data from our clinical development program. Additionally, qualification for any expedited review procedure does not ensure that we will ultimately obtain regulatory approval for such drug candidate.

We may be exposed to product liability risks, and clinical and preclinical liability risks, which could place a substantial financial burden upon us should we be sued.

Our business exposes us to potential product liability and other liability risks that are inherent in the testing, manufacturing and marketing of pharmaceutical formulations and products. We cannot be sure that claims will not be asserted against us. A successful liability claim or series of claims brought against us could have a material adverse effect on our business, financial condition and results of operations.

We cannot give assurances that we will be able to continue to obtain or maintain adequate product liability insurance on acceptable terms, if at all, or that such insurance will provide adequate coverage against potential liabilities. Claims or losses in excess of any product liability insurance coverage that we may obtain could have a material adverse effect on our business, financial condition and results of operations.

Our products may have undesirable side effects which may delay or prevent marketing approval, or, if approval is received, require it to be taken off the market, require it to include safety warnings or otherwise limit sales of the product.

Unforeseen side effects from our products and product candidates could arise either during clinical development or, if approved, after the products have been marketed. This could cause regulatory approvals for, or market acceptance of, the products to be harder and more costly to obtain.

To date, no serious adverse events have been attributed to our products and product candidates. The results of our planned or any future clinical trials may show that our products and product candidates cause undesirable or unacceptable side effects, which could interrupt, delay or halt clinical trials, and result in delay of, or failure to obtain, marketing approval from the FDA and other regulatory authorities, or result in marketing approval from the FDA and other regulatory authorities with restrictive label warnings. If our product candidates receive marketing approval and we or others later identify undesirable or unacceptable side effects caused by the use of our products:

- regulatory authorities may withdraw their approval of the products, which would force us to remove its products from the market;
- regulatory authorities may require the addition of labeling statements, specific warnings, a contraindication, or field alerts to physicians, pharmacies and others;
- we may be required to change instructions regarding the way the products are administered, conduct additional clinical trials or change the labeling of the products;
- we may be subject to limitations on how it may promote the products;
- sales of the products may decrease significantly;
- we may be subject to litigation or product liability claims; and
- our reputation may suffer.

Any of these events could prevent us or our potential future collaborators from achieving or maintaining market acceptance of the products or could substantially increase commercialization costs and expenses, which in turn could delay or prevent us from generating significant revenues from the sale of our products.

We currently have a limited marketing and sales organization and we have no direct experience marketing pharmaceutical products. If we are unable to establish our own marketing and sales capabilities, or enter into agreements with third parties to market and sell our products after approval, we may not be able to generate product revenues.

We do not have a sales organization for the marketing, sales and distribution of any pharmaceutical products. In order to commercialize our products or any other product candidates we may develop or acquire in the future, we must develop these capabilities on our own or make arrangements with third parties for the marketing, sales and distribution of its products. The establishment and development of our own sales force will be expensive and time consuming and could delay any product launch, and we cannot be certain that it would be able to successfully develop this capability. As a result, we may seek one or more partners to handle some or all of the sales, marketing and distribution of our products. There also may be certain markets within the United States and elsewhere for our products for which we may seek a co-promotion arrangement. However, we may not be able to enter into arrangements with third parties to sell our products on favorable terms, or at all. In the event, we are unable to develop its own marketing and sales force or collaborate with a third party marketing and sales organization, we will not be able to commercialize our products or any other product candidates that we develop, which will negatively impact our ability to generate product revenues. Furthermore, whether we commercialize products on our own or rely on a third party to do so, our ability to generate revenue would be dependent on the effectiveness of the sales force. In addition, to the extent we rely on third parties to commercialize our approved products, we would likely receive less revenues than if we commercialized these products ourselves.

The market for our products is rapidly changing and competitive, and new drugs, which may be developed by others, could impair our ability to maintain and grow our business and remain competitive.

The pharmaceutical industry is subject to rapid and substantial technological change. Developments by others may render our technologies and products noncompetitive or obsolete. We also may be unable to keep pace with technological developments and other market factors. Technological competition from medical device, pharmaceutical and biotechnology companies, universities, governmental entities and others diversifying into the field is intense and is expected to increase. Many of these entities have significantly greater research and development capabilities and budgets than we do, as well as substantially more marketing, manufacturing, financial and managerial resources. These entities represent significant competition for us.

Our reliance on collaborations with third parties to develop and commercialize our products, such as the Adapt Agreement to develop and commercialize, NARCAN® is subject to inherent risks and may result in delays in product development and lost or reduced revenues, restricting our ability to commercialize our products and adversely affecting our profitability.

With respect to the products we have licensed, we depend upon collaborations with third parties to develop these product candidates and also depend substantially upon third parties to commercialize these products. As a result, our ability to develop, obtain regulatory approval of, manufacture and commercialize our existing and possibly future product candidates depends upon our ability to maintain existing, and enter into and maintain new, contractual and collaborative arrangements with others. We also engage, and intend in the future to continue to engage, contract manufacturers and clinical trial investigators.

In addition, although not a primary component of our current strategy, the identification of new compounds or product candidates for development has led us in the past, and may continue to require us, to enter into license or other collaborative agreements with others, including other pharmaceutical companies and research institutions. Such collaborative agreements for the acquisition of new compounds or product candidates would typically require us to pay license fees, make milestone payments and/or pay royalties. Furthermore, these agreements may result in our revenues being lower than if we developed our product candidates and in our loss of control over the development of our product candidates.

Contractors or collaborators may have the right to terminate their agreements with us or reduce their payments to us under those agreements on limited or no notice and for no reason or reasons outside of our control. For example, we may be unable to maintain our relationship with Adapt/EBS on a commercially reasonable basis, if at all, as the Adapt Agreement may be terminated by Adapt/EBS in its sole discretion, either in its entirety or in respect of one or more countries, at any time by providing 60 days prior notice to us. In addition, Adapt/EBS may have similar or more established relationships with our competitors or larger customers which may negatively impact our relationship with Adapt/EBS. Moreover, the loss for any reason of Adapt/EBS as a key partner could have a materially significant and adverse impact on our business. If we are unable to retain Adapt/EBS as a partner on commercially acceptable terms, we may not be able to commercialize NARCAN® and we may experience delays in or suspension of the marketing of our products. The same could apply to other product candidates we may develop or acquire in the future. Our dependence upon third parties to assist with the development and commercialization of our product candidates may adversely affect our ability to generate profits or acceptable profit margins and our ability to develop and deliver such products on a timely and competitive basis. Additionally, our Aegis License Agreement shall expire upon the expiration of our obligation to pay royalties under the Aegis License Agreement; provided, however, that we 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.

If our current or future licensees exercise termination rights they may have, or if these license agreements terminate because of delays in obtaining regulatory approvals, or for other reasons, and we are not able to establish replacement or additional research and development collaborations or licensing arrangements, we may not be able to develop and/or commercialize our product candidates. Moreover, any future collaborations or license arrangements we may enter into may not be on terms favorable to us.

A further risk we face with the collaborations is that business combinations and changes in the collaborator or their business strategy may adversely affect their willingness or ability to complete their obligations to us.

Our current or any future collaborations or license arrangements ultimately may not be successful. Our agreements with collaborators typically allows them discretion in electing whether to pursue various development, regulatory, commercialization and other activities, such as the Adapt Agreement.

If any collaborator were to breach its agreement with us or otherwise fail to conduct collaborative activities in a timely or successful manner, the pre-clinical or clinical development or commercialization of the affected product candidate or research program would be delayed or terminated.

Other risks associated with our collaborative and contractual arrangements with others include the following:

- we may not have day-to-day control over the activities of our contractors or collaborators;
- our collaborators may fail to defend or enforce patents they own on compounds or technologies that are incorporated into the products we develop with them;
- third parties may not fulfill their regulatory or other obligations; and
- we may not realize the contemplated or expected benefits from collaborative or other arrangements; and disagreements may arise regarding a breach of the arrangement, the interpretation of the agreement, ownership of proprietary rights, clinical results or regulatory approvals.

These factors could lead to delays in the development of our product candidates and/or the commercialization of our products or reduction in the milestone payments we receive, or could result in us not being able to commercialize our products. Further, disagreements with our contractors or collaborators could require or result in litigation or arbitration, which would be time-consuming and expensive. Our ultimate success may depend upon the success and performance on the part of these third parties. If we fail to maintain these relationships or establish new relationships as required, development of our product candidates and/or the commercialization of our products will be delayed or may never be realized.

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

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

We are exposed to product liability, non-clinical and clinical liability risks which could place a substantial financial burden upon us should lawsuits be filed against us.

Our business exposes us to potential product liability and other liability risks that are inherent in the testing, manufacturing and marketing of pharmaceutical formulations and products. We expect that such claims are likely to be asserted against us at some point. In addition, the use in our clinical trials of pharmaceutical formulations and products and the subsequent sale of these formulations or products by us or our potential collaborators may cause us to bear a portion of or all product liability risks. Any claim under any existing insurance policies or any insurance policies secured in the future may be subject to certain exceptions, and may not be honored fully, in part, in a timely manner, or at all, and may not cover the full extent of liability we may actually face. Therefore, a successful liability claim or series of claims brought against us could have a material adverse effect on our business, financial condition and results of operations.

Security breaches and other disruptions could compromise our information and expose us to liability, which would cause our business and reputation to suffer.

In the ordinary course of our business, we collect and store sensitive data, including intellectual property, our proprietary business information and that of our customers, suppliers and business partners and personally identifiable information of our customers and employees, in our data centers and on our networks. The secure processing, maintenance and transmission of this information is critical to our operations and business strategy. Despite our security measures, our information technology and infrastructure may be vulnerable to attacks by hackers or breached due to employee error, malfeasance or other disruptions. Any such breach could compromise our networks and the information stored there could be accessed, publicly disclosed, lost or stolen. Any such access, disclosure or other loss of information could result in legal claims or proceedings, liability under laws that protect the privacy of personal information, and regulatory penalties, disrupt our operations and the products we provide to customers, and damage our reputation, and cause a loss of confidence in our products, which could adversely affect our business/operating margins, revenues and competitive position.

Risks Related to Government Regulation of our Industry

Legislative or regulatory reform of the healthcare system may affect our ability to sell our products profitably.

In both the U.S. and certain foreign jurisdictions, there have been a number of legislative and regulatory proposals to change the healthcare system in ways that could impact our ability to sell future products and profitability. On March 23, 2010, President Obama signed into law the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (collectively, “PPACA”), which includes a number of health care reform provisions and requires most U.S. citizens to have health insurance. The new law, among other things, imposes a significant annual fee on companies that manufacture or import branded prescription drug products, addresses a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected, increases the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extends the rebate program to individuals enrolled in Medicaid managed care organizations, and establishes a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer’s outpatient drugs to be covered under Medicare Part D. Substantial new provisions affecting compliance also have been added, which may require modification of business practices with health care practitioners.

In the coming years, additional changes could be made to governmental healthcare programs that could significantly impact the success of our future products, and we could be adversely affected by current and future health care reforms.

We are subject to intense regulation from the U.S. Government and such other governments and quasi-official regulatory bodies where our products are and product candidates may be sold.

Both before and after regulatory approval to market a particular product candidate, including our product candidates, the manufacturing, labeling, packaging, adverse event reporting, storage, advertising, promotion, distribution and record keeping related to the product are subject to extensive, ongoing regulatory requirements, including, without limitation, submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with ("cGMP") requirements and good clinical practice requirements for any clinical trials we conduct post-approval. As a result, we are subject to a number of governmental and other regulatory risks, which include:

- clinical development is a long, expensive and uncertain process; delay and failure can occur at any stage of our clinical trials;
- our clinical trials are dependent on patient enrollment and regulatory approvals; we do not know whether our planned trials will begin on time, or at all, or will be completed on schedule, or at all;
- the FDA or other regulatory authorities may not approve a clinical trial protocol or may place a clinical trial on hold;
- we rely on third parties, such as consultants, contract research organizations, medical institutions and clinical investigators, to conduct clinical trials for our drug candidates and if we or any of our third-party contractors fail to comply with applicable regulatory requirements, such as cGMP requirements, the clinical data generated in our clinical trials may be deemed unreliable and the FDA, the European Medicines Agency or comparable foreign regulatory authorities may require us to perform additional clinical trials;
- if the clinical development process is completed successfully, our ability to derive revenues from the sale of our product candidates will depend on us first obtaining FDA or other comparable foreign regulatory approvals, each of which are subject to unique risks and uncertainties;
- there is no assurance that we will receive FDA or corollary foreign approval for any of our product candidates for any indication; we are subject to government regulation for the commercialization of our product candidates
- we have not received regulatory approval in the United States for the commercial sale of any of our product candidates;
- even if one or more of our product candidates does obtain approval, regulatory authorities may approve such product candidate for fewer or more limited indications than our requests, may not approve the price we intend to charge for our products, may grant approval contingent on the performance of costly post-marketing clinical trials or may approve with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate;
- undesirable side effects caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign authorities;
- later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with the regulatory requirements of FDA and other applicable United Statesc and foreign regulatory authorities could subject us to administrative or judicially imposed sanctions;
- the FDA's policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our drug candidates, and if we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained; and
- we may be liable for contamination or other harm caused by hazardous materials used in the operations of our business.

In addition, our operations are also subject to various federal and state fraud and abuse, physician payment transparency and privacy and security laws, including, without limitation:

- The federal Anti-Kickback Statute, which prohibits, among other things, knowingly and willfully soliciting, receiving, offering or providing remuneration to induce the purchase or recommendation of an item or service reimbursable under a federal healthcare program, such as the Medicare or Medicaid programs. This statute has been applied to pharmaceutical manufacturer marketing practices, educational programs, pricing policies and relationships with healthcare providers. A person or entity does not need to have actual knowledge of this statute or specific intent to violate it to have committed a violation;
- Federal civil and criminal false claims laws and civil monetary penalty laws, including civil whistleblower or qui tam actions that prohibit, among other things, knowingly presenting, or causing to be present, claims for payment or approval to the federal government that are false or fraudulent, knowingly making a false statement material to an obligation to

pay or transmit money or property to the federal government or knowingly concealing or knowingly and improperly avoiding or decreasing an obligation to pay or transmit money or property to the federal government. The government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the false claims statutes;

- The Health Insurance Portability and Accountability Act of 1996 (“HIPAA”) and its implementing regulations, which created federal criminal laws that prohibit, among other things, executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, also imposes certain regulatory and contractual requirements regarding the privacy, security and transmission of individually identifiable health information;
- Federal “sunshine” requirements imposed by the PPACA on drug manufacturers regarding any “transfer of value” made or distributed to physicians and teaching hospitals, and any ownership and investment interests held by such physicians and their immediate family members. Failure to submit the required information may result in civil monetary penalties of up an aggregate of $150,000 per year (and up to an aggregate of $1 million per year for “knowing failures”), for all payments, transfers of value or ownership or investment interests not reported in an annual submission, and may result in liability under other federal laws or regulations; and
- State and foreign law equivalents of each of the above federal laws, such as anti-kickback and false claims laws that may apply to items or services reimbursed by any third-party payor, including commercial insurers; state laws that require drug manufacturers to comply with the industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers; state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and state laws governing the privacy and security of certain health information, many of which differ from each other in significant ways and often are not preempted by HIPAA.

Many of our business practices are subject to scrutiny by regulatory and government enforcement authorities, as well as to lawsuits brought by private citizens under federal and state laws. Failure to comply with applicable law or an adverse decision in lawsuits may result in adverse consequences to us.

The laws governing our conduct in the U.S., and the conduct of collaborators, licensors or licensees on whom the success of our business relies, are enforceable by administrative, civil, and criminal penalties. Violations of laws such as the Federal Food, Drug, and Cosmetic Act, the Social Security Act (including the Anti-Kickback Statute), and the Federal False Claims Act, and any regulations promulgated under the authority of the preceding, may result in a range of enforcement action including jail sentences, fines integrity oversight and reporting obligations and/or exclusion from federal and state healthcare programs, as may be determined by Medicare, Medicaid and the Department of Health and Human Services and other regulatory authorities as well as by the courts in response to actions brought by the Department of Justice. FDA regulates drugs throughout the development process, from preclinical and clinical trials through approval and postmarketing requirements. Failure to fully comply with FDA law may cause the FDA to issue inspectional observations, untitled or warning letters, bring an enforcement action, suspend or withdraw an approved product from the market, require a recall or institute fines or civil fines, or could result in disgorgement of money, operating restrictions, injunctions or criminal prosecution, any of which (whether applied directly to us or to our collaborators, licensors, or licensees) could harm our reputation and our business. There can be no assurance that our activities, or those of our collaborators, licensors or licensees, will not come under the scrutiny of regulators and other government authorities or that our practices will not be found to violate applicable laws, rules and regulations or prompt lawsuits by private citizen "relators" under federal or state false claims laws.

Clinical trials for our product candidates have in some cases or may in the future be conducted outside the United States and not under an IND, and where this is the case, the FDA may not accept data from such trials.

Although the FDA may accept data from clinical trials conducted outside the United States and not under an IND in support of research or marketing applications for our product candidates, this is subject to certain conditions set out in 21 C.F.R. § 312.120. For example, such foreign clinical trials should be conducted in accordance with GCP, including review and approval by an independent ethics committee and obtaining the informed consent from subjects of the clinical trials. The FDA must also be able to validate the data from the study through an onsite inspection if the agency deems it necessary. The foreign clinical data should also be applicable to the United States population and United States medical practice. Other factors that may affect the acceptance of foreign clinical data include differences in clinical conditions, study populations or regulatory requirements between the United States and the foreign country.

Laws impacting the U.S. healthcare system are subject to a great deal of uncertainty, which may result in adverse consequences to our business.

There have been a number of legislative and regulatory proposals to change the healthcare system, reduce the costs of healthcare and change medical reimbursement policies. Doctors, clinics, hospitals and other users of our products may decline to purchase our products to the extent there is uncertainty regarding coverage from government or commercial payors. Further proposed legislation, regulation and policy changes affecting third-party reimbursement are likely. Among other things, Congress has in the past proposed changes to and the repeal of the PPACA, and lawsuits have been brought challenging aspects of the law at various points. There have been repeated recent attempts by Congress to repeal or replace the PPACA. Some of the provisions of the PPACA have yet to be implemented, and there have been legal and political challenges to certain aspects of the PPACA. Since January 2017, President Trump has signed two executive orders and other directives designed to delay, circumvent, or loosen certain requirements mandated by the PPACA. Concurrently, Congress has considered legislation that would repeal and replace all or part of the PPACA. While Congress has previously been successful at passing comprehensive repeal legislation through both Chambers of Congress, it had then been vetoed by former President Obama and full repeal legislation is unlikely in the current political climate. However, Congress has passed two bills affecting the implementation of certain taxes under the PPACA. The Tax Cuts and Jobs Act passed in December of 2017 included a provision that would repeal one of the primary pillars of the law, the PPACA's individual mandate penalty that essentially assessed a monetary penalty or fine on certain individuals who fail to maintain qualifying health coverage for all or part of a year. Additionally, on January 22, 2018, President Trump signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain fees mandated by the PPACA, including the so-called "Cadillac" tax on certain high cost employer-sponsored insurance plans and the annual fee imposed on certain health insurance providers based on market share. Moreover, the Bipartisan Budget Act of 2018 among other things, amends the PPACA, effective January 1, 2019, to increase from 50% to 70% the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D and to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole". Congress may consider other legislation to repeal or replace elements of the PPACA on a provision-by-provision basis. In addition, there have been recent congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, control drug costs, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. We are unable to predict what legislation or regulation, if any, relating to the health care industry or third-party coverage and reimbursement may be enacted in the future at the state or federal level, or what effect such legislation or regulation may have on us. Denial of coverage and reimbursement of our products, or the revocation or changes to coverage and reimbursement policies, could have a material adverse effect on our business, results of operations and financial condition.

We are planning to pursue the FDA 505(b)(2) pathway for our product candidates, and if we are not able to successfully do so, seeking approval of these product candidates through the 505(b)(1) NDA pathway would require full reports of investigations of safety and effectiveness. Although we find the feedback received from the FDA to date generally encouraging toward our interest in pursuing the 505(b)(2) pathway for the treatment of AUD and opioid overdose, such feedback is preliminary only and includes a number of comments and recommendations that we will need to address in our drug development program to meet FDA standards for approval. In addition, our nasally delivered product candidates will include a drug delivery device, and that constituent part will be evaluated by the FDA, as will the combination products as a whole, under our NDA. Even if we are able to pursue the 505(b)(2), we could be subject to legal challenges and regulatory changes which might result in extensive delays or result in our 505(b)(2) application being unsuccessful.

Section 505(b)(2) of the FDA permits the filing of an NDA where at least some of the information required for approval comes from studies that were not conducted by or for the applicant and for which the applicant has not obtained a right of reference. Section 505(b)(2), if applicable to us, would allow an NDA we submit to the FDA to rely in part on data in the public domain or the FDA's prior conclusions regarding the safety and effectiveness of approved compounds, which could expedite the development program for a product candidate by potentially decreasing the amount of clinical data that we would need to generate in order to obtain FDA approval. We plan to pursue this pathway for our product candidates.

If the FDA does not allow us to pursue the Section 505(b)(2) regulatory pathway as anticipated, we would need to reconsider our plans and might not be able to commercialize our product candidates in a cost-efficient manner, or at all. If we were to pursue approval under the 505(b)(1) NDA pathway, we would be subject to more extensive requirements and risks.

In addition, medical products containing a combination of new drugs, biological products, or medical devices are regulated as "combination products" in the United States. Each constituent part of a combination product is subject to the requirements established by the FDA for that type of constituent part, whether a new drug, biologic, or device. In order to facilitate pre-market review of combination products, the FDA designates one of its centers to have primary jurisdiction for the pre-market review and regulation of the overall product based upon a determination by FDA of the primary mode of action of

the combination product, and typically one application (e.g., for a drug/device combination product assigned to CDER, an NDA - either under 505(b)(1) or 505(b)(2)) will be made.

When evaluating products that utilize a specific drug delivery system or device, the FDA will evaluate the characteristics of that delivery system and its functionality, as well as the potential for undesirable interactions between the drug and the delivery system, including the potential to negatively impact the safety or effectiveness of the drug. The FDA review process can be more complicated for combination products, and may result in delays, particularly if novel delivery systems are involved. We rely on third parties for the design and manufacture of the delivery systems for our products, and in some cases for the right to refer to their data on file with the FDA or other regulators. Quality or design concerns with the delivery system, or commercial disputes with these third-parties, could delay or prevent regulatory approval and commercialization of our product candidates.

In some instances over the last few years, certain brand-name pharmaceutical companies and others have objected to the FDA's interpretation of Section 505(b)(2) and legally challenged decisions by the agency. If an FDA decision or action relative to our product candidate, or the FDA's interpretation of Section 505(b)(2) more generally, is successfully challenged, it could result in delays or even prevent the FDA from approving a 505(b)(2) application for our product candidates.

The pharmaceutical industry is highly competitive, and Section 505(b)(2) NDAs are subject to special requirements designed to protect the patent rights of sponsors of previously approved drugs that are referenced in a Section 505(b)(2) NDA. A claim by the applicant that a patent is invalid or will not be infringed is subject to challenge by the patent holder, requirements may give rise to patent litigation and mandatory delays in approval (i.e., a 30-month stay) of a 505(b)(2) application. It is not uncommon for a manufacturer of an approved product to file a citizen petition with the FDA seeking to delay approval of, or impose additional approval requirements for, pending competing products. If successful, such petitions can significantly delay, or even prevent, the approval of the new product. However, even if the FDA ultimately denies such a petition, the FDA may substantially delay approval while it considers and responds to the petition.

Even if we are able to utilize the Section 505(b)(2) regulatory pathway, there is no guarantee this would ultimately lead to accelerated product development or earlier approval. Even if approved pursuant to the Section 505(b)(2) regulatory pathway, a drug may be subject to the same post-approval limitations, conditions and requirements as any other drug.

Risks Related to Ownership of our Common Stock

The price of our Common Stock could be highly volatile due to a number of factors, which could lead to losses by investors and costly securities litigation.

On August 24, 2017, we received approval for up-listing to the Nasdaq Capital Market and our Common Stock began trading on the Nasdaq Capital Market on August 29, 2017. Our Common Stock closed as high as $50.50 and as low as $10.25 per share between August 29, 2017 and March 2, 2020. On March 2, 2020 the closing price of our Common Stock, as reported on the Nasdaq Capital Market was $11.70. Our Common Stock has experienced extreme price fluctuations. Some of the factors leading to this volatility include, but are not limited to:

- fluctuations in our operating results;
- announcements of product releases by us or our competitors;
- announcements of acquisitions and/or partnerships by us or our competitors; and
- general market conditions.

Although shares of our Common Stock currently trade on the Nasdaq Capital Market under the symbol “OPNT”, there is no assurance that our stock will not continue to be volatile while listed on the Nasdaq Capital Market in the future.

We do not anticipate declaring any cash dividends on our Common Stock.

We currently intend to retain any future earnings for use in the operation and expansion of our business. Accordingly, we do not expect to pay any dividends in the foreseeable future, but will review this policy from time to time as circumstances dictate.

Anti-takeover provisions in our charter documents and under Delaware law could prevent or delay transactions that our stockholders may favor and may prevent stockholders from changing the direction of our business or management.

Our Certificate of Incorporation and Bylaws may discourage, delay or prevent a merger or acquisition that our stockholders may consider favorable, including transactions in which stockholders might otherwise receive a premium for their shares, and may also frustrate or prevent any attempt by stockholders to change our direction or management. For example, these provisions:

- prohibit stockholder action by written consent;
- establish advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted on by stockholders at stockholder meetings;
- establish a staggered board of directors such that all members of the Board are not elected at one time;
- allow only the Board to fill any vacancy in the Board by reason of death, resignation or otherwise, or if the number of directors shall be increased; and
- require a vote of a majority of the shares of our outstanding stock entitled to vote at an election of directors to remove a director.

Compliance with changing corporate governance and public disclosure regulations may result in additional expense.

Keeping abreast of, and in compliance with, changing laws, regulations and standards relating to corporate governance and public disclosure, including the Sarbanes-Oxley Act of 2002, and any new Securities and Exchange Commission regulations will require an increased amount of management attention and external resources. We intend to continue to invest all reasonably necessary resources to comply with evolving standards, which may result in increased general and administrative expense and a diversion of management time and attention from revenue-generating activities to compliance activities.

Our Common Stock is thinly traded on the Nasdaq Capital Market exchange and no assurances can be made about stock performance, liquidity, or maintenance of our Nasdaq listing.

Historically, our Common Stock was quoted on the OTCQB, which provided significantly less liquidity than a securities exchange (such as the New York Stock Exchange or the Nasdaq Stock Market). On August 24, 2017, our Common Stock was approved for trading on the Nasdaq Capital Market. Beginning on August 29, 2017, our Common Stock began trading on the Nasdaq Capital Market under the symbol “OPNT”. Although currently listed on the Nasdaq Capital Market, there can be no assurance that we will continue to meet the Nasdaq Capital Market’s minimum listing requirements or that of any other national exchange. In addition, there can be no assurances that a liquid market will be created for our Common Stock. If we are unable to maintain listing on the Nasdaq Capital Market or if a liquid market for our Common Stock does not develop, our common stock may remain thinly traded.

Item 1B. Unresolved Staff Comments.

This information is not required for smaller reporting companies.

Item 2. Properties.

The Company does not currently own any physical property.

On May 29, 2017, we entered into a Sublease (the "Sublease") with Standish Management, LLC to sublease approximately 1,500 square feet of office space located at 201 Santa Monica Boulevard, Suite 500, Santa Monica, CA 90401. Per the terms of the Sublease, the term commenced on August 1, 2017 and as of September 1, 2018 is on a month to month basis. We provided notice to terminate the lease effective July 31, 2019.

On May 7, 2019, we 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 our headquarters. The lease commenced on July 1, 2019 and expires August 31, 2021.

On April 20, 2017, we entered into an Office Service Agreement (the "Office Service Agreement") with Regus and leased approximately 1,000 square feet of office space at 83 Baker Street, London, England, W1U 6AG. The original term of the lease expired May 31, 2018 and effective June 1, 2018 either party may terminate the lease with a 90 day advance notice.
We provided notice to terminate the lease effective July 31, 2019.

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

Item 3. Legal Proceedings.

On September 15, 2016, the Company and Adapt received notice from Teva, pursuant to 21 U.S.C. § 355(j)(2)(B)(ii) (the "September 2016 Notice Letter"), that Teva USA had filed the Teva ANDA with the FDA seeking regulatory approval to market a generic version of NARCAN® before the expiration of the '253 patent. The '253 patent is listed with respect to NARCAN® in the FDA's Approved Drug Products with Therapeutic Equivalents Evaluations publication (commonly referred to as the "Orange Book") and expires on March 16, 2035. Teva's September 2016 Notice Letter asserts that its generic product will not infringe the '253 patent and/or that the '253 patent is invalid or unenforceable. On October 21, 2016, the Plaintiffs filed a complaint for patent infringement against Teva in the United States District Court for the District of New Jersey arising from Teva USA's filing of the Teva ANDA with the FDA with respect to the '253 patent.

On January 3, 2017, the Company and Adapt received notice from Teva, pursuant to 21 U.S.C. § 355(j)(2)(B)(ii) (the "January 2017 Notice Letter"), that Teva USA is seeking regulatory approval to market a generic version of NARCAN® before the expiration of the '747 patent. The '747 patent is listed with respect to NARCAN® in the FDA's Orange Book and expires on March 16, 2035. Teva's January 2017 Notice Letter asserts that its generic product will not infringe the '747 patent or that the '747 patent is invalid or unenforceable. On February 8, 2017, the Plaintiffs filed a complaint for patent infringement against Teva in the United States District Court for the District of New Jersey arising from Teva USA's filing of the Teva ANDA with the FDA with respect to the '747 patent.

On March 17, 2017, the Company and Adapt received notice from Teva, pursuant to 21 U.S.C. § 355(j)(2)(B)(ii) (the "March 2017 Notice Letter"), that Teva USA is seeking regulatory approval to market a generic version of NARCAN before the expiration of the '177 patent. The '177 patent is listed with respect to NARCAN® in the FDA's Orange Book and expires on March 16, 2035. Teva's March 2017 Notice Letter asserts that its generic product will not infringe the '177 patent and/or that the '177 patent is invalid or unenforceable. On April 26, 2017, the Plaintiffs filed a complaint for patent infringement against Teva in the United States District Court for the District of New Jersey arising from Teva USA's filing of the Teva ANDA with the FDA with respect to the '177 patent.

On June 2, 2017, the Company and Adapt received notice from Teva, pursuant to 21 U.S.C. § 355(j)(2)(B)(ii) (the "June 2017 Notice Letter"), that Teva USA is seeking regulatory approval to market a generic version of NARCAN® before the expiration of the '965 patent. The '965 patent is listed with respect to NARCAN® in the FDA's Orange Book and expires on March 16, 2035. Teva's June 2017 Notice Letter asserts that its generic product will not infringe the '965 patent and/or that the '965 patent is invalid or unenforceable. On July 12, 2017, the Plaintiffs filed a complaint for patent infringement against Teva in the United States District Court for the District of New Jersey arising from Teva USA's filing of the Teva ANDA with the FDA with respect to the '965 patent.

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

On October 25, 2018, Emergent BioSolutions' Adapt subsidiaries and Opiant (collectively, the "Plaintiffs") filed a complaint for patent infringement against Perrigo in the United States District Court for the District of New Jersey arising from Perrigo's ANDA filing with the FDA. As a result of timely filing the lawsuit in accordance with the Hatch-Waxman Act, a 30-month stay of approval will be imposed by the FDA on Perrigo's ANDA, which is expected to remain in effect until March 2021 absent an earlier judgment, unfavorable to the Plaintiffs, by the 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 that it had filed fifteen petitions for *inter partes* review ("IPR") 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 ("PTAB") of the United States Patent and Trademark Office. The PTAB instituted IPR's for three of these petitions, and denied institution on twelve of these petitions. The three cases that were instituted are currently pending. Opiant continues to be confident in the intellectual property portfolio related to NARCAN Nasal Spray.

On February 12, 2020, Plaintiffs and Perrigo entered into a settlement agreement to resolve the ongoing litigation. Under the terms of the settlement, Perrigo has received a non-exclusive license under the Company's patents licensed to Adapt to make, have made and market its generic naloxone hydrochloride nasal spray under its own ANDA. Perrigo's license will be effective as of January 5, 2033 or earlier under certain circumstances including circumstances related to the outcome of the current litigation against Teva or litigation against future ANDA filers. The Perrigo settlement agreement is subject to review by the U.S. Department of Justice and the Federal Trade Commission, and entry of an order dismissing the litigation by the U.S. District Court for the District of New Jersey. (See Note 16, Subsequent Events).

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 4. Mine Safety Disclosures.

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Market Information

Our Common Stock trades on the Nasdaq Capital Market under the symbol "OPNT."

Price Range of Common Stock

The following table shows, for the periods indicated, the high and low sale prices per share of our Common Stock as reported by Nasdaq.

	High	Low
Year Ended 2017		
First quarter ended March 31, 2017	$ 8.50	$ 5.60
Second quarter ended June 30, 2017	$ 7.64	$ 5.35
Third quarter ended September 30, 2017	$ 50.50	$ 6.33
Fourth quarter ended December 31, 2017	$ 40.15	$ 18.16
Year Ended 2018		
First quarter ended March 31, 2018	$ 26.50	$ 18.80
Second quarter ended June 30, 2018	$ 20.59	$ 14.31
Third quarter ended September 30, 2018	$ 23.43	$ 12.89
Fourth quarter ended December 31, 2018	$ 18.79	$ 13.84
Year Ended 2019		
First quarter ended March 31, 2019	$ 15.94	$ 13.02
Second quarter ended June 30, 2019	$ 13.98	$ 10.25
Third quarter ended September 30, 2019	$ 16.48	$ 11.26
Fourth quarter ended December 31, 2019	$ 15.96	$ 13.16

Approximate Number of Equity Security Holders

As of February 27, 2020, there were approximately 41 stockholders of record. Because shares of our Common Stock are held by depositories, brokers and other nominees, the number of beneficial holders of our shares is substantially larger than the number of stockholders of record.

Dividends

We have not declared or paid any cash dividends on our Common Stock, and we do not anticipate declaring or paying cash dividends for the foreseeable future. We are not subject to any legal restrictions respecting the payment of dividends, except that we may not pay dividends if the payment would render us insolvent. Any future determination as to the payment of cash dividends on our Common Stock will be at the discretion of our Board and will depend on our financial condition, operating results, capital requirements and other factors that the Board considers to be relevant.

Securities Authorized for Issuance under Equity Compensation Plans

The following table sets forth certain information regarding our equity compensation plans as of December 31, 2019:

Plan Category	Number of securities to be issued upon exercise of outstanding options		Weighted-average exercise price of outstanding options	Number of securities remaining available for future issuance under equity compensation plans
Equity compensation plans approved by security holders	491,950	$	24.08	136,295
Equity compensation plans not approved by security holders	2,454,390	$	6.98	—
Total	2,946,340			136,295

Unregistered Sales of Equity Securities

The following represents a summary of the Company's unregistered issuances of its equity securities during the last three years. Each of the issuances were made pursuant to Section 4(a)(2) of the Securities Act. These issuances qualified for exemption under Section 4(2) since they did not involve a public offering. The offering was not a "public offering" as defined in Section 4(2) due to the insubstantial number of persons involved in the deal, size of the offering, manner of the offering and number of shares offered. The Company did not undertake an offering in which the Company sold a high number of shares to a high number of investors. In addition, the investors had the necessary investment intent as required by Section 4(2) because they agreed to and received share certificates bearing a legend stating that such shares are restricted pursuant to Rule 144 of the Securities Act. This restriction ensures that these shares would not be immediately redistributed into the market and therefore not be part of a "public offering." Based on an analysis of the above factors, the Company has met the requirements to qualify for exemption under Section 4(2) of the Securities Act for these transactions.

Year Ended 2019 - Common Stock

On December 9, 2019, we issued 11,788 shares of our Common Stock pursuant to the LOI, between us and a third party pharmaceutical company, dated November 19, 2015 (see Note 10 - Commitments). We received no proceeds from the issuance of these shares.

Year Ended 2018 - Common Stock

On April 19, 2018, the Company issued 37,866 shares of its Common Stock pursuant to the LOI dated November 19, 2015 (see Note 10 - Commitments). The Company received no proceeds from the issuance of these shares.

On September 5, 2018, the Company issued 160,000 shares of its Common Stock to the Valour Fund, LLC, as a result of Valour's exercise of its option to change its interest in certain product revenues for Common Stock of the Company (see Note 8 - Deferred Revenue).

On December 18, 2018, the Company issued 6,498 shares of its Common Stock to Torreya Partners (Europe) LLP ("Torreya"). These shares were issued as payment in full for a $100 thousand accrued liability owed by the Company to Torreya pursuant to that certain Supplemental Engagement Letter between the Company and Torreya, dated September 8, 2017 (the "Supplemental Agreement").

Year Ended 2017 - Common Stock

On September 8, 2017, we entered into an agreement (the "Supplemental Agreement") with Torreya, which modifies and supplements the Engagement Letter dated December 18, 2014 (the "2014 Agreement") between the Company and Torreya regarding the engagement of Torreya to provide financial advisory services with respect to the licensing of the intellectual and property rights to develop and commercialize certain Products (as defined in the 2014 Agreement) with Adapt. The Supplemental Agreement amends the total consideration to be paid by the Company under the 2014 Agreement from "3.75% of Total Consideration" to, include, among other consideration, shares of Common Stock equal to an aggregate value of $300,000, to be issued by us to Torreya in three equal installments over a 16-month period commencing September 2017. Payments in the

form of shares of Common Stock will be a defined number of shares calculated based upon the average closing price of the Common Stock for the 10 trading days prior to the relevant date for the payment. On September 23, 2017, the Company issued 3,283 shares to the Torreya in relation to the Supplemental Agreement. This issuance of Common Stock to Torreya was made pursuant to Section 4(a)(2) of the Securities Act. On December 22, 2017, the Company issued 3,455 shares to the Torreya in relation to the Supplemental Agreement. This issuance of Common Stock to Torreya was made pursuant to Section 4(a)(2) of the Securities Act.

On September 11, 2017, we issued 7,997 shares of Common Stock as a result of the cashless exercise of 10,000 option shares by a consultant. The non-statutory stock option was granted to the consultant, in exchange for services rendered, on July 15, 2015, was fully vested on the date of grant and had an exercise price of $10.00 per share. We claimed exemption from registration under the Securities Act for the grant of the option and issuance of Common Stock to the consultant under Rule 701 promulgated under the Securities Act ("Rule 701"), in that the option was granted, and the shares of Common Stock were subsequently issued, pursuant to a written contract relating to compensation, as provided by Rule 701.

On June 22, 2017, in consideration for the grant of the License under the License Agreement with Aegis, we agreed to pay Aegis two immaterial upfront payments, of which we may elect to pay up to 50% by issuing our Common Stock to Aegis, with the number of shares to be issued equal to 75% of the average closing price of our Common Stock over the 20 trading days preceding the date of payment.

On March 16, 2017, we issued 10,745 shares of Common Stock pursuant to a binding letter of intent to agree to negotiate and enter into an exclusive license agreement and collaboration agreement (the "LOI") with a pharmaceutical company with certain desirable proprietary information. Per the terms of the LOI, we were obligated to issue these shares upon the one year anniversary of our receipt of a milestone payment from Adapt for the first commercial sale of our product, NARCAN®, in the U.S.

On March 13, 2017, pursuant to the Third Miles Amendment, and in partial consideration for Mr. Miles' continued service to us as an advisor through December 31, 2017, we issued Mr. Miles 1,875 shares of Common Stock; and (ii) granted to Mr. Miles a warrant to purchase 45,000 shares of Common Stock (the "Miles Warrant"). The Miles Warrant, which is fully vested on the date of grant, has an exercise price of $10.00, an expiration date of three years from the date of grant and may be exercised solely by payment of cash.

The issuances described above qualified for exemption under Section 4(2) since it did not involve a public offering. The offering was not a "public offering" as defined in Section 4(2) due to the insubstantial number of persons involved in the deal, size of the offering, manner of the offering and number of shares offered. The Company did not undertake an offering in which the Company sold a high number of shares to a high number of investors. Based on an analysis of the above factors, we believe the Company has met the requirements to qualify for exemption under Section 4(2) of the Securities Act for this transaction.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

We did not repurchase any of our securities during any of the periods presented in this report.

Item 6. Selected Financial Data.

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

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

The following discussion and analysis of the results of operations and financial condition for the years ended December 31, 2019 and December 31, 2018 and financial condition as of December 31, 2019 and December 31, 2018 and should be read in conjunction with the "Cautionary Note Regarding Forward-Looking Statements" contained in Part 1 of this report on Form 10-K (this "Report"), the "Risk Factors" contained in Item 1A of this Report, our consolidated financial statements and the notes thereto contained in Item 8 of this Report, and the other information appearing elsewhere in, or incorporated by reference into this Report.

Overview

We are a specialty pharmaceutical company developing medicines for addictions 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.

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

We developed NARCAN®, a treatment to reverse opioid overdoses, which was conceived, licensed, developed, approved by the FDA and commercialized in less than three years. We plan to replicate this relatively low cost, successful business strategy primarily through developing nasal opioid antagonists in the field of developing pharmacological treatments for substance use, addictive, and eating disorders. We aim to identify and progress drug development opportunities with the potential to file additional New Drug Application ("NDAs") with the FDA within three years. We also plan to identify and progress drug development opportunities with potentially larger markets, potentially larger addressable patient populations and greater revenue potential. In addition, we plan to invest in long-term development opportunities by identifying early stage product candidates with novel modes of action.

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

Comparison of the years ended December 31, 2019 and December 31, 2018.

	For the Year Ended		Increase (Decrease)
Revenues	December 31, 2019	December 31, 2018	Amount
Royalty and licensing revenue	$ 37,592,401	$ 13,262,321	$ 24,330,080
Treatment investment revenue	643,955	250,549	393,406
Grant and contract revenue	2,283,444	469,307	1,814,137
Total revenue	40,519,800	13,982,177	26,537,623
Operating expenses			
General and administrative	12,197,111	11,477,701	719,410
Research and development	9,079,351	8,478,817	600,534
Sales and marketing	611,571	—	611,571
Royalty expenses	7,720,280	1,491,099	6,229,181
License fees	—	13,725,000	(13,725,000)
Total operating expenses	29,608,313	35,172,617	(5,564,304)
Income (loss) from operations	10,911,487	(21,190,440)	32,101,927
Other income, net	504,328	46,407	457,921
Income (loss) before income taxes	11,415,815	(21,144,033)	32,559,848
Income tax (expense) benefit	177,235	(51,283)	228,518
Net income (loss)	$ 11,593,050	$ (21,195,316)	$ 32,788,366

Net Revenue

During the year ended December 31, 2019, we recorded net revenue of $40.5 million, which represents an increase of approximately $26.5 million from the $14.0 million of net revenue recorded during the year ended December 31, 2018. The $26.5 million year-over-year increase in net revenue was primarily due to a $24.3 million increase in revenue related to NARCAN® sales and related milestone payments for the comparable periods. The remaining $2.2 million increase is related to our grant and contract revenue which increased by $1.8 million, and an increase in investment treatment revenue of $0.4 million for the comparable periods.

General and Administrative

For the year ended December 31, 2019 general and administrative expenses totaled $12.2 million, which represents an increase of approximately $0.7 million compared to $11.5 million of general and administrative expenses incurred during the year ended December 31, 2018. Personnel and related expenses increased by $1.4 million, advisory fees increased by $0.8 million, and professional fees increased by $0.1 million, partially offset by a $1.6 million decrease in stock based compensation expense for the year ended December 31, 2019 as compared to the year ended December 31, 2018.

Research and Development

During the year ended December 31, 2019 we recorded research and development expenses totaling $9.1 million, which represents an increase of $0.6 million as compared to the $8.5 million of research and development expenses incurred during the year ended December 31, 2018. The increase in research and development expenses is attributed to a $1.1 million increase for third party expenses associated with our research and development programs, $0.6 million increase for personnel and related expense, partially offset by a decrease in stock based compensation expense of $1.1 million.

Sales and Marketing

During the year ended December 31, 2019 we recorded sales and marketing expenses $0.6 million as we commenced initial pre-commercialization efforts related to our nasal nalmafene product, which is under clinical development. We did not have sales and marketing expenses during 2018.

Royalty Expenses

Royalty expenses were approximately $7.7 million and $1.5 million for the years ended December 31, 2019 and 2018, respectively and are related to NARCAN® sales and related milestone payments we received. During 2019, net sales of NARCAN® increased 64%, as reported by EBS, and as net NARCAN® sales exceeded $200 million during 2019 we received the final milestone payment due us of $13.5 million.

License Fees

We recorded $13.7 million in expense associated with license fees incurred during the year ended December 31, 2018. The license fees relate to the License Agreement with Adapt of which $5.6 million was paid during 2018, and $8.1 million was a liability at December 31, 2018. (see Note 9 - License Fees Payable). All license fees have been paid as of December 31, 2019. There were no license fee expenses during the year ended December 31, 2019.

Other Income (Expense)

The following table details our Other Income (Expense):

	For the Year Ended		
	December 31, 2019	**December 31, 2018**	**Change**
Other income (expense)			
Interest income, net	$ 437,653	$ 144,696	$ 292,957
Gain (loss) on debt settlement	16,503	(49,983)	66,486
Gain (loss) on foreign exchange	50,172	(48,306)	98,478
Total other income	$ 504,328	$ 46,407	$ 457,921

Liquidity and Capital Resources

Our cash balance at December 31, 2019 was $31.0 million, which represents an increase of $6.4 million from the $24.6 million cash balance at December 31, 2018. Our working capital was $33.6 million as of December 31, 2019.

During the year ended December 31, 2019, we received net cash proceeds of approximately $2.7 million from the exercise of stock options and warrants.

On September 27, 2018, the Company completed a registered public offering with Cantor Fitzgerald as underwriter and sold 811,764 shares of its Common stock (including 105,882 shares purchased by Cantor Fitzgerald on September 28, 2018 upon the exercise in full of its right to purchase up to an additional 105,882 shares to cover over-allotments) at a price of $17.00 per share. The Company received approximately $13.0 million of net proceeds from the offering after deducting sales commissions.

In addition, during 2018 the Company sold 239,270 shares of Common Stock for gross proceeds of $4.31 million and received net proceeds of $4.18 million, after sales commissions.

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

	Year ended	
	December 31, 2019	December 31, 2018
Net cash provided by (used in)		
Operating activities	$ 4,063,890	$ (522,972)
Investing activities	(302,475)	—
Financing activities	2,605,420	17,020,707
Net increase in cash and cash equivalents	$ 6,366,835	$ 16,497,735

Cash (used in) provided by operating activities

During the year ended December 31, 2019, net cash provided by operating activities was $4.1 million, which was due to net income of $11.6 million, depreciation and operating lease amortization expense of $0.2 million, stock based compensation and common stock issuance expense of $3.2 million, offset by net changes in assets and liabilities of $10.9 million.

During the year ended December 31, 2018, net cash used in operating activities was $0.5 million, which was due to net loss of $21.2 million mostly offset by the non-cash expenses of $5.8 million for stock compensation expense, $0.8 million related to stock issued for services, and net cash changes in assets and liabilities of $14.1 million.

Cash used in by investing activities

During the year ended December 31, 2019 net cash used in investing activities was $0.3 million from leasehold improvements and related office furniture and equipment purchases.

Cash (used in) provided by financing activities

During the year ended December 31, 2019, net cash provided by financing activities was $2.6 million from the net proceeds received from stock option and warrant exercises.

During the year ended December 31, 2018, net cash provided by financing activities was $17.0 million primarily from net proceeds received from sale of Common Stock.

Plan of Operation

We initiated a Phase 2 clinical trial to evaluate OPNT001, nasal naloxone, as a potential treatment for BN in 2017. The Phase 2 randomized, double-blind, placebo-controlled study evaluated the safety and tolerability of OPNT001, as well as its impact on various clinical outcomes, including changes in eating behavior. The primary endpoint of the study is a reduction in binge eating days. The study included a total of 86 patients across 19 clinical sites in the United Kingdom. Patient enrollment was completed on September 4, 2018. On November 2, 2018, we announced the last patient, last visit and we therefore expect to report top-line data from this trial in the first quarter of 2019. On February 21, 2019, we announced that our Phase 2 clinical trial did not meet the primary endpoint of reducing the number of binging days from baseline to week eight. Key secondary endpoints were also not met. Based on these results, we will not devote additional resources to the development of OPNT001.

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-lasting opioid antagonist for the treatment of opioid overdose. Based on feedback from the FDA in connection with this meeting, we intend to pursue a 505(b)(2) development path, with a potential to submit 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.

On January 27, 2020, the Company received a letter from the FDA formalizing the "clinical hold", which was discussed during a telephone conversation on January 16, 2020, on the clinical study for the Company's product candidate

OPNT003 (intranasal nalmefene) as a potent long-acting opioid antagonist for the treatment of opioid overdose. The FDA has requested additional information be provided to evaluate the sensitization and irritation endpoints of the final finished device.

We have full commercial rights to OPNT003 and we were awarded a grant of approximately $7.4 million from the National Institutes of Health (“NIH”). The grant provides us with additional resources for the ongoing development of OPNT003. We have been awarded approximately $5.6 million funded through the period ended March 31, 2021, with the balance of $1.8 million expected to be funded, subject to available funds and satisfactory progress on the development of OPNT003. We have also received a contract for approximately $4.6 million from the Biological Advance Research and Development Agency (“BARDA”) to fund development of this project through NDA submission. BARDA has awarded approximately $3.0 million of the contract through December 20, 2021, with the balance expected to be funded, subject to satisfactory project progress, availability of funds and certain other conditions. In 2017, NIH leadership called for the development of a stronger, longer-acting formulations of antagonists to counteract the very high potency synthetic opioids that are now claiming thousands of lives each year.

In January 2020, we signed a Letter of Intent with the National Center for Advancing Translational Sciences ("NCATS") to collaborate on the development of OPNT004. NCATS is one of 27 divisions and centers of the NIH. NCATS will provide development resources around certain pre-clinical activities and studies to support our planned filing of an Investigational New Drug application for OPNT004. This collaboration will be carried out under a Cooperative Research and Development Agreement with us and the NIH.

On September 27, 2018, we completed a registered public offering with Cantor Fitzgerald as underwriter and sold 811,764 shares our Common stock at a price of $17.00 per share. The Company received approximately $13.0 million of net proceeds from the offering after deducting underwriting discounts and offering expenses.

During the year ended December 31, 2019, we earned $37.6 million in royalties and milestones under the Adapt Agreement. In addition, during the year ended December 31, 2019, we received $2.7 million from the exercise of stock options and warrants.

On November 14, 2019, we entered into a Open Market Sale Agreement℠ (the "Sales Agreement") with Jefferies LLC, as agent, pursuant to which we may offer and sell, from time to time through Jefferies LLC, shares of our Common Stock. During the year ended December 31, 2019, we did not sell any shares under the Sales Agreement.

After considering the proceeds received during the year ended December 31, 2019, 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.

Net Profit Interests

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

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

Potomac Construction Limited (“Potomac”)

On April 16, 2013, we entered into an agreement with Potomac (as clarified by the letter agreement dated October 15, 2014 (“Potomac Agreement No. 1”)) for funding from Potomac for the research, development, marketing and commercialization of the Opioid Overdose Reversal Treatment Product in the amount of $600 thousand, in exchange for a 6.0% interest in the OORT Net Profit in perpetuity. On April 12, 2017, we entered into an amendment with Potomac whereby Potomac granted us certain buyback rights that have expired as of December 31, 2018.

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

an additional 1.5% interest in the OORT Net Profit in perpetuity. On April 12, 2017, we entered into an amendment with Potomac whereby Potomac granted us certain buyback rights that expired as of December 31, 2018.

On September 9, 2014, we entered into a new agreement with Potomac (as clarified by that certain letter agreement dated October 15, 2014, "Potomac Agreement No. 3") for additional funding from Potomac in the amount of $500 thousand for use by us for any purpose, in exchange for an additional 0.98% interest in the OORT Net Profit in perpetuity. 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. The buyback right has expired as of December 31, 2019.

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

On December 8, 2015, we entered into a new agreement with Potomac ("Potomac Agreement No. 5") for additional funding in the amount of $500 thousand for use by us for any purpose, in exchange for an additional 0.75% interest in the OORT Net Profit in perpetuity. On April 12, 2017, we entered into an amendment with Potomac whereby Potomac granted us the right, during the period from April 12, 2017 until December 17, 2020, to buyback all or any portion of the interest at the price of $500 thousand for the full 0.75% interest (the "Potomac Interest No. 5 Buyback Amount"); provided, that in the event we exercise this right within 3.25 years of the date of the investment, we will pay Potomac 1.8 times the Potomac Interest No. 5 Buyback Amount; provided, further, that in the event we exercise this right within after 3.25 years of the date of the Investment and on or prior to December 17, 2020, we will pay Potomac 3.15 times the Potomac Interest No. 5 Buyback Amount.

Ernst Welmers ("Welmers")

On May 15, 2014, we entered into an agreement with Welmers (the "Welmers Agreement") and received funding from Welmers in the amount of $300 thousand for use by us for any purpose, in exchange for a 1.5% interest in the OORT Net Profit in perpetuity. 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 OORT Net Profit in perpetuity. On July 28, 2014, we received an initial investment of $111.5 thousand from the Foundation in exchange for a 0.22294% interest. On August 13, 2014, September 8, 2014, November 13, 2014 and February 17, 2015, we made capital calls of $422.0 thousand, $444.5 thousand, $1.034 million, and $988.0 thousand, respectively, from the Foundation in exchange for 0.844687%, 0.888906%, 2.067228% and 1.976085% interests, respectively, in the OORT Net Profit. The Opioid Overdose Reversal Treatment Product was approved by the FDA on November 18, 2015, and, as a result of such approval occurring prior to July 22, 2016, the option to exchange its interest for shares of our Common Stock at an exchange rate of 10 shares for every dollar of its investment terminated by its terms.

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, we determined to not continue development efforts on the BED Treatment Product.

Other Activities

In September 2015, we received a $1.6 million commitment from the Foundation which later assigned its interest to Valour, from which we had the right to make capital calls from the Foundation for the research, development, any other activities connected to our opioid antagonist treatments for addictions and related disorders that materially rely on certain studies funded by the Foundation's investment, excluding the Opioid Overdose Reversal Treatment Product (the "Certain Studies Products"), certain operating expenses, and any other purpose consistent with the goals of the Foundation. In exchange for funds invested by the Foundation, Valour currently owns a 2.13% interest in any pre-tax revenue received by us that was derived from the sale of the Certain Studies Products less any and all expenses incurred by and payments made by us in connection with the Certain Studies Products (the "Certain Studies Products Net Revenue"). Additionally, we may buyback, in whole or in part, the 2.13% interest from Valour within 2.5 years or after 2.5 years of the initial investment at a price of two times or 3.5 times, respectively, the relevant investment amount represented by the interests to be bought back. If an aforementioned treatment is not introduced to the market by September 22, 2018, Valour will have a 60-day option to exchange its 2.13% interest for shares of our Common Stock at an exchange rate of one-tenth of a share for every dollar of its investment. In October 2015, December 2015 and May 2016, we made capital calls of $618 thousand, $716 thousand, and $267 thousand from the Foundation in exchange for 0.824%, 0.954% and 0.355333% interests in the aforementioned treatments, respectively. During September 2018, Valour elected to exchange its interest for stock and accordingly we issued 160,000 shares of our Common Stock to Valour.

On March 13, 2017, we entered into a third amendment (the "Third Miles Amendment") to the Senior Advisor Agreement with Brad Miles, dated January 22, 2013 (the "Initial Miles Agreement"), as previously amended on February 24, 2015 (the "First Miles Amendment") and March 19, 2015 (the "Second Miles Amendment" and, together with the Initial Miles Agreement, the First Miles Amendment and the Third Miles Amendment, the "Miles Agreement"). As provided by the Third Miles Amendment, and in consideration for Mr. Miles' continued service to us as an advisor through December 31, 2017, we: (i) paid Mr. Miles $107.8 thousand in cash and issued Mr. Miles 1,875 shares of Common Stock; (ii) granted to Mr. Miles the right to receive, subject to adjustment under the Third Miles Amendment, 1.25% of the Net Profit (as defined by the Third Miles Amendment) generated from the Product (as defined by the Third Miles Amendment) from the Effective Date (as defined by the Third Miles Amendment) (which amounts shall be paid quarterly per the terms of the Third Amendment), and, in the event of a Divestiture (as defined by the Third Miles Amendment), 1.25% of the net proceeds of such sale, subject to adjustments and, in the event of sale of the Company, the Fair Market Value (as defined by the Third Miles Amendment) of the Product; (iii) will pay Mr. Miles $17 thousand per calendar quarter during 2017; and (iv) granted to Mr. Miles a warrant to purchase 45,000 shares of our Common Stock (the "Miles Warrant"). The Miles Warrant, which is fully vested on the date of grant, has an exercise price of $10.00, an expiration date of three years from the date of grant and may be exercised solely by payment of cash. Additionally, pursuant to the Third Amendment, from the Effective Date until the fourth anniversary of the Effective Date, Miles granted us the right to buyback the 1.25% interest or any portion thereof at a price of $187.5 thousand for the full 1.25% interest (the "Miles Buyback Amount"); provided, however, that, in the event we exercise this right within 2.5 years after the Effective Date, we will pay Mr. Miles two times the Miles Buyback Amount; provided, further, that, in the event we exercise such right after 2.5 years after the Effective Date and prior to the four year anniversary of the Effective Date, we will pay Mr. Miles 3.5 times the Miles Buyback Amount. During September, 2019, we notified Mr. Miles of our intent to exercise our right to buy back the entire 1.25% interest in the Product at the Buyback amount of $375,000. The payment was made in September, 2019.

We valued the Miles Warrant using the Black-Scholes option pricing model, which resulted in a value of approximately $229.4 thousand. We recorded the entire $229.4 thousand as a non-recurring, and non-cash, expense during the year ended July 31, 2017. Furthermore, we paid Mr. Miles $51 thousand in cash compensation, which represents payment in full for the first three calendar quarters of 2017.

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% OORT 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. During September, 2019, we notified Welmers of our intent to exercise our right to buy back the entire 0.375% DAVINCI Interest at the Buyback amount of $112,500. The payment was made in October, 2019.

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 Net Profit generated from NARCAN® net sales by Adapt in perpetuity. The following table sets forth the royalty payable to our Net Profit Partners at December 31, 2019:

(in thousands)	**Net Profit %**	**December 31, 2019**
Potomac	10.2%	$ 698
LYL	5.0%	341
Welmers	1.5%	103
Foundation	6.0%	410
Pendergast	1.0%	68
Royalty payable	23.7%	$ 1,620

On February 28, 2018, we were notified that Adapt, 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 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 $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, 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 the Company.

As of December 31, 2019, the maximum amount payable of $8.1 million has been paid by us, as net sales of NARCAN® exceeded $200 million during the 2019 calendar year. No further license fees are payable.

Critical Accounting Policies and Estimates

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

We prepare our consolidated financial statements in conformity with generally accepted accounting principles in the United States. 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 consolidated financial statements and the reported amounts of revenues and expenses during the reporting period. We believe that these estimates are reasonable and have been discussed with the Board; however, actual results could differ from those estimates.

We issue restricted stock to consultants for various services and employees for compensation. Cost for these transactions are measured at the fair value of the consideration received or the fair value of the equity instruments issued, whichever is measurable more reliably measurable.

We issue options and warrants to consultants, directors, and officers as compensation for services. These options and warrants are valued using the Black-Scholes 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 consolidated 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 cash equivalents, accounts receivable, and accounts payable. Fair values were assumed to approximate carrying values for these financial instruments since they are short-term in nature and their carrying amounts approximate fair values or they are receivable or payable on demand.

Revenue Recognition

In May 2014, the FASB issued an accounting standard update (‘ASU”), 2014-09, *Revenue from Contracts with Customers (Topic 606).* This ASU amends the existing accounting standards for revenue recognition and is based on the principle that revenue should be recognized to depict the transfer of goods or services to a customer at an amount that reflects the consideration a company expects to receive in exchange for those goods or services.

On January 1, 2018, we adopted the new Accounting Standards Codification (“ASC”) 606, *Revenue from Contracts with Customers* and 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 are paid accordingly by the royalty report provided by Adapt on a quarterly basis. There is no disaggregation of revenue given that the licensing revenue is based on one agreement, and the nature and timing of revenue is predicated on the sales of NARCAN® reported to us by Adapt each quarter. 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 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. (See Note 8 to the Consolidated Financial Statements - Deferred Revenue).

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 that they fall within the scope of ASU 958, and revenue should be recognized in accordance with Topic 958 guidance. Accordingly, we recognize revenue from our grants and contracts in the period during which the related costs are incurred, provided that the conditions under which the grants and contracts were provided have been met and only perfunctory 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. During the year ended December 31, 2019 and 2018 we recognized net royalty and milestone revenue of $37,592,401 and $13,262,321, respectively related to this agreement.

Treatment Investments

With respect to investments in interests in treatments, if an agreement provides an option that allows the investor in the treatment to convert an interest in a treatment into shares of our Common Stock, then revenue is deferred until such time that the option expires or milestones are achieved that eliminate the investor's right to exercise the option. Upon expiration of the exercise option, the deliverables of the arrangement are reviewed and evaluated under ASC 606. In the event the investor chooses to convert interests into shares of Common Stock, that transaction will be accounted for similar to a sale of shares of Common Stock for cash.

Effect of Inflation

Inflation did not have a significant impact on our net sales, revenues, or income from continuing operations in 2019 and 2018.

Off-Balance Sheet Arrangements

None.

Recent Accounting Pronouncements

We have 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 consolidated financial statements and in this, Report, filed on Form 10-K for the year ended December 31, 2019 (See Note 3 - Summary of Significant Accounting Policies).

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

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

Item 8. Financial Statements and Supplementary Data.

Opiant Pharmaceuticals, Inc.
Index to Consolidated Financial Statements

To the Shareholders and Board of Directors of
Opiant Pharmaceuticals, Inc.
Santa Monica, California

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Opiant Pharmaceuticals, Inc. and its subsidiary (collectively, the "Company") as of December 31, 2019 and 2018, and the related consolidated statements of operations, stockholders' equity, and cash flows for the years then ended, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2019 and 2018, and the results of their operations and their cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ *MaloneBailey, LLP*
www.malonebailey.com
We have served as the Company's auditor since 2013.
Houston, Texas
March 4, 2020

Opiant Pharmaceuticals, Inc.
Consolidated Balance Sheets

	December 31, 2019	December 31, 2018
Assets		
Current assets		
Cash and cash equivalents	$ 30,980,473	$ 24,613,638
Accounts receivable	7,218,367	4,489,317
Prepaid expenses and other current assets	1,055,816	267,623
Total current assets	39,254,656	29,370,578
Other assets		
Property and equipment, net	243,039	—
Right of use assets - operating leases	768,441	—
Patents and patent applications, net	14,373	15,746
Total assets	$ 40,280,509	$ 29,386,324
Liabilities and Stockholders' Equity		
Liabilities		
Current liabilities		
Accounts payable and accrued liabilities	1,316,773	1,132,960
License fees payable	—	5,400,000
Accrued salaries and wages	1,237,661	1,083,644
Royalty payable	1,620,182	998,305
Deferred revenue	918,272	1,212,149
Operating leases - current	516,931	—
Total current liabilities	5,609,819	9,827,058
Long-term liabilities		
Operating leases - long term	254,664	—
License fees payable, net of current portion	—	2,700,000
Total liabilities	5,864,483	12,527,058
Stockholders' equity		
Common stock; par value $0.001; 200,000,000 shares authorized;		
4,186,438 and 3,845,361 shares issued and outstanding at December 31, 2019 and 2018, respectively.	4,187	3,846
Additional paid-in capital	97,239,455	91,276,086
Accumulated deficit	(62,827,616)	(74,420,666)
Total stockholders' equity	34,416,026	16,859,266
Total liabilities and stockholders' equity	$ 40,280,509	$ 29,386,324

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

Opiant Pharmaceuticals, Inc.
Consolidated Statements of Operations

	For the Year Ended December 31, 2019	For the Year Ended December 31, 2018
Revenues		
Royalty and licensing revenue	$ 37,592,401	$ 13,262,321
Treatment investment revenue	643,955	250,549
Grant and contract revenue	2,283,444	469,307
Total Revenue	40,519,800	13,982,177
Operating expenses		
General and administrative	12,197,111	11,477,701
Research and development	9,079,351	8,478,817
Sales and marketing	611,571	—
Royalty expenses	7,720,280	1,491,099
License fees	—	13,725,000
Total operating expenses	29,608,313	35,172,617
Income (loss) from operations	10,911,487	(21,190,440)
Other income (expense)		
Interest income, net	437,653	144,696
Gain (loss) on debt settlement	16,503	(49,983)
Gain (loss) on foreign exchange	50,172	(48,306)
Total other income	504,328	46,407
Income (loss) before income taxes	11,415,815	(21,144,033)
Income tax (expense) benefit	177,235	(51,283)
Net income (loss)	$ 11,593,050	$ (21,195,316)
Income (loss) per share of common stock:		
Basic	$ 2.88	$ (7.10)
Diluted	$ 2.17	$ (7.10)
Weighted average common stock outstanding		
Basic	4,018,464	2,985,335
Diluted	5,342,378	2,985,335

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

Opiant Pharmaceuticals, Inc.
Consolidated Statements of Stockholders' Equity

	Common Stock		Additional Paid-In	Accumulated	
	Shares	Amount	Capital	Deficit	Total
Balance at December 31, 2017	2,535,766	$ 2,536	$ 66,223,066	$ (53,225,350)	$ 13,000,252
Exercise of stock options	50,497	50	(50)	—	—
Exercise of warrants	3,400	3	33,997	—	34,000
Stock issued for services	44,664	45	882,187	—	882,232
Stock issued to net profit partner	160,000	160	1,599,840	—	1,600,000
Stock based compensation	—	—	5,760,432	—	5,760,432
Issuance of common stock for cash, net of issuance costs	1,051,034	1,052	16,776,614	—	16,777,666
Net Loss	—	—	—	(21,195,316)	(21,195,316)
Balance at December 31, 2018	3,845,361	$ 3,846	$ 91,276,086	$ (74,420,666)	$ 16,859,266
Exercise of stock options	318,289	318	2,565,102	—	2,565,420
Exercise of warrants	11,000	11	109,989	—	110,000
Stock issued for services	11,788	12	160,894	—	160,906
Stock based compensation	—	—	3,197,384	—	3,197,384
Offering Fees	—	—	(70,000)	—	(70,000)
Net income	—	—	—	11,593,050	11,593,050
Balance at December 31, 2019	4,186,438	$ 4,187	$ 97,239,455	$ (62,827,616)	$ 34,416,026

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

Opiant Pharmaceuticals, Inc.
Consolidated Statements of Cash Flows

	For the Year Ended December 31, 2019	For the Year Ended December 31, 2018
Cash flows provided by (used in) operating activities		
Net income (loss)	$ 11,593,050	$ (21,195,316)
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:		
Depreciation and amortization	60,809	2,556
Operating leases amortization	176,980	
Issuance of common stock for services	—	732,249
Stock based compensation from issuance of options	3,197,384	5,760,432
(Gain) loss on settlement of debt	(16,503)	49,983
Changes in assets and liabilities:		
Accounts receivable	(2,729,050)	7,207,359
Prepaid expenses and other current assets	(788,194)	465,705
Accounts payable and accrued liabilities	361,223	(1,924,032)
License fees payable	(8,100,000)	8,100,000
Accrued salaries and wages	154,017	370,155
Decrease in operating lease liabilities	(173,826)	—
Royalty payable	621,877	(409,707)
Deferred revenue	(293,877)	317,644
Net cash provided by (used in) operating activities	4,063,890	(522,972)
Cash flows used in investing activities		
Purchase of property and equipment	(302,475)	—
Net cash used in investing activities	(302,475)	—
Cash flows provided by financing activities		
Proceeds from exercise of options and warrants	2,675,420	34,000
Payment of financing costs	(70,000)	(166,419)
Proceeds from sale of common stock	—	17,153,126
Net cash provided by financing activities	2,605,420	17,020,707
Net increase in cash and cash equivalents	6,366,835	16,497,735
Cash and cash equivalents, beginning of year	24,613,638	8,115,903
Cash and cash equivalents, end of year	$ 30,980,473	$ 24,613,638
Supplemental disclosure		
Taxes paid during the year	$ 800	$ 174,000
Non-Cash Investing and Financing Transactions		

Cashless exercise of options	$ 19	$ 50
Issuance of common stock to net profit partner	$ —	$ 1,600,000
Issuance of common stock as settlement of liability	$ 160,906	$ 100,000
Right of use assets obtained in exchange for new lease obligations	$ 948,575	$ —
Offset of deferred financing costs against APIC	$ —	$ 209,042

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

Opiant Pharmaceuticals, Inc.
Notes to Consolidated Financial Statements
For the years ended December 31, 2019 and 2018

Note 1. Organization and Basis of Presentation

Opiant Pharmaceuticals, Inc. (the “Company”), a Nevada corporation, is a specialty pharmaceutical company developing medicines for addictions and drug overdose. The Company was incorporated in the State of Nevada on June 21, 2005 as Madrona Ventures, Inc. and, on September 16, 2009, the Company changed its name to Lightlake Therapeutics Inc. On January 28, 2016, the Company again changed its name to Opiant Pharmaceuticals, Inc. The Company also has developed a treatment to reverse opioid overdoses, which is now known as NARCAN®.

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

Note 2. Liquidity and Financial Condition

The Company had net income of $11.6 million for the year ended December 31, 2019 and has an accumulated deficit of $62.8 million at December 31, 2019. The Company has $33.6 million of working capital at December 31, 2019. The Company has financed its operations from sale of common stock, and through non-equity cash investments by a number of investors, in exchange for an interest in any pre-tax profits received by the Company that was derived from the sale of the Opioid Overdose Reversal Treatment Product less any and all expenses incurred by and payments made by the Company in connection with the Opioid Overdose Reversal Treatment Product ("OORT") (see Note 8 – Deferred Revenue).

During the year ended December 31, 2019, the Company received net cash proceeds of approximately $2.7 million from the exercise of stock options and warrants.

On September 27, 2018, the Company completed a registered public offering with Cantor Fitzgerald as underwriter and sold 811,764 shares of its Common stock (including 105,882 shares purchased by Cantor Fitzgerald upon the exercise in full of its right to purchase up to an additional 105,882 shares to cover over-allotments) at a price of $17.00 per share. The Company received approximately $13.0 million of net proceeds from the offering after deducting sales commissions. In addition, during the year ended December 31, 2018, the Company sold 239,270 shares of Common Stock under the Sales Agreement entered into with Cantor Fitzgerald for gross proceeds of $4.31 million and received net proceeds of $4.18 million, after sales commissions.

The Company believes that it has sufficient capital resources to sustain operations through at least the next twelve months from the date of this filing.

Note 3. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying 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 Securities and Exchange Commission (“SEC”).

Principles of Consolidation

The consolidated financial statements have been prepared in accordance with GAAP and include the accounts for the Company and its wholly-owned subsidiary, Opiant Pharmaceuticals UK Limited. All inter-company transactions and balances have been eliminated in consolidation.

Use of Estimates

The preparation of consolidated financial statements in conformity with GAAP requires 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 reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

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 $31.0 million, and $24.6 million at December 31, 2019 and December 31, 2018 . The Company maintains cash balances at financial institutions insured up to $250,000 by the Federal Deposit Insurance Corporation ("FDIC") and as of December 31, 2019 maintains the majority of its cash balances in money market funds not insured by the FDIC. The Company also transfers certain daily available cash balances to an overnight account which earns interest and the amounts are not insured by the FDIC. Balances in the United Kingdom are insured up to £85,000 by the Financial Services Compensation Scheme (United Kingdom Equivalent). Although the Company’s cash balances exceeded these insured amounts, the Company has not experienced any losses on its cash and cash equivalents for the periods presented.

Accounts Receivable

The Company routinely assesses the recoverability of receivables to determine collectability by considering factors such as historical experience, credit quality, the age of the accounts receivable balances, and current economic conditions that may affect a customer's ability to pay. The Company determines its allowance for doubtful accounts by considering such factors as the length of time balances are past due, the Company’s previous loss history, the customer’s current ability to pay its obligations to the Company and the condition of the general economy and the industry as a whole.

The Company has evaluated its accounts receivable history and determined that no allowance for doubtful accounts is required for the years ended December 31, 2019 and 2018. At December 31, 2019 and 2018 the Company's accounts receivable were primarily concentrated with one party, Adapt.

Long-Lived Assets

The Company follows ASC 360, *Property, Plant, and Equipment*, for its fixed assets. Property and equipment is stated at cost less accumulated depreciation. Depreciation is computed by the straight-line method over estimated useful lives (3 to7 years). The Company’s capitalizes all asset purchases greater than $2,500 having a useful life greater than one year. The Company follows ASC 350, *Intangibles – Goodwill and Other* for its intellectual property asset. Intellectual property consists of patents which are stated at their fair value acquisition cost. Amortization is calculated by the straight-line method over their estimated useful lives (20 years). The Company recorded depreciation and amortization of $60,809 and $2,556 for the years ended December 31, 2019 and 2018, respectively.

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

Earnings (Loss) per Share

The Company follows ASC 260, *Earnings 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 consolidated financial statements.

Fully diluted earnings (loss) per share is computed similar 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.

At December 31, 2019, potentially dilutive common stock equivalents are 3,335,060 which consist of options and warrants. The following table illustrates the dilutive effect of the assumed exercise of the Company's outstanding stock options and warrants, using the treasury stock method, as of December 31, 2019 and 2018:

	Year Ended	Year Ended
Numerator:	December 31, 2019	December 31, 2018
Net Income (loss)	$ 11,593,050	$ (21,195,316)
Denominator:		
Denominator for basic income (loss) per share - weighted average shares	4,018,464	2,985,335
Effect of dilutive securities:		
Stock options and warrants	1,323,914	—
Denominator for diluted income (loss) per share	5,342,378	2,985,335
Income (loss) per share - Basic	$ 2.88	$ (7.10)
Income (loss) per share - Diluted	$ 2.17	$ (7.10)

Research and Development Costs

The Company follows ASC 730, *Research and Development*, and expenses all research and development costs as incurred for which there is no alternative future use. These costs also include the expensing of employee compensation and employee stock based compensation

Foreign Currency Translation

The Company's functional and reporting currency is the United States dollar. Transactions occur in British Pounds and management has adopted ASC 830, *Foreign Currency Translation Matters*. Monetary assets and liabilities denominated in foreign currencies are translated using the exchange rate prevailing at the balance sheet date. Gains and losses arising on translation or settlement of foreign currency denominated transactions or balances are included in the determination of income.

Stock-Based Compensation

ASC 718 *Compensation – Stock Compensation* prescribes accounting and reporting standards for all share-based payment transactions in which employee services are acquired. Transactions include incurring liabilities, or issuing or offering to issue shares, options, and other equity instruments such as employee stock ownership plans and stock appreciation rights. Share-based payments to employees, including grants of employee stock options, are recognized as compensation expense in the consolidated financial statements based on their fair values. That expense is recognized over the period during which an employee is required to provide services in exchange for the award, known as the requisite service period (usually the vesting period).

In June 2018, the Financial Accounting Standards Board (the "FASB") issued Accounting Standards Update ("ASU") No. 2018-07, Compensation—Stock Compensation (Topic 718): Improvements to Non-employee Share-Based Payment Accounting, which aligns the accounting for share-based payment awards issued to non-employees with the guidance applicable to grants to employees. Under this new standard, equity-classified share-based payment awards issued to non-employees will be measured on the grant date, instead of the current requirement to remeasure the awards through the

performance completion date. Further, compensation cost for awards with performance conditions will be recognized when it is probable the conditions will be achieved, rather than upon actual achievement of the conditions. The Company adopted this standard January 1, 2019. The adoption of this guidance did not have a material impact on the Company's consolidated financial statements.

The Company had stock-based compensation of $3.2 million and $5.8 million for the years ended December 31, 2019 and 2018, respectively.

Fair Value of Financial Instruments

ASC 820 *Fair Value Measurements and Disclosures* defines fair value as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. ASC 820 also establishes a fair value hierarchy that distinguishes between (1)market participant assumptions developed based on market data obtained from independent sources (observable inputs) and (2) an entity's own assumptions about market participant assumptions developed based on the best information available in the circumstances (unobservable inputs). The fair value hierarchy consists of three broad levels, which gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (Level 1) and the lowest priority to unobservable inputs (Level 3).

The three levels of the fair value hierarchy are described below:

Level 1 - Unadjusted quoted prices in active markets that are accessible at the measurement date for identical, unrestricted assets or liabilities.

Level 2 - Inputs other than quoted prices included within Level 1 that are observable for the asset or liability, either directly or indirectly, including quoted prices for similar assets or liabilities in active markets; quoted prices for identical or similar assets or liabilities in markets that are not active; inputs other than quoted prices that are observable for the asset or liability (e.g., interest rates); and inputs that are derived principally from or corroborated by observable market data by correlation or other means.

Level 3 - Inputs that are both significant to the fair value measurement and unobservable.

The carrying value of certain on-balance-sheet financial instruments approximated their fair values due to the short-term nature of these instruments. These financial instruments include cash and cash equivalents, accounts receivable, and accounts payable.

At December 31, 2019 and December 31, 2018, the Company did not have any financial assets or liabilities measured and recorded at fair value on the Company's consolidated balance sheets on a recurring basis.

Related Parties

The Company follows ASC 850, *Related Party Disclosures*, for the identification of related parties and disclosure of related party transactions. Related party balances as of December 31, 2019 and 2018 were zero. The Company uses office space free of charge from related parties (see Note 4 - Related Party Transactions).

Revenue Recognition

The Company generates a large majority of revenue from the agreement with Adapt. During the year ended December 31, 2019, the Company recognized 93% of revenue from its agreement with Adapt.

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, the Company adopted the new Accounting Standards Codification ("ASC") 606, *Revenue from Contracts with Customers* using the modified retrospective method, and the Company determined the new guidance does not change the Company's policy of revenue recognition. The Company's primary source of revenue is through the recognition of royalty and milestone payments from Adapt. Milestone revenue is recognized upon successful accomplishment of certain sales targets set forth in the Adapt Agreement. Royalty revenue is determined based on the agreed upon royalty rate applied to NARCAN sales reported by Adapt. There are no performance obligations by the Company and the Company recognizes revenue according to the royalty report provided by Adapt on quarterly basis.

In regards to treatment revenue, the Company received certain investments from investors in return for an interest in its existing treatments. Investors carry an option to exchange investment into shares of the Company. Revenue is deferred until such time that the option expires or milestones are achieved that eliminate the investor's right to exercise the option. Once the option has expired, the Company determined its performance obligations under the agreement which typically is to perform R&D services related to treatments and recognizes revenue over a period of time which is usually the expected research and development period. The treatment revenue is disaggregated by program treatments. (See Note 8 to the Consolidated Financial Statements - Deferred Revenue).

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. The Company has evaluated its 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, the Company recognizes revenue from its 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, the Company provided a global license to develop and commercialize the Company's intranasal naloxone opioid overdose reversal treatment, now known as NARCAN®.

On December 15, 2014, the Company entered into a License Agreement with Adapt. Pursuant to the License Agreement, we provided a global license to develop and commercialize our intranasal naloxone opioid overdose reversal treatment, now known as NARCAN®. In addition, on the SWK Closing Date, in connection with the SWK Purchase Agreement, as disclosed below, we entered into the Adapt Amendment which amends the terms of the License Agreement relating to the grant of a commercial sublicense outside of the United States and diligence efforts for commercialization of our Opioid Overdose Reversal Treatment Product. Under the terms of the Adapt Amendment, Adapt is required to use commercially reasonable efforts to commercialize the Opioid Overdose Reversal Treatment Product in the United States In the event that Adapt wishes to grant a commercial sublicense to a third party in the European Union or the United Kingdom, we have agreed to negotiate an additional amendment to the License Agreement to include reduced financial terms with respect to the commercial sublicense.

The Company also receives payments upon reaching various sales and regulatory milestones, as well as royalty payments for commercial sales of NARCAN® generated by Adapt. During the years ended December 31, 2019 and 2018, the Company recognized royalty and milestone revenue of $37.6 million and $13.3 million, respectively.

Interest in Treatments

With respect to investments in interests in treatments, if an agreement provides an option that allows the investor in the treatment to convert an interest in a treatment into shares of Common Stock of the Company, then revenue is deferred until such time that the option expires or milestones are achieved that eliminate the investor's right to exercise the option. Upon expiration of the exercise option, the deliverables of the arrangement are reviewed and evaluated under ASC 606. In the event the investor chooses to convert interests into shares of Common Stock, that transaction will be accounted for similar to a sale of shares of Common Stock for cash.

Recently Issued 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.

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 Consolidated Balance Sheets, with the expense related to these short-term leases recorded within total operating expenses within the Consolidated Statements of Operations.

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.

In August 2018, the FASB issued ASU 2018-15, *"Customer's Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That Is a Service Contract"* (ASU No. 2018-15). The new standard describes the accounting for implementation, set-up, and other upfront costs incurred in a cloud computing arrangement (CCA). Under the new guidance, customers will assess if a CCA includes a software license and if a CCA does include a software license, implementation and set-up costs will be accounted for consistent with existing internal-use software implementation guidance. Implementation costs associated with a CCA that does not include a software license would be expensed to operating expenses. The standard also provides classification guidance on these implementation costs as well as additional quantitative and qualitative disclosures. The standard is effective for public business entities for fiscal years beginning after December 15, 2019, and interim periods within those fiscal years. The Company will adopt this ASU effective January 1, 2020 using the prospective method and does not expect a material impact on its 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 4. Related Party Transactions

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

Note 5. Accounts Receivable

As of December 31, 2019 the Company had accounts receivable of $7.2 million which relates to royalty revenue from sales of NARCAN®. At December 31, 2019 the Company's accounts receivable were primarily concentrated with one party, Adapt.

Note 6. Prepaid Expenses and Other Current Assets

As of December 31, 2019, the Company had approximately $1.1 million recorded as prepaid expenses and other current assets. Of this amount approximately $0.7 million was for prepaid directors and officers insurance and the remaining $0.4 million was for other prepaid insurance, rent, software services, and other general prepaid items.

As of December 31, 2018, the Company had approximately $268 thousand recorded as prepaid expenses and other current assets. Of this amount approximately $74 thousand was for research and development supplies related to product development work being performed by Renaissance Lakewood, LLC, and the remaining $194 thousand was for prepaid expenses such as rent, insurance, and software licenses.

Note 7. Leases

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

The Company entered into two operating leases during the year ended December 31, 2019 with terms greater than 12 months. In accordance with the guidance of Topic 842, the two leases which are classified as operating leases are included in the Company's Consolidated Balance Sheet as of December 31, 2019. The Company's two operating leases do not include options to renew, do not contain residual value guarantees, do not have variable lease components, or impose significant restrictions or covenants.

Right of use assets, "ROU assets", represent the right to use an underlying asset for the lease term, and lease liabilities represent the obligation to make lease payments over the respective lease term, with the ROU asset adjusted for deferred rent liability. Lease expense is recognized on a straight line basis over the lease term. As the implicit rate on the leases is not determinable, the Company used an estimated incremental borrowing rate of 9% as the discount rate to determine the present value of lease payments. The weighted average discount rate used was 9% and the weighted average remaining lease term is 1.5 years at December 31, 2019. The ROU assets and corresponding operating lease liability recognized at lease inception was$949 thousand.

The following table summarizes information related to the Company's two operating leases and are included in the Company's Balance Sheet as of December 31, 2019.

Balance Sheet descriptions		
Assets:		**(in thousands)**
Right of use assets - operating leases	$	768
Liabilities:		
Operating leases - current	$	517
Operating leases - long term		255
Total lease liabilities	$	772

The following table summarizes the components of operating lease cost for the year ended December 31, 2019.

Lease costs **(in thousands)**		
Operating expenses - lease costs	$	177

As of December 31, 2019, future minimum operating leases payments related to the Company’s operating lease liabilities were as follows:

(in thousands)		
2020	$	542
2021		287
Total lease payments		829
Less imputed interest		(57)
Present value of operating lease liabilities	$	772

Note 8. 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. During the years ended December 31, 2019 and 2018 the Company recognized approximately $115.9 thousand $58 thousand, respectively of revenue relating to the agreement.

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%I nvestor 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 years ended December 31, 2019 and 2018 the Company recognized approximately $313.7 thousand $156.9 thousand, respectively of revenue relating to the 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 years ended December 31, 2019 and 2018, the Company recognized revenue of approximately $214.3 thousand and $35.7 thousand, respectively related to this agreement.

On September 22, 2015, the Company received a $1.6 million commitment from the Foundation which later assigned its interest to Valour in October 2016, from which the Company had the right to make capital calls from the Foundation for the research, development, any other activities connected to the Company's opioid antagonist treatments for addictions and related disorders that materially rely on certain studies funded by the Foundation's investment, excluding the Opioid Overdose Reversal Treatment Product (the "Certain Studies Products"), certain operating expenses, and any other purpose consistent with the goals of the Foundation. In exchange for funds invested by the Foundation, Valour currently owns 2.1333% interest in the Certain Studies Products Net Profit (the " 2.1333% Interest"). The "Certain Studies Net Profit" is defined as any pre-tax revenue received by the Company that was derived from the sale of the Certain Studies Products less any and all expenses incurred by and payments made by the Company in connection with the Certain Studies Products, including but not limited to an allocation of Company overhead based on the proportionate time, expenses and resources devoted by the Company to Certain Studies Product-related activities, which allocation shall be determined in good faith by the Company. Valour also has rights with respect to its up to a 2.1333% Interest if the Certain Studies Product is sold or the Company is sold. Additionally, the Company may buy back, in whole or in part, the 2.1333% Interest from Valour within 2.5 years or after 2.5 years of the initial investment at a price of two times or 3.5 times, respectively, the relevant investment amount represented by the interests to be bought back. If an aforementioned treatment is not introduced to the market by September 22, 2018, Valour will have a 60-day option to exchange its 2.1333% Interest for shares of the Common Stock of the Company at an exchange rate of one-tenth of a share for every dollar of its investment. On October 2, 2015, December 23, 2015, and May 28, 2016, the Company made capital calls of approximately $618 thousand , $715.5 thousand, and $266.5 thousand from the Foundation in exchange for 0.824%, 0.954% and 0.355333% interests in the aforementioned treatments, respectively. The Company will defer recording revenue until such time as Valour's option expires or milestones are achieved that eliminates Valour's right to exercise the option. In the event Valour chooses to exchange its 2.1333% Interest, in whole or in part, for shares of Common Stock of the Company, that transaction will be accounted for similar to a sale of shares of Common Stock for cash. During September 2018 Valour elected to exchange its interest for shares of Common Stock and accordingly the Company issued 160,000 shares of its Common Stock to Valour.

On April 17, 2018, the Company was awarded a grant of approximately $7.4 million from the National Institutes of Health's National Institute on Drug Abuse, ("NIDA"). The grant provides the Company with additional resources for the ongoing development of OPNT003 (intranasal nalmefene), a long-lasting opioid antagonist for the treatment of opioid overdose. The Company has been awarded approximately $5.6 million through the period ending March 31, 2021, with the remaining $1.8 million balance expected to be funded, subject to available funds and satisfactory progress on the development

of OPNT003. Government grants are agreements that generally provide cost reimbursement for certain types of expenditures in return for research and development activities over a contractually defined period. The Company recognizes 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 years ended December 31, 2019 and 2018, the Company received cash of $2.4 million and $1.0 million, respectively and recognized revenue of $2.0 million and $432 thousand, respectively 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. BARDA has awarded approximately $3.0 million of the contract through December 20, 2021, with the balance expected to be funded, subject to satisfactory project progress, availability of funds and certain other conditions. During the year ended December 31, 2019, the Company recognized revenue of $234 thousand related to this contract.

The following is a summary of the Company’s deferred revenue activity for the year ended December 31, 2019 and 2018:

(in thousands)	NIH Grant	BED	Total
Balance as of December 31, 2017	$ —	$ 895	$ 2,495
Cash Received NIH	1,000	—	1,000
Converted to Equity	—	—	(1,600)
Recognized as revenue	(432)	(251)	(683)
Balance as of December 31, 2018	$ 568	$ 644	$ 1,212
Cash Received NIH	2,400	—	2,400
Recognized as revenue	(2,050)	(644)	(2,694)
Balance as of December 31, 2019	$ 918	$ —	$ 918

As of December 31, 2019, the Company had recorded approximately $0.9 million of its deferred revenue as a current liability because the Company expects to recognize that amount as revenue during the next 12 months. Current and long-term deferred revenue are detailed in the following table:

Deferred Revenue (in thousands)	NIH Grant	BED	Total
Current portion	$ 918	$ —	$ 918
Long-term portion	—	—	—
Total	$ 918	$ —	$ 918

Note 9. License Fee Payable

On February 28, 2018, the Company was notified that Adapt, 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. Adapt reduced such milestone payment by $6.25 million pursuant to Section 5.5 of the License Agreement. 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 (see Note 17, Subsequent Events), Adapt has made has made and will in the future make payments to the Third Party Licensee 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 has 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 ended 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 December 31, 2019, the Company has paid the amount payable of $8.1 million as net sales of NARCAN® exceeded $200 million during the nine months ended September 30, 2019. Accordingly, as of December 31, 2019 no further payments are due related to the License Fee Payable.

Note 10. Royalty Payable

The Company entered into various agreements and subsequently received funding from investors for use by the Company for the research and development its OORT Product. In exchange for this funding, the Company agreed to provide investors with interest in the OORT Net Profit generated from its OORT Product in perpetuity. The following table sets forth the royalty payable to certain investors as of December 31, 2019 and 2018:

(in thousands)	Net Profit %	December 31, 2019	December 31, 2018
Potomac	10.2%	$ 698	$ 422
LYL	5.0%	341	206
Welmers	1.5%	103	62
Foundation	6.0%	410	248
Pendergast	1.0%	68	60
Royalty payable	23.7%	$ 1,620	$ 998

In connection with these agreements and a senior advisor agreement, the Company also granted net profit interests in DAVINCI (as defined in the related agreements) (the "DAVINCI interest"). The Company has buy back rights to the DAVINCI interest which it exercised during the year ended December 31, 2019 for a total consideration of approximately $1.25 million which was all paid during 2019.

Note 11. Commitments and Contingencies

Commitments

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

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

During the year ended December 31, 2019, the Company incurred approximately, $995,370 in aggregate fees related to Torreya. As of December 31, 2019 the Company has an accrued liability of $243,560 owed to Torreya.

During the year ended December 31, 2018, the Company incurred approximately $447 thousand in aggregate fees related to Torreya. In addition during December 2018 the Company paid Torreya $100 thousand in cash and issued 6,498 shares of Common Stock representing a total of $200 thousand of fees owed by the Company to Torreya which had been recorded

as accrued liability as of December 31, 2017. As of December 31, 2018 the Company has an accrued liability of $151 thousand owed to Torreya.

b. 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.

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

As of September 30, 2019 the Company was required to issue an additional 11,788 shares of unregistered Common Stock pursuant to the LOI. The Company was obligated to issue these shares as a milestone payment when net NARCAN® Sales exceed $200.0 million, which occurred during the nine months ended September 30, 2019. The shares were issued December 9, 2019, and the Company recorded non-cash research and development expense of $177,409, and a $16,503 gain on settlement of liability recorded to other expense.

c. In October 2016, the Company in-licensed a heroin vaccine from Walter Reed Army Institute of Research ("WRAIR"). In consideration for the license the Company agreed to pay a royalty of 3% of net sales if the Company commercializes the vaccine, or 4% if the vaccine is sublicensed. In addition, the Company agreed to pay a minimum annual royalty of $10 thousand, as well as fixed payments of up to approximately $715.7 thousand if all of the specified milestones are met. During the five months ended December 31, 2017, the Company paid $60 thousand in cash to WRAIR, of which $50 thousand was a non-recurring "execution" fee and the remaining $10 thousand was the minimum annual royalty for the period of September 2017 through August 2018. The $10 thousand minimum annual royalty was recorded as a prepaid expense and is being expensed at the rate of $833 per month, beginning in September 2017 and ending in August 2018.

d. 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. Prior, the Company had a Sublease with Standish Management, LLC to sublease office space on a month-to-month basis, located at 201 Santa Monica Boulevard, Suite 500, Santa Monica, CA 90401, which was the Company's headquarters. The Company provided notice to terminate the lease with Standish Management, LLC effective July 31, 2019.

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 commenced on August 1, 2019 and ends May 31, 2021 with monthly rent of 20,000 GBP. Prior, the Company had an Office Service Agreement to lease office space at 83 Baker Street, London, England, W1U 6AG. Effective May 31, 2018 either party was able to terminate the Office Service Agreement by providing three months advance written notice of termination. The Company provided notice to terminate the lease effective July 31, 2019.

During the years ended December 31, 2019 and 2018 Company incurred approximately $523 thousand and $321 thousand, respectively of rent expense.

e. On June 1, 2017 (the “LYL Effective Date”), the Company 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 the Company certain buyback provisions that have expired as of December 31, 2018. In consideration for LYL entering into the LYL Amendment, upon the Company's receipt after the LYL Effective Date of at least $3 million from (i) SWK under the SWK Purchase Agreement and/or (ii) Adapt under the Adapt Agreement, fifty percent of all actual amounts received by the Company from SWK will be used in determining the Net Profit (as defined in the LYL Agreement).

f. 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 (“Aegis 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 Aegis 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 Aegis Products during the Royalty Term (as defined in the License Agreement) according to a tiered royalty rate based on Annual Net Sales of the Aegis Products by the Company, the Company's sublicensees and affiliates. The Company shall also pay to Aegis a sublicense fee based on a sublicense rate negotiated in good faith by the parties. The License Agreement contains customary representations and warranties, ownership, patent rights, confidentiality, indemnification and insurance provisions. The License Agreement shall expire upon the expiration of the Company's obligation to pay royalties under such License Agreement; provided, however, that the Company shall have the right to terminate the License granted on a product-by-product or country-by-country basis upon 30 days’ prior written notice to Aegis.

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

Under the License Agreement, the Company will be required to pay Aegis $250,000 upon the successful filing of an NDA.

For the years ended December 31, 2019 and 2018, the Company recorded $0 and $350 thousand, respectively in expense associated with the License Agreement.

Contingencies

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

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

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

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

Note 12. Stockholder's Equity

Common Stock

During the year ended December 31, 2019

Common Stock

During the year ended December 31, 2019 the Company issued 299,167 shares of Common Stock as a result of employee stock option exercises presented in the tables below, and received net cash proceeds of approximately $2.7 million.

During the year ended December 31, 2019, the Company issued 19,122 shares of its Common Stock in relation to the cashless exercise of stock options that were granted outside of the Company's 2017 Long-Term Incentive Stock Plan (the "2017 Plan"). A total of 80,000 stock options were exercised with exercise prices between $10.00 and $15.00 per share.

During the year ended December 31, 2019, the Company issued 11,000 shares of its Common Stock as a result of the exercise of stock purchase warrants with an exercise price of $10.00 per share for total proceeds of $110,000.

During the year ended December 31, 2019 the Company issued 11,788 shares of its Common stock with an aggregate value of $160.9 thousand for services provided to the Company.

During the year ended December 31, 2018

During the year ended December 31, 2018, the Company issued 50,497 shares of its Common Stock in relation to the cashless exercise of stock options that were granted outside of the Company's 2017 Long-Term Incentive Stock Plan (the "2017 Plan"). A total of 95,000 stock options were exercised with exercise prices between $7.25 and $10.00 per share.

During the year ended December 31, 2018, the Company issued 3,400 shares of its Common Stock as a result of the exercise of stock purchase warrants with an exercise price of $10.00 per share for total proceeds of $34,000.

During the year ended December 31, 2018 the Company issued 38,166 shares of its Common stock with an aggregate value of $782 thousand for services provided to the Company.

On September 5, 2018, the Company also issued 160,000 shares of Common Stock to Valour Fund, LLC, as a result of Valour's exercise of its option to exchange its interest in certain product revenues for Common Stock of the Company.

On December 18, 2018, the Company issued 6,498 shares of its Common Stock to Torreya. These shares were issued as payment in full for a $100 thousand accrued liability owed by the Company to Torreya pursuant to that certain Supplemental Engagement Letter between the Company and Torreya, dated September 8, 2017 (the "Supplemental Engagement Letter").

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

During the year ended December 31, 2018 under the Sales Agreement with Cantor, the Company sold 239,270 shares of Common Stock for gross proceeds of $4.31 million and received net proceeds of $4.18 million after deducting sales commissions.

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

Stock Options

On September 8, 2017, the Company held its Annual Meeting of Stockholders (the “Annual Meeting”), at which time the 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 of December 31, 2019, the Company had 136,295 shares available for future issuance under the 2017 Plan.

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

Stock option activity for the Pre-2017 Non-Qualified Stock Options for the years ended December 31, 2019 and 2018, 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, 2017	2,980,500	$ 7.33	7.06	$ 46,606,210
Exercised	(95,000)	$ 8.24		
Forfeited	—	$ —		
Outstanding at December 31, 2018	2,885,500	$ 7.30	6.04	$ 20,633,100
Exercised	(379,167)	$ 9.03		
Forfeited	(5,833)	$ 10.00		
Outstanding at December 31, 2019	2,500,500	$ 7.03	5.05	$ 18,426,235
Exercisable at December 31, 2019	2,454,390	$ 6.98	5.10	$ 18,212,329

A summary of the status of the Company's vested and non-vested Pre-2017 Non-Qualified Stock Options as of December 31, 2019 and 2018, are presented below:

	Number of Options	Weighted Average Grant Date Fair Value
Vested at December 31, 2018	150,552	$ 7.92
Non-vested at December 31, 2018	138,350	$ 7.84
Vested at December 31, 2019	86,407	$ 7.84
Non-vested at December 31, 2019	46,110	$ 7.71

During the years ended December 31, 2019 and 2018, the Company recognized approximately $0.2 million and $0.9 million of non-cash expense related to vested Pre-2017 Non-Qualified Stock Options granted in prior periods. As of December 31, 2019, there was $1,235 of unrecognized compensation costs related to non-vested stock options.

The 2017 Plan

The assumptions used in the valuation of options granted under the 2017 Plan during the years ended December 31, 2019 and 2018 were as follows:

	Year Ended December 31, 2019	Year Ended December 31, 2018
Market value of stock on measurement date	$11.26 to $15.65	$14.31 to $24.84
Risk-free interest rate	1.67 % to 2.57%	2.47 % to 3.05%
Dividend yield	—%	—%
Volatility factor	104% to 139%	121% to 324%
Term (years)	5.5 to 6.25	5.5 to 10.0

Stock option activity for options granted under the 2017 Plan during the years ended December 31, 2019 and 2018 is presented in the table below:

	Number of Shares Outstanding	Weighted-average Exercise Price	Weighted-average Remaining Contractual Term (years)	Aggregate Intrinsic Value
Outstanding at December 31, 2017	174,000	$ 34.78	9.71	$ 14,430
Granted	196,550	$ 23.26		
Expired	—			
Forfeited	(27,000)	$ 24.84		
Balance at December 31, 2018	343,550	$ 28.97	8.95	840
Granted	193,700	$ 13.82		
Expired	—			
Forfeited	(45,300)	$ 17.90		
Balance at December 31, 2019	491,950	$ 24.08	8.43	$ 81,888

A summary of the status of the Company's vested and non-vested options granted under the 2017 Plan as of December 31, 2019 and 2018 are presented in the following table:

	Number of Shares	Weighted Average Grant Date Fair Value Per Share
Non-vested at December 31, 2018	288,047	$ 27.62
Vested at December 31, 2018	55,503	$ 34.66
Non-vested at December 31, 2019	299,590	$ 20.35
Vested at December 31, 2019	192,360	$ 27.67

During the year ended December 31, 2019 and 2018, the Company recognized approximately $3.0 million and $4.9 million of non-cash expense related to vested options granted during these periods. As of December 31, 2019, there was approximately $2.4 million of unrecognized compensation costs related to non-vested stock options that were granted under the 2017 Plan.

Restricted Stock Units

Restricted stock activity during the year ended December 31, 2019 is presented in the following table.

	Number of Shares		Grant Date Fair Value Per Share
Restricted stock units outstanding and non-vested	27,000	$	14.51

During the year ended December 31, 2019, the Company recognized approximately $68.0 thousand of non-cash expense related to restricted stock.

Warrants

Warrant activity for the years ended December 31, 2019 and 2018 is presented in the table below:

	Number of Warrants		Weighted-average Exercise Price	Weighted-average Remaining Contractual Term (years)		Aggregate Intrinsic Value
Outstanding at December 31, 2017	357,010	$	9.78	5.57	$	4,708,020
Exercised	(3,400)	$	10.00			
Outstanding at December 31, 2018	353,610	$	9.78	4.60	$	1,651,165
Exercised	(11,000)	$	10.00			
Outstanding at December 31, 2019	342,610	$	9.77	3.71	$	1,585,084

Note 13. Sale of Royalties

On December 13, 2016, the Company entered into the SWK Purchase Agreement with SWK pursuant to which the Company sold, and SWK purchased, the Company's right to receive, commencing on October 1, 2016, certain Royalties (as defined in the SWK Purchase Agreement) arising from the sale by Adapt, pursuant to the Adapt Agreement of NARCAN®.

As of December 31, 2017, all amounts due SWK under the SWK Purchase Agreement have been paid. SWK retains a 10% interest for all royalties and milestones that the Company received in the years ended December 31, 2019 and 2018, and will receive in future years.

Note 14. Potomac Amendment

On April 12, 2017 (the "Potomac Effective Date"), the Company and Potomac Construction Limited ("Potomac") entered into an amendment (the "Potomac Amendment") to the following investment agreements with Potomac to provide for (in the case of Potomac Agreement No. 1 and Potomac Agreement No. 2), or modify (in the case of Potomac Agreement No. 3, Potomac Agreement No. 4 and Potomac Agreement No. 5 (each as defined below)), the Company's right to buyback the Interest (as defined in each Potomac Amendment) in each Potomac Agreement (as defined below) from Potomac: (i) that certain Investment Agreement, dated as of April 16, 2013, as clarified by that certain letter agreement dated October 15, 2014 ("Potomac Agreement No. 1"); (ii) that certain Investment Agreement, dated as of May 30, 2013, as clarified by that certain letter agreement dated October 15, 2014 ("Potomac Agreement No. 2"); (iii) that certain Investment Agreement, dated as of September 9, 2014, as clarified by that certain letter agreement dated October 15, 2014 ("Potomac Agreement No. 3"); (iv) that certain Investment Agreement, dated as of October 31, 2014, as clarified by that certain letter agreement dated October 31, 2014 ("Potomac Agreement No. 4"); and (v) that certain Investment Agreement, dated as of December 8, 2015 ("Potomac Agreement No. 5") ((i)–(v) collectively, the "Potomac Agreements" and, each, a "Potomac Agreement").

As of December 31, 2018, the buyback provisions under the Potomac Amendment for the Potomac Agreement No. 1 and Potomac Agreement No. 2 have expired.

Pursuant to the Potomac Amendment, from the Potomac Effective Date until September 30, 2019, the five year anniversary of the date of the Investment (as defined in Potomac Agreement No. 3) (the "Potomac Interest No. 3 Buyback Expiration Date"), the Company shall have the right to buyback all or any portion of the Interest (as defined in Potomac Agreement No. 3) from Potomac upon written notice to Potomac (the "Potomac Interest No. 3 Buyback Notice"), at the price of $500,000 per 0.98% of Interest (the "Potomac Interest No. 3 Buyback Amount"); provided, that in the event the Potomac Interest No. 3 Buyback Notice is provided within 3.25 years of the date of the Investment, the Company shall pay Potomac 1.8 times the Potomac Interest No. 3 Buyback Amount within ten business days of providing the Potomac Interest No. 3 Buyback Notice; provided, further, that in the event the Potomac Interest No. 3 Buyback Notice is provided after 3.25 years of the date of the Investment and on or prior to the Potomac Interest No. 3 Buyback Expiration Date, the Company shall pay Potomac 3.15 times the Potomac Interest No. 3 Buyback Amount within ten business days of providing the Potomac Interest No. 3 Buyback Notice. As of December 31, 2019 the buyback rights have expired.

Pursuant to the Potomac Amendment, from the Potomac Effective Date until November 28, 2019, the five year anniversary of the date of the Investment (as defined in Potomac Agreement No. 4) (the "Potomac Interest No. 4 Buyback Expiration Date"), the Company shall have the right to buyback all or any portion of the Interest (as defined in Potomac Agreement No. 4) from Potomac upon written notice to Potomac (the "Potomac Interest No. 4 Buyback Notice"), at the price of $500,000 per 0.98% of Interest (the "Potomac Interest No. 4 Buyback Amount"); provided, that in the event the Potomac Interest No. 4 Buyback Notice is provided within 3.25 years of the date of the Investment, the Company shall pay Potomac 1.8 times the Potomac Interest No. 4 Buyback Amount within ten business days of providing the Potomac Interest No. 4 Buyback Notice; provided, further, that in the event the Potomac Interest No. 4 Buyback Notice is provided after 3.25 years of the date of the Investment and on or prior to the Potomac Interest No. 4 Buyback Expiration Date, the Company shall pay Potomac 3.15 times the Potomac Interest No. 4 Buyback Amount within ten business days of providing the Potomac Interest No. 4 Buyback Notice. As of December 31, 2019 the buyback rights have expired.

Pursuant to the Potomac Amendment, from the Potomac Effective Date until December 17, 2020, the five year anniversary of the date of the Investment (as defined in Potomac Agreement No. 5) (the "Potomac Interest No. 5 Buyback Expiration Date"), the Company shall have the right to buyback all or any portion of the Interest (as defined in Potomac Agreement No. 5) from Potomac upon written notice to Potomac (the "Potomac Interest No. 5 Buyback Notice"), at the price of $500,000 per 0.75% of Interest (the "Potomac Interest No. 5 Buyback Amount"); provided, that in the event the Potomac Interest No. 5 Buyback Notice is provided within 3.25 years of the date of the Investment, the Company shall pay Potomac 1.8 times the Potomac Interest No. 5 Buyback Amount within ten business days of providing the Potomac Interest No. 5 Buyback

Notice; provided, further, that in the event the Potomac Interest No. 5 Buyback Notice is provided after 3.25 years of the date of the Investment and on or prior to the Potomac Interest No. 5 Buyback Expiration Date, the Company shall pay Potomac 3.15 times the Potomac Interest No. 5 Buyback Amount within ten business days of providing the Potomac Interest No. 5 Buyback Notice.

Pursuant to the Potomac Amendment, if the Additional Investment (as defined in Potomac Agreement No. 5) is funded by Potomac, then, from the date of funding of such Additional Investment until the five year anniversary of such funding date (the "Potomac Additional Interest Buyback Expiration Date"), the Company shall have the right to buyback all or any portion of the Additional Interest (as defined in Potomac Agreement No. 5) upon written notice to Potomac (the "Potomac Additional Interest Buyback Notice"), at the price of $500,000 per 0.75% of Additional Interest (the "Potomac Additional Interest Buyback Amount"); provided, that in the event the Potomac Additional Interest Buyback Notice is provided within 3.25 years of the date of the Additional Investment, the Company shall pay Potomac 1.8 times the Potomac Additional Interest Buyback Amount within ten business days of providing the Potomac Additional Interest Buyback Notice; provided, further, that in the event the Potomac Additional Interest Buyback Notice is provided after 3.25 years of the date of the Additional Investment and on or prior to the Potomac Additional Interest Buyback Expiration Date, the Company shall pay Potomac 3.15 times the Potomac Additional Interest Buyback Amount within ten business days of providing the Potomac Additional Interest Buyback Notice. However, Potomac opted, at its sole discretion, not to make the $1,000,000 Additional Investment, and the deadline for Potomac to make the Additional Investment has passed.

In consideration for Potomac entering into the Potomac Amendment, the Company agreed to pay Potomac, within 15 business days of the Potomac Effective Date, $159,500. The Company recorded the $159,500 payment to Potomac as a non-recurring general and administrative expense during the year ended July 31, 2017.

Furthermore, the Company granted Potomac the right to receive 2.5525% of the Net Profit (as defined in the Potomac Agreements) generated from DAVINCI (as defined in the Potomac Amendment). In the event that the Company is sold, Potomac will receive 2.5525% of the net proceeds of such sale, after the deduction of all expenses and costs related to such sale. Additionally, from the Potomac Effective Date until the four year anniversary of the Potomac Effective Date (the "Potomac DAVINCI Interest Buyback Expiration Date"), the Company may buyback all or any portion of the DAVINCI Interest (as defined in the Potomac Amendment) upon written notice to Potomac (the "Potomac DAVINCI Interest Buyback Notice), at the price of $382,875 per 2.5525% of DAVINCI Interest (the "Potomac DAVINCI Interest Buyback Amount"); provided, that in the event the Potomac DAVINCI Interest Buyback Notice is provided within 2.5 years of the Potomac Effective Date, the Company shall pay Potomac two times the Potomac DAVINCI Interest Buyback Amount within ten business days of providing the Potomac DAVINCI Interest Buyback Notice; provided, further, that, in the event the Potomac DAVINCI Interest Buyback Notice is provided after 2.5 years of the Potomac Effective Date and on or prior to the Potomac DAVINCI Interest Buyback Expiration Date, the Company will pay Potomac 3.5 times the Potomac DAVINCI Interest Buyback Amount within ten business days of providing the Potomac DAVINCI Interest Buyback Notice. During September, 2019, we notified Potomac of our intent to exercise our right to buy back the entire 2.5525% DAVINCI Interest at the Buyback amount of $765,500. The payment was made in October 2019.

Note 15. Income Taxes

The Company recognizes deferred tax assets and liabilities using the asset and liability method. Deferred tax assets and liabilities are recorded based on the differences between the financial statement and tax bases of assets and liabilities and the tax rates in effect when these differences are expected to reverse. This method requires the reduction of deferred tax assets by a valuation allowance if, based on the weight of available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized. As of December 31, 2019, the Company's deferred tax assets relate to net operating loss ("NOL") carryforwards that were derived from operating losses and stock based compensation from prior years. A full valuation allowance has been applied to the Company's deferred tax assets. The valuation allowance will be reduced when and if the Company determines it is more likely than not that the related deferred income tax assets will be realized. At December 31, 2019, the Company had federal net operating loss carry forwards, which are available to offset future taxable income, of 21,737,936. The Company's NOL carryforwards can be carried forward to offset future taxable income for a period of 20 years for each tax year's loss. These NOL carryforwards begin to expire in 2026. No provision was made for federal income taxes as the Company has significant NOLs. All of the Company's income tax years remained open for examination by taxing authorities. The provision for income taxes differs from the amounts which would be provided by applying the statutory federal income tax rate to the net loss before provision for income taxes for the following reasons:

	December 31, 2019	December 31, 2018
Net loss before taxes at statutory rate	$ 2,852,268	$ (6,015,352)
Permanent items	717,020	1,471,275
Temporary items	(2,169,777)	2,444,934
Income tax expense at statutory rate	1,399,511	(2,099,143)
Valuation allowance	(1,576,746)	2,150,426
Income tax expense per books	$ (177,235)	$ 51,283

Net deferred tax assets consist of the following components as of:

	December 31, 2019	December 31, 2018
Net operating loss carryover at statutory rate	$ 3,960,658	$ 5,753,943
Stock-based compensation expense	3,056,099	4,939,759
Fixed asset depreciation	(24,681)	—
Intangibles amortization	(997)	(1,148)
Other	103,604	2,046,961
Total	$ 7,094,683	$ 12,739,515
Valuation allowance	$ (7,094,683)	$ (12,739,515)
Net deferred tax asset	$ —	$ —

The Company had no uncertain tax positions at December 31, 2019 and December 31, 2018.

On December 22, 2017, H.R. 1, formally known as the Tax Cut and Jobs Act (the "Act") was enacted into law. The Act provides for significant tax law changes and modifications with varying effective dates. The major change that affects the Company is reducing the corporate income tax rate from 35% to 21%. In connection with the Company's initial analysis of the impact of the Tax Act, no discrete net tax benefit or expense in the period ended December 31, 2017 is recorded. This is primarily due to the change in valuation allowance offsets a net benefit or expense for the corporate rate reduction. Open federal tax years are July 31, 2015, July 31, 2016, July 31, 2017, December 31, 2017, and December 21, 2018. Open state tax years are July 31, 2014, July 31, 2015, July 31, 2016, July 31, 2017, December 31, 2017 and December 31, 2018.

Note 16. Subsequent Events

On January 7, 2020, the Company granted options to employees to purchase 78,800 shares of the Company's Common Stock at an exercise price of $13.60 per share, which represents the per share closing price of the Company's Common Stock on the dates of grant. These options were issued under the 2017 Plan and have a ten year term. The options vest as follows: 1/48th of the option shares vest every month on the anniversary of the grant date.

On January 7, 2020, the Company also issued restricted common shares to certain employees for 26,600 shares of the Company's Common Stock. The price of the Company's common stock on the date of issuance was $13.60 per share. The restricted stock options (RSU) were issued under the 2017 Plan. The RSU's vest 25% each year for the next four years on the anniversary of the grant date.

From January 1 through March 2, 2020, the Company issued a total of 52,157 shares of Common Stock in connection with stock option and stock warrant exercises. As a result of the stock option and warrant exercises, the Company received aggregate proceeds of $490,000.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.

None.

Item 9A. 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 Annual Report on Form 10-K, 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.

Internal Control over Financial Reporting

Management's Annual Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rule 13a-15(f) under the Exchange Act. Internal control over financial reporting is a process designed by, or under the supervision of, our Principal Executive Officer and Principal Financial Officer, and effected by our Board, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with GAAP, including those policies and procedures that: (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect our transactions and the disposition of our assets, (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of consolidated financial statements in accordance with GAAP and that receipts and expenditures are being made only in accordance with authorizations of our management and Board, and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of our assets that could have a material effect on the consolidated financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with policies and procedures may deteriorate.

Management conducted an evaluation of the effectiveness of our control over financial reporting based on the 2013 framework in Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this evaluation, management concluded that our internal control over financial reporting was effective as of December 31, 2019.

This Annual Report does not include an attestation report of our registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by our registered public accounting firm pursuant to temporary rules of the SEC that permit us to provide only management's report in this Annual Report.

Changes in Internal Controls over Financial Reporting

There were no significant changes to our internal controls over financial reporting that occurred during the year ended December 31, 2019 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

The information required by this item is incorporated by reference to our Definitive Proxy Statement for our 2020 Annual Meeting of Stockholders. The Definitive Proxy Statement will be filed with the Securities and Exchange Commission within 120 days after the end of the period covered by this Annual Report on Form 10-K.

Item 11. Executive Compensation.

The information required by this item is incorporated by reference to our Definitive Proxy Statement for our 2020 Annual Meeting of Stockholders. The Definitive Proxy Statement will be filed with the Securities and Exchange Commission within 120 days after the end of the period covered by this Annual Report on Form 10-K.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

The information required by this item is incorporated by reference to our Definitive Proxy Statement for our 2020 Annual Meeting of Stockholders. The Definitive Proxy Statement will be filed with the Securities and Exchange Commission within 120 days after the end of the period covered by this Annual Report on Form 10-K.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

The information required by this item is incorporated by reference to our Definitive Proxy Statement for our 2020 Annual Meeting of Stockholders. The Definitive Proxy Statement will be filed with the Securities and Exchange Commission within 120 days after the end of the period covered by this Annual Report on Form 10-K.

Item 14. Principal Accounting Fees and Services.

The information required by this item is incorporated by reference to our Definitive Proxy Statement for our 2020 Annual Meeting of Stockholders. The Definitive Proxy Statement will be filed with the Securities and Exchange Commission within 120 days after the end of the period covered by this Annual Report on Form 10-K.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

Exhibit Number	Exhibit Description
2.1	Agreement and Plan of Merger, dated October 2, 2017, between Opiant Pharmaceuticals, Inc., a Nevada corporation, and Opiant Pharmaceuticals, Inc., a Delaware corporation (incorporated herein by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K filed on October 6, 2017).
3(i).1	First Amended and Restated Certificate of Incorporation of Opiant Pharmaceuticals, Inc., a Delaware corporation, filed on October 2, 2017 (incorporated herein by reference to Exhibit 3(i).4 to the Company's Current Report on Form 8-K filed on October 6, 2017).
3(i).2	Nevada Articles of Merger, filed October 2, 2017 (incorporated herein by reference to Exhibit 3(i).2 to the Company's Current Report on Form 8-K filed on October 6, 2017).
3(i).3	Delaware Certificate of Merger, filed October 2, 2017 (incorporated herein by reference to Exhibit 3(i).3 to the Company's Current Report on Form 8-K filed on October 6, 2017).
3(ii).1	Bylaws of Opiant Pharmaceuticals, Inc., a Delaware corporation (incorporated herein by reference to Exhibit 3(ii).1 to the Company's Current Report on Form 8-K filed on October 6, 2017).
4.1	Specimen Common Stock Certificate of Opiant Pharmaceuticals, Inc., a Delaware corporation (incorporated herein by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed on October 6, 2017).
4.2	Description of the Registrant's Securities Registered Pursuant to Section 12 of the Securities Exchange Act of 1934.
10.1+	License Agreement, dated as of December 15, 2014, by and between the Company and Adapt Pharma Operations Limited (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on March 5, 2018).
10.2+	Amendment No. 1 to License Agreement, dated as of December 13, 2016, by and between the Company and Adapt Pharma Operations Limited (incorporated herein by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed on April 19, 2017).
10.3+	Amended and Restated Material Transfer, Option and Research License Agreement, dated as of April 26, 2016, by and between the Company and Aegis Therapeutics, LLC (incorporated herein by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed on June 8, 2016).
10.4+	Letter Agreement, dated as of April 26, 2016, by and between the Company and Aegis Therapeutics, LLC (incorporated herein by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q filed on June 8, 2016).
10.5+	License Agreement, dated as of June 22, 2017, by and between the Company and Aegis Therapeutics, LLC (incorporated by reference to Exhibit 10.5 to the Company's Annual Report on Form 10-K filed on October 13, 2017).

10.6+	Supply Agreement, dated as of June 22, 2017, by and between the Company and Aegis Therapeutics, LLC (incorporated by reference to Exhibit 10.6 to the Company's Annual Report on Form 10-K filed on October 13, 2017).
10.7+	Research and Development Agreement, dated as of July 14, 2017, by and between the Company and Renaissance Lakewood, LLC (incorporated by reference to Exhibit 10.7 to the Company's Annual Report on Form 10-K filed on October 13, 2017).
10.8+	Purchase and Sale Agreement, dated as of December 13, 2016, by and between the Company and SWK Funding LLC (incorporated herein by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q filed on March 15, 2017).
10.9+†	Separation Agreement and General Release, dated as of September 5, 2017, by and between the Company and Kevin Pollack (incorporated by reference to Exhibit 10.9 to the Company's Annual Report on Form 10-K filed on October 13, 2017).
10.10†	Employment Agreement, dated as of January 11, 2018, by and between the Company and Dr. Roger Crystal (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on January 16, 2018).
10.11†	Employment Agreement Acknowledgement, dated as of March 31, 2017, by and between the Company and Dr. Roger Crystal (incorporated herein by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed on April 6, 2017).
10.12†	Employment Agreement, dated as of January 11, 2018, by and between the Company and Dr. Phil Skolnick (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on January 16, 2018).
10.13†	Employment Agreement, dated as of January 11, 2018, by and between the Company and David O'Toole (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on January 16, 2018).
10.14†	Director Agreement, dated as of December 31, 2012, by and between the Company and Geoffrey Wolf (incorporated herein by reference to Exhibit 10.11 to the Company's Annual Report on Form 10-K filed on October 29, 2013).
10.15†	Director Agreement, dated as of May 5, 2016, by and between the Company and Ann MacDougall (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on May 11, 2016).
10.16†	Director Agreement, dated as of May 5, 2016, by and between the Company and Dr. Gabrielle Silver (incorporated herein by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed on May 11, 2016).
10.17†	Director Agreement, dated as of November 4, 2016, by and between the Company and Thomas T. Thomas (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on November 10, 2016).

10.18†	Senior Advisor Agreement, dated as of January 22, 2013, by and between the Company and Brad Miles (incorporated herein by reference to Exhibit 10.6 to the Company's Quarterly Report on Form 10-Q filed on March 15, 2017).
10.19†	First Amendment to Senior Advisor Agreement, dated as of February 24, 2015, by and between the Company and Brad Miles (incorporated herein by reference to Exhibit 10.7 to the Company's Quarterly Report on Form 10-Q filed on March 15, 2017).
10.20†	Second Amendment to Senior Advisor Agreement, dated as of March 19, 2015, by and between the Company and Brad Miles (incorporated herein by reference to Exhibit 10.8 to the Company's Quarterly Report on Form 10-Q filed on March 15, 2017).
10.21†	Third Amendment to Senior Advisor Agreement, dated as of March 13, 2017, by and between the Company and Brad Miles (incorporated herein by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q filed on June 14, 2017).
10.22	Sublease, effective as of August 1, 2017, by and between the Company and Standish Management, LLC, as amended by that certain letter agreement, dated as of August 1, 2017 (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on September 5, 2017).
10.23	Engagement Letter, dated December 18, 2014, by and between the Company and Torreya Partners (Europe) LLP (incorporated herein by reference to Exhibit 10.33 to the Company's Annual Report on Form 10-K filed on October 28, 2016).
10.24	Supplemental Engagement Letter, dated as of September 8, 2017, by and between the Company and Torreya Partners (Europe) LLP (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on September 14, 2017).
10.25	Investment Agreement, dated as of April 16, 2013, by and between the Company and Potomac Construction Limited (incorporated herein by reference to Exhibit 10.15 to the Company's Annual Report on Form 10-K filed on October 28, 2016).
10.26	Letter Agreement, dated as of October 15, 2014, by and between the Company and Potomac Construction Limited (incorporated herein by reference to Exhibit 10.16 to the Company's Annual Report on Form 10-K filed on October 28, 2016).
10.27	Investment Agreement, dated as of May 30, 2013, by and between the Company and Potomac Construction Limited (incorporated herein by reference to Exhibit 10.17 to the Company's Annual Report on Form 10-K filed on October 28, 2016).
10.28	Letter Agreement, dated as of October 15, 2014, by and between the Company and Potomac Construction Limited (incorporated herein by reference to Exhibit 10.18 to the Company's Annual Report on Form 10-K filed on October 28, 2016).
10.29	Investment Agreement, dated as of December 20, 2013, by and between the Company and Potomac Construction Limited (incorporated herein by reference to Exhibit 10.28 to the Company's Annual Report on Form 10-K filed on October 28, 2016).
10.30	Investment Agreement, dated as of September 9, 2014, by and between the Company and Potomac Construction Limited (incorporated herein by reference to Exhibit 10.23 to the Company's Annual Report on Form 10-K filed on October 28, 2016).
10.31	Letter Agreement, dated as of October 15, 2014, by and between the Company and Potomac Construction Limited (incorporated herein by reference to Exhibit 10.24 to the Company's Annual Report on Form 10-K filed on October 28, 2016).

10.32	Investment Agreement, dated as of September 17, 2014, by and between the Company and Potomac Construction Limited (incorporated herein by reference to Exhibit 10.29 to the Company's Annual Report on Form 10-K filed on October 28, 2016).
10.33	Investment Agreement, dated as of October 31, 2014, by and between the Company and Potomac Construction Limited (incorporated herein by reference to Exhibit 10.25 to the Company's Annual Report on Form 10-K filed on October 28, 2016).
10.34	Letter Agreement, dated as of October 31, 2014, by and between the Company and Potomac Construction Limited (incorporated herein by reference to Exhibit 10.26 to the Company's Annual Report on Form 10-K filed on October 28, 2016).
10.35	Investment Agreement, dated as of July 20, 2015, by and between the Company and Potomac Construction Limited (incorporated herein by reference to Exhibit 10.30 to the Company's Annual Report on Form 10-K filed on October 28, 2016).
10.36	Investment Agreement, dated as of December 8, 2015, by and between the Company and Potomac Construction Limited (incorporated herein by reference to Exhibit 10.27 to the Company's Annual Report on Form 10-K filed on October 28, 2016).
10.37	Amendment to Investment Agreement, dated as of April 12, 2017, by and between the Company and Potomac Construction Limited (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on April 18, 2017).
10.38	Investment Agreement, dated as of May 15, 2014, by and between the Company and Ernst Welmers (incorporated herein by reference to Exhibit 10.20 to the Company's Annual Report on Form 10-K filed on October 28, 2016).
10.39	Letter Agreement, dated as of October 15, 2014, by and between the Company and Ernst Welmers (incorporated herein by reference to Exhibit 10.21 to the Company's Annual Report on Form 10-K filed on October 28, 2016).
10.40	Amendment to Investment Agreement, dated as of June 1, 2017, by and between the Company and Ernst Welmers (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on June 2, 2017).
10.41	Amended and Restated Interest Agreement, dated as of October 24, 2016, by and between the Company and Valour Fund, LLC (incorporated herein by reference to Exhibit 10.22 to the Company's Annual Report on Form 10-K filed on October 28, 2016).
10.42	Amended and Restated Interest Agreement, dated as of October 24, 2016, by and between the Company and Valour Fund, LLC (incorporated herein by reference to Exhibit 10.31 to the Company's Annual Report on Form 10-K filed on October 28, 2016).
10.43†	Amended and Restated Consulting Agreement, dated as of October 25, 2016, by and between the Company and LYL Holdings Inc. (incorporated herein by reference to Exhibit 10.19 to the Company's Annual Report on Form 10-K filed on October 28, 2016).
10.44†	Amendment to Amended and Restated Consulting Agreement, dated as of June 1, 2017, by and between the Company and LYL Holdings Inc. (incorporated herein by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed on June 2, 2017).
10.45†	Regulatory and Strategic Advisor Consultancy Agreement, dated as of September 1, 2015, by and between the Company and Mary Pendergast (incorporated herein by reference to Exhibit 10.32 to the Company's Annual Report on Form 10-K filed on October 28, 2016).

10.46†	Opiant Pharmaceuticals, Inc. 2017 Long-Term Incentive Plan (incorporated by reference to Exhibit 10.52 to the Company's Annual Report on Form 10-K filed on October 13, 2017).
10.47†	Stock Option Grant Agreement, dated October 27, 2015, by and between the Company and Dr. Michael Sinclair (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on October 29, 2015).
10.48†	Stock Option Grant Agreement, dated October 27, 2015, by and between the Company and Dr. Roger Crystal (incorporated herein by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed on October 29, 2015).
10.49†	Stock Option Grant Agreement, dated October 27, 2015, by and between the Company and Kevin Pollack (incorporated herein by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K filed on October 29, 2015).
10.50†	Stock Option Grant Agreement, dated October 27, 2015, by and between the Company and Geoffrey Wolf (incorporated herein by reference to Exhibit 10.4 to the Company's Current Report on Form 8-K filed on October 29, 2015).
10.51†	Controlled Equity OfferingSM Sales Agreement, dated October 13, 2017, by and between Opiant Pharmaceuticals, Inc. and Cantor Fitzgerald & Co. (incorporated herein by reference to Exhibit 1.2 to the Company's Registration Statement on Form S-3 filed on October 13, 2017)
10.52†	Forms of Incentive Stock Option Notice and Incentive Stock Option Agreement under the Opiant Pharmaceuticals, Inc. 2017 Long-Term Incentive Plan (incorporated by reference to Exhibit 10.6 to the Company's Quarterly Report on Form 10-Q filed on December 4, 2017).
10.53†	Forms of Nonstatutory Stock Option Notice and Nonstatutory Stock Option Agreement under the Opiant Pharmaceuticals, Inc. 2017 Long-Term Incentive Plan (incorporated by reference to Exhibit 10.7 to the Company's Quarterly Report on Form 10-Q filed on December 4, 2017).
10.54†	Form of Restricted Stock Agreement under the Opiant Pharmaceuticals, Inc. 2017 Long-Term Incentive Plan (incorporated by reference to Exhibit 10.8 to the Company's Quarterly Report on Form 10-Q filed on December 4, 2017).
10.55†	Stock Option Grant Agreement, dated December 31, 2013, by and between the Registrant and Dr. Michael Sinclair (incorporated by reference to Exhibit 10.1 to the Company's Registration Statement on Form S-8 filed on November 27, 2017).
10.56†	Stock Option Grant Agreement, dated June 15, 2014, by and between the Registrant and Dr. Michael Sinclair (incorporated by reference to Exhibit 10.2 to the Company's Registration Statement on Form S-8 filed on November 27, 2017).
10.57†	Stock Option Grant Agreement, dated June 15, 2014, by and between the Registrant and Dr. Michael Sinclair (incorporated by reference to Exhibit 10.3 to the Company's Registration Statement on Form S-8 filed on November 27, 2017).
10.58†	Stock Option Grant Agreement, dated December 31, 2013, by and between the Registrant and Dr. Roger Crystal (incorporated by reference to Exhibit 10.5 to the Company's Registration Statement on Form S-8 filed on November 27, 2017).
10.59†	Stock Option Grant Agreement, dated June 15, 2014, by and between the Registrant and Dr. Roger Crystal (incorporated by reference to Exhibit 10.6 to the Company's Registration Statement on Form S-8 filed on November 27, 2017).

10.60†	Stock Option Grant Agreement, dated December 31, 2013, by and between the Registrant and Kevin Pollack (incorporated by reference to Exhibit 10.8 to the Company's Registration Statement on Form S-8 filed on November 27, 2017).
10.61†	Stock Option Grant Agreement, dated December 31, 2013, by and between the Registrant and Kevin Pollack (incorporated by reference to Exhibit 10.9 to the Company's Registration Statement on Form S-8 filed on November 27, 2017).
10.62†	Stock Option Grant Agreement, dated June 15, 2014, by and between the Registrant and Kevin Pollack (incorporated by reference to Exhibit 10.10 to the Company's Registration Statement on Form S-8 filed on November 27, 2017).
10.63†	Stock Option Grant Agreement, dated June 15, 2014, by and between the Registrant and Kevin Pollack (incorporated by reference to Exhibit 10.11 to the Company's Registration Statement on Form S-8 filed on November 27, 2017).
10.64†	Stock Option Grant Agreement, dated December 31, 2012, by and between the Registrant and Geoffrey Wolf (incorporated by reference to Exhibit 10.13 to the Company's Registration Statement on Form S-8 filed on November 27, 2017).
10.65†	Warrant Agreement, dated December 31, 2012, by and between the Registrant and Geoffrey Wolf (incorporated by reference to Exhibit 10.14 to the Company's Registration Statement on Form S-8 filed on November 27, 2017).
10.66†	Stock Option Grant Agreement, dated June 15, 2014, by and between the Registrant and Geoffrey Wolf (incorporated by reference to Exhibit 10.15 to the Company's Registration Statement on Form S-8 filed on November 27, 2017).
10.67†	Stock Option Grant Agreement, dated June 15, 2014, by and between the Registrant and Geoffrey Wolf (incorporated by reference to Exhibit 10.16 to the Company's Registration Statement on Form S-8 filed on November 27, 2017).
10.68†	Stock Option Grant Agreement, dated November 12, 2014, by and between the Registrant and Arvind Agrawal (incorporated by reference to Exhibit 10.18 to the Company's Registration Statement on Form S-8 filed on November 27, 2017).
10.69†	Stock Option Grant Agreement, dated November 12, 2014, by and between the Registrant and Arvind Agrawal (incorporated by reference to Exhibit 10.19 to the Company's Registration Statement on Form S-8 filed on November 27, 2017).
10.70†	Stock Option Grant Agreement, dated October 27, 2015, by and between the Registrant and Arvind Agrawal (incorporated by reference to Exhibit 10.20 to the Company's Registration Statement on Form S-8 filed on November 27, 2017).
10.71†	Stock Option Grant Agreement, dated January 22, 2013, by and between the Registrant and Brad Miles (incorporated by reference to Exhibit 10.21 to the Company's Registration Statement on Form S-8 filed on November 27, 2017).
10.72†	Warrant Agreement, dated March 19, 2015, by and between the Registrant and Brad Miles (incorporated by reference to Exhibit 10.22 to the Company's Registration Statement on Form S-8 filed on November 27, 2017).
10.73†	Stock Option Grant Agreement, dated March 19, 2015, by and between the Registrant and Brad Miles (incorporated by reference to Exhibit 10.23 to the Company's Registration Statement on Form S-8 filed on November 27, 2017).
10.74†	Stock Option Grant Agreement, dated March 19, 2015, by and between the Registrant and Brad Miles (incorporated by reference to Exhibit 10.24 to the Company's Registration Statement on Form S-8 filed on November 27, 2017).

10.75†	Stock Option Grant Agreement, dated October 6, 2016, by and between the Registrant and Jenny Lee (incorporated by reference to Exhibit 10.25 to the Company's Registration Statement on Form S-8 filed on November 27, 2017).
10.76†	Stock Option Grant Agreement, dated October 6, 2016, by and between the Registrant and Quan Vu (incorporated by reference to Exhibit 10.26 to the Company's Registration Statement on Form S-8 filed on November 27, 2017).
10.77†	Stock Option Grant Agreement, dated December 24, 2016, by and between the Registrant and Quan Vu (incorporated by reference to Exhibit 10.27 to the Company's Registration Statement on Form S-8 filed on November 27, 2017).
10.78†	Stock Option Grant Agreement, dated February 6, 2017, by and between the Registrant and Dr. Phil Skolnick (incorporated by reference to Exhibit 10.28 to the Company's Registration Statement on Form S-8 filed on November 27, 2017).
10.79†	Stock Option Grant Agreement, dated November 4, 2016, by and between the Registrant and Thomas T. Thomas (incorporated by reference to Exhibit 10.29 to the Company's Registration Statement on Form S-8 filed on November 27, 2017).
10.80†	Stock Option Grant Agreement, dated May 17, 2016, by and between the Registrant and Dr. Gabrielle Silver (incorporated by reference to Exhibit 10.30 to the Company's Registration Statement on Form S-8 filed on November 27, 2017).
10.81†	Stock Option Grant Agreement, dated May 17, 2016, by and between the Registrant and Ann MacDougall (incorporated by reference to Exhibit 10.31 to the Company's Registration Statement on Form S-8 filed on November 27, 2017).
10.82†	Letter Agreement, dated as of November 12, 2014, by and between the Registrant and Arvind Agrawal (incorporated by reference to Exhibit 10.41 to the Company's Registration Statement on Form S-8 filed on November 27, 2017).
10.83†	Warrant Agreement, dated as of March 13, 2017, by and between the Registrant and Brad Miles (incorporated by reference to Exhibit 10.43 to the Company's Registration Statement on Form S-8 filed on November 27, 2017).
10.84†	Executive Employment Agreement, dated January 11, 2018, by and between Dr. Roger Crystal and the Registrant (incorporated by reference to Exhibit 10.1 of the Company’s Current Report on Form 8-K filed January 16, 2018).
10.85†	Executive Employment Agreement, dated January 11, 2018, by and between Mr. David O’Toole and the Registrant (incorporated by reference to Exhibit 10.2 of the Company’s Current Report on Form 8-K filed January 16, 2018).
10.86†	Executive Employment Agreement, dated January 11, 2018, by and between Dr. Phil Skolnick and the Registrant (incorporated by reference to Exhibit 10.3 of the Company’s Current Report on Form 8-K filed January 16, 2018).
10.87*	Amendment No. 2 to License Agreement, dated March 18, 2019, by and between Registrant and Adapt Pharma Operations Limited.
10.88†	Director Agreement, effective June 12, 2018, by and between the Registrant and Richard Daly (incorporated by reference to Exhibit 10.1 of the Company’s Current Report on Form 8-K filed June 12, 2018).
10.89†	Development and Manufacturing Agreement between the Registrant and Aesica Queensborough Limited dated September 7, 2018 (incorporated by reference to Exhibit 10.84 of the Company’s Current Report on Form 8-K filed September 10, 2018).
10.90†	Agreement for Reimbursement of Capital Expenditures and Service Fees between the Registrant and Aesica Queensborough Limited dated September 7, 2018 (incorporated by reference to Exhibit 10.85 of the Company’s Current Report on Form 8-K filed September 10, 2018).

10.91†	Contract between the Registrant and Biomedical Advanced Research and Development Authority dated September 19, 2018 (incorporated by reference to Exhibit 10.86 of the Company's Current Report on Form 8-K/A filed December 4, 2018).
10.92†	Director Agreement, effective October 29, 2018, by and between Opiant Pharmaceuticals, Inc. and Craig A. Collard (incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K filed October 29, 2018).
10.93†	License Agreement between the Registrant and Sanofi dated December 21, 2018 (incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K filed December 28, 2018).
21.1	Subsidiaries of the Company (incorporated by reference to Exhibit 21.1 to the Company's Annual Report on Form 10-K filed on October 13, 2017).
23.1*	Consent of MaloneBailey, LLP, Independent Registered Public Accounting Firm.
31.1*	Certification of the Chief Executive Officer pursuant to Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of the Chief Financial Officer pursuant to Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1**	Certification of the Chief Executive Officer pursuant to 18 U.S.C Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2**	Certification of the Chief Financial Officer pursuant to 18 U.S.C Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101	The following materials from the Opiant Pharmaceuticals, Inc. Form 10-K for the years ended December 31, 2019 and 2018, formatted in Extensible Business Reporting Language (XBRL): (i) Consolidated Balance Sheets as of December 31, 2019 and 2018, (ii) Consolidated Statements of Operations for the years ended December 31, 2019 and 2018, (iii) Consolidated Statement of Stockholders' Equity (Deficit) for the years ended December 31, 2019 and 2018, (iv) Consolidated Statements of Cash Flows for the year ended December 31, 2019 and 2018, and (v) Notes to Consolidated Financial Statements.

+ Confidential Treatment Granted. Confidential Materials omitted and filed separately with the Securities and Exchange Commission.

† Indicates a management contract or compensatory plan or arrangement, as required by Item 15(a) (3) of Form 10-K.

* File herewith

** In accordance with SEC Release 33-8238, Exhibits 32.1 and 32.2 are being furnished and not filed

Item 16. Form 10-K Summary

None

SIGNATURES

In accordance with Section 13 or 15(d) of the Securities Exchange Act, the registrant caused this Annual Report to be signed on its behalf by the undersigned, thereunto duly authorized.

Opiant Pharmaceuticals, Inc.

Date: March 4, 2020

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

In accordance with the Exchange Act, this Annual Report has been signed below by the following persons on behalf of the registrant and in the capacities indicated on March 4, 2020.

By:	/s/ *Dr. Roger Crystal* Dr. Roger Crystal	Director & Chief Executive Officer (Principal Executive Officer)
By:	/s/ *David D. O'Toole* David D. O'Toole	Chief Financial Officer (Principal Financial and Accounting Officer)
By:	/s/ *Dr. Michael Sinclair* Dr. Michael Sinclair	Director
By:	/s/ *Thomas T. Thomas* Thomas T. Thomas	Director
By:	/s/ *Dr. Gabrielle Silver* Dr. Gabrielle Silver	Lead Independent Director
By:	/s/ *Ann MacDougall* Ann MacDougall	Director
By:	/s/ *Richard J. Daly* Richard J. Daly	Director
By:	/s/ *Craig Collard* Craig Collard	Director

Exhibit 4.2

DESCRIPTION OF THE REGISTRANT'S SECURITIES
REGISTERED PURSUANT TO SECTION 12 OF THE SECURITIES
EXCHANGE ACT OF 1934

Opiant Pharmaceuticals, Inc. (the "Company") has one class of securities registered under Section 12 of the Securities Exchange Act of 1934, as amended: our Common Stock, par value $0.001 per share.

As used in this summary, the terms "Opiant," "the Company," "we," "our" and "us" refer to Opiant Pharmaceuticals, Inc.

The following is a description of the material terms and provisions relating to our Common Stock. The following description is a summary that is not complete and is subject to and qualified in its entirety by reference to our Certificate of Incorporation and our Bylaws, and to provisions of the Delaware General Corporation Law. Copies of our Certificate of Incorporation and our Bylaws, each of which may be amended from time to time, are included as exhibits to the Annual Report on Form 10-K to which this description is an Exhibit.

Common Stock

Under our Certificate of Incorporation, we have the authority to issue 200,000,000 shares of our Common Stock.

Voting. For all matters submitted to a vote of stockholders, each holder of our Common Stock is entitled to one vote for each share registered in his or her name. Except as may be required by law and in connection with some significant actions, such as mergers, consolidations, or amendments to our Certificate of Incorporation that affect the rights of stockholders, holders of our Common Stock vote together as a single class. There is no cumulative voting in the election of our directors, which means that a plurality of the votes cast at a meeting of stockholders at which a quorum is present is sufficient to elect a director. As such, the holders of more than 50% of the outstanding shares of Common Stock, in a vote for the election of directors, may elect all of the directors to be elected, if they so choose, and, in that event, the holders of the remaining shares of Common Stock will not be able to elect any of the Company's directors.

Dividends. The holders of shares of our Common Stock are entitled to receive dividends, including dividends of our stock, as and when declared by our Board, subject to any limitations under the DGCL. We have never declared or paid any cash dividends on our Common Stock. We do not anticipate paying any cash dividends to stockholders in the foreseeable future. In addition, any future determination to pay cash dividends will be at the discretion of our Board and will be dependent upon our financial condition, results of operations, capital requirements, and such other factors as our Board deems relevant.

Liquidation. In the event we are liquidated, dissolved or our affairs are wound up, after we pay or make adequate provision for all of our known debts and liabilities, each holder of our Common Stock will be entitled to share ratably in all assets that remain.

Other Rights and Restrictions. All shares of our Common Stock have equal dividend, distribution, liquidation and other rights, and have no preference, appraisal or exchange rights, except for any appraisal rights provided by the DGCL. Furthermore, holders of our Common Stock have no conversion, sinking fund or redemption rights, or preemptive rights to subscribe for any of our securities. Our Certificate of Incorporation and Bylaws do not restrict the ability of a holder of our Common Stock to transfer his or her shares of our Common Stock.

Listing. Our Common Stock is listed on the Nasdaq Capital Market under the symbol "OPNT."

Transfer Agent and Registrar. The transfer agent and registrar for our common stock is American Stock Transfer & Trust Company (AST), LLC, 6201 15th Avenue, Brooklyn, NY 11219.

Certain Effects of Authorized but Unissued Stock

We have shares of Common Stock available for future issuance without stockholder approval. We may issue these additional shares for a variety of corporate purposes, including future public offerings to raise additional capital or facilitate corporate acquisitions or for payment as a dividend on our capital stock. The existence of unissued and unreserved Common Stock may enable our Board to issue shares to persons friendly to current management, thereby protecting the continuity of our management.

Delaware Law and Certificate of Incorporation and Bylaws Provisions

Board of Directors. Our Bylaws provide that:

- any directors, or the entire Board, may be removed from office at any time, but only with cause, by the affirmative vote of at least seventy-five percent (75%) of all eligible votes present in person or by proxy at a meeting of stockholders at which a quorum is present; and

- vacancies in the Board resulting from such removal may be filled by a majority of the directors then in office, though less than a quorum, or by the sole remaining director. Directors so chosen shall hold office until the next annual meeting of stockholders at which the term of office of the class to which they have been elected expires.

These provisions could discourage, delay or prevent a change in control of our Company or an acquisition of our Company at a price which many stockholders may find attractive. The existence of these provisions could limit the price that investors might be willing to pay in the future for shares of our Common Stock. These provisions may also have the effect of discouraging a third party from initiating a proxy contest, making a tender offer or attempting to change the composition or policies of our Board.

Stockholder Action; *Special Meeting of Stockholders*. Our Bylaws also provide that:

- stockholder action may be taken only at a duly called and convened annual or special meeting of stockholders and then only if properly brought before the meeting;

- stockholder action may not be taken by written action in lieu of a meeting;

- special meetings of stockholders may be called only by our Board, the Chairman of the Board or the Chief Executive Officer; and

- in order for any matter to be considered “properly brought” before a meeting, a stockholder must comply with requirements regarding specified information and advance notice to us.

These provisions could delay, until the next stockholders’ meeting, actions which are favored by the holders of a majority of our outstanding voting securities. These provisions may also discourage another person or entity from making a tender offer for our Common Stock, because a person or entity, even if it acquired a majority of our outstanding voting securities, would be able to take action as a stockholder only at a duly called stockholders’ meeting, and not by written consent.

Indemnification. Our Certificate of Incorporation provides that we shall, to the fullest extent permitted by, and in accordance with the provisions of, the DGCL, indemnify each of our directors or officers or employees against expenses (including attorneys’ fees), judgments, taxes, fines and amounts paid in settlement, incurred by him in connection with, and shall advance expenses (including attorneys’ fees) incurred by him in defending, any threatened, pending or completed action, suit or proceeding (whether civil, criminal, administrative or investigative) to which he is, or is threatened to be made, a party by reason of the fact that he is or was a director or officer or employee of ours, or is or

was serving at the request of us as a director, officer, partner, employee or agent of another domestic or foreign corporation, partnership, joint venture, trust or other enterprise. Advancement of expenses shall be made upon receipt of an undertaking, with such security, if any, as the Board or stockholders may reasonably require, by or on behalf of the person seeking indemnification to repay amounts advanced if it shall ultimately be determined that he is not entitled to be indemnified us as authorized therein.

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in Registration Statements on Form S-3 (File No. 333-220976) and Form- S-8 (File Nos. 333-221759 and 333-224239) of our report dated March 4, 2020 with respect to the audited consolidated financial statements of Opiant Pharmaceuticals, Inc. included in the Annual Report on Form 10 K for the year ended December 31, 2019.

/s/ MaloneBailey, LLP www.malonebailey.com
Houston, Texas
March 4, 2020

EXHIBIT 31.1

CERTIFICATION PURSUANT TO RULE 13A-14 OR 15D-14 OF THE SECURITIES EXCHANGE ACT OF 1934, 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 Annual Report on Form 10-K of Opiant Pharmaceuticals, Inc.;

2. Based on my knowledge, this Annual 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 Annual Report;

3. Based on my knowledge, the financial statements, and other financial information included in this Annual 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 Annual 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 me by others within those entities, particularly during the period in which this Annual 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 Annual Report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this Annual Report based on such evaluation; and

d) Disclosed in this Annual 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: March 4, 2020

By: /s/ *Dr. Roger Crystal*

Dr. Roger Crystal

Chief Executive Officer

EXHIBIT 31.2

CERTIFICATION PURSUANT TO RULE 13A-14 OR 15D-14 OF THE SECURITIES EXCHANGE ACT OF 1934, AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

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

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

2. Based on my knowledge, this Annual 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 Annual Report;

3. Based on my knowledge, the financial statements, and other financial information included in this Annual 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 Annual 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:

e) 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 me by others within those entities, particularly during the period in which this Annual Report is being prepared;

f) 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;

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

h) Disclosed in this Annual 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):

c) 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

d) 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: March 4, 2020

By: /s/ *David O'Toole*

David O'Toole

Chief Financial Officer

EXHIBIT 32.1

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

In connection with the Annual Report on Form 10-K of Opiant Pharmaceuticals, Inc. (the “Company") for the year ended December 31, 2018, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), Dr. Roger Crystal, as Chief Executive Officer of the Company, hereby certifies, pursuant to 18 U.S.C. ss.1350, as adopted pursuant to ss.906 of the Sarbanes-Oxley Act of 2002, that:

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

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

Date: March 4, 2020

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

This certification accompanies each Report pursuant to ss. 906 of the Sarbanes-Oxley Act of 2002 and shall not, except to the extent required by the Sarbanes-Oxley Act of 2002, be deemed filed by the Company for purposes of ss.18 of the Securities Exchange Act of 1934, as amended.

A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

EXHIBIT 32.2

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

In connection with the Annual Report on Form 10-K of Opiant Pharmaceuticals, Inc. (the “Company") for the year ended December 31, 2018, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), Dr. Roger Crystal, as Chief Executive Officer of the Company, hereby certifies, pursuant to 18 U.S.C. ss.1350, as adopted pursuant to ss.906 of the Sarbanes-Oxley Act of 2002, that:

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

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

Date: March 4, 2020

By: /s/ *David O'Toole*
David O'Toole
Chief Executive Officer

This certification accompanies each Report pursuant to ss. 906 of the Sarbanes-Oxley Act of 2002 and shall not, except to the extent required by the Sarbanes-Oxley Act of 2002, be deemed filed by the Company for purposes of ss.18 of the Securities Exchange Act of 1934, as amended.

A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

EXHIBIT 32.2

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

In connection with the Annual Report on Form 10-K of Opiant Pharmaceuticals, Inc. (the “Company") for the year ended December 31, 2018, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), David O'Toole as Chief Financial Officer of the Company, hereby certifies, pursuant to 18 U.S.C. ss.1350, as adopted pursuant to ss.906 of the Sarbanes-Oxley Act of 2002, that:

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

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

Date: March 4, 2020

By: */s/ David O'Toole*
David O'Toole
Chief Financial Officer

This certification accompanies each Report pursuant to ss. 906 of the Sarbanes-Oxley Act of 2002 and shall not, except to the extent required by the Sarbanes-Oxley Act of 2002, be deemed filed by the Company for purposes of ss.18 of the Securities Exchange Act of 1934, as amended.

A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.